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Anesthesia services management, economics, and new technologies

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Sociedade Brasileira de Anestesiologia

Brazilian Journal of ANESTHESIOLOGY

EDITORIAL

Anesthesia services management, economics, and new technologies

A significant number of us are keen on expanding our knowledge of anesthesia service management and its intricacies, eagerly anticipating this year's CBIGS (Congresso Brasileiro de Inovação e Gestão em Saúde, Brazilian Meeting on Health Management and Innovation). While we await CBIGS, this issue of the Brazilian Journal of Anesthesiology (BJAN) will provide invaluable insights into the latest evidence for managers.

Anesthesia services must consider various competing perspectives, given that they often serve multiple clients simultaneously, including patients, surgeons, and hospitals. Achieving balanced results that satisfy these different perspectives is challenging. In Brazil, residency programs tend to emphasize on clinical and practical knowledge, making it easier for most providers to satisfy patients' and surgeons' perspectives. Nonetheless, hospital managers' requests may appear peculiar and daunting, as they frequently summon anesthesia services leaders to take measures to enhance efficiency and expand coverage, rather than focus on clinical outcomes. In this editorial, we explore some pertinent topics related to efficiency (economics) and coverage (operating room management).

In this edition, BJAN invites leaders of anesthesia services to peruse the new articles we have selected to enhance their understanding of operating room management and anesthesia efficiency.

Operating room management

Services that experience high demand for surgeries should take into account in their strategic planning the need to attract procedures that generate higher profits. It is important to be cautious when investing in procedures with high expected contribution margins, such as complex surgeries, as their hourly profitability may turn out to be low if either they take longer than expected or if their length of stay is longer than predicted, as evidenced by Saporito et al.[1] Anesthesiology groups should also consider this idea, as investing in performing low-complexity procedures can sometimes be more profitable than investing in high-complexity procedures. Low-complexity procedures typically exhibit consistent demand and shorter durations, thus yielding a high hourly profitability.

Another issue regarding high complexity is related to the size of nurse and anesthesia teams, as larger teams present high fixed costs and variable demand results in lower profitability. Optimizing the tasks of Postoperative Care Unit nurses, for example, could reduce the risk of clinical complications, nurse burnout, and improve efficiency, as suggested by Vacheron et al.[2] This interesting study employs an artificial intelligence model (C 5.0) to select the primary predictors of the type of multitask performed. Leaders can directly apply the study's results and indirectly adopt the same methodology to analyze internal data, thereby learning from this exemplary approach.

Anesthesia efficiency and new technologies

In the literature, one significant topic discussed with hospital managers about anesthesia efficiency is the choice of anesthesia for some procedures, as the direct costs for regional or general anesthesia are readily available for them, which is controversial. Graff et al.'s literature review found inconsistent results, except in cases where there is a high demand for ambulatory anesthesia and well-systematized processes.[3] Therefore, managers must exercise caution when discussing this matter with anesthesia providers. This challenge is further heightened by the findings of Calciolari et al, which indicate that regional anesthesia is associated with significant adverse effects and costs.[4]

In addition, they discuss the challenge of evaluating the cost-effectiveness of implementing new technology in anesthesiology. Due to the lack of studies on cost-effectiveness for most technologies presented to us, which tend to focus on efficacy, anesthesiologists face challenges in this area. As such, there is high demand for formal cost-effectiveness studies, prompting governments and larger healthcare

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organizations to invest in specialized teams to assess the economics of new technologies, such as REBRATS (https://rebrats.saude.gov.br/) and numerous "NATS" (Núcleo de Avaliação de Tecnologias) found in almost every hospital in Brazil. Without such studies, anesthesia service leaders face pressure from their teams and the industry, which often makes promises or raises expectations of higher clinical quality, while also facing questions from hospital administrators seeking evidence for cheaper alternatives, including not using such technology.

Babazade et al provided a timely cost-minimization analysis for a new technology, to replace the loss of resistance technique used to identify the epidural space, and that has been shown to reduce costs by mitigating postdural puncture headache.[5] While this may not be the most ideal design for decision-making, particularly with regard to cost-utility or cost-effectiveness studies, it still provides us with superior evidence when compared to most of the new technology we currently use.

We hope our readers get a sip of all this new knowledge and apply it to improve their services while we wait for CBIGS.

Conflicts of interest

The authors declare no conflicts of interest.

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ORIGINAL INVESTIGATION

Contribution margin per hour of operating room to reallocate unutilized operating room time: a cost-effectiveness analysis

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KEYWORDS
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Abstract
Background and objectives: Contribution margin per hour (CMH) has been proposed in healthcare systems to increase the profitability of operating suites. The aim of our study is to propose a simple and reproducible model to calculate CMH and to increase cost-effectiveness.
Methods: For the ten most commonly performed surgical procedures at our Institution, we prospectively collected their diagnosis-related group (DRG) reimbursement, variable costs and mean procedural time. We quantified the portion of total staffed operating room time to be reallocated with a minimal risk of overrun. Moreover, we calculated the total CMH with a random reallocation on a first come-first served basis. Finally, prioritizing procedures with higher CMH, we ran a simulation by calculating the total CMH.
Results: Over a two-months period, we identified 14.5 hours of unutilized operating room to reallocate. In the case of a random ''first come–first serve'' basis, the total earnings were 87,117 United States dollars (USD). Conversely, with a reallocation which prioritized procedures with a high CMH, it was possible to earn 140,444 USD ($p < 0.001$).
Conclusion: Surgical activity may be one of the most profitable activities for hospitals, but a cost-effective management requires a comprehension of its cost profile. Reallocation of unused operating room time according to CMH may represent a simple, reproducible and reliable tool for elective cases on a waiting list. In our experience, it helped improving the operating suite cost-effectiveness.

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Introduction

In the last decades, industrialized countries have witnessed a continuous and uncontrolled rise in healthcare costs.[1] The sustainability of healthcare systems is intended as long-term practices to maintain and improve the standard of care by an economical point of view, without negatively impact on social and health aspects of the community. Sustainability will be one of the crucial challenges that all developed countries will have to face in the near future. The political pressure on hospitals and clinics to reduce healthcare expenses will increase in the next years and ultimately affect daily clinical decisions. Therefore, the relevance of economic criteria in clinical decision-making will increase consensually.[2] The conundrum of healthcare systems sustainability has become a well-recognized ethical issue, with the consequent risk of cream-skimming (i.e., a practice where only patients and medical/surgical services bringing significant profits to the healthcare facility are selected) and unequal access to healthcare.

The introduction of the diagnosis-related group (DRG) in the 1990s overall helped in containing costs, aiming to increase turnover, lower the length of stay[3] and perform more cases. DRG-based payments were gradually introduced in many other countries and nowadays have become the principal form of hospitals reimbursement in most developed countries.[4–6] The cost-effectiveness ratio of a surgical activity is mainly determined by an optimization of its fixed costs.[7,8] Personnel costs represent the major contributor to fixed costs and go in parallel with the duration of surgical procedures, namely operating room time. Thus, the operating suite is a service at constant risk of switching from being a source of profit to being a source of important losses for the hospital. Nevertheless, a hospital's mission implies offering some services to the population even when they are not profitable. In order to increase profitability without compromising accessibility, operating room time may be allocated by prioritizing elective cases with a higher contribution.[8–10]

The contribution margin (CM) represents the difference between the DRG-based reimbursement and variable costs of a surgical procedure. The calculation of CM has already been used in some healthcare settings to assess the profitability of a given service or department, with important implications for the hospital's policy. The concept of the CM has become important in healthcare management, particularly in relation to the DRG. The CM provides one way to show the profit potential of a particular surgical intervention and helps to cover fixed costs. However, the calculation of the CM of surgical cases is not a valuable parameter to assess its profitability, unless it is related to time, i.e., the time required for a given procedure.[11]

The aim of our study is to propose a simple and reproducible model to calculate the CM per hour (CMH), to evaluate a possible economic gain, and, ultimately, to increase cost-effectiveness.

Methods

Setting

Based on real data from the operating suite of a Swiss secondary level public hospital, Bellinzona Regional Hospital, we identified the ten most-commonly performed elective non-oncological surgical operations in 2017 (Fig. 1). No informed consents nor institutional review board approval was required since all financial data were fully anonymized, in accordance to the present Swiss legislation.

Data collection

For each operation, we considered its total DRG-based reimbursement, variable costs and procedural time. Consequently, we calculated the CMH. In particular, the CMH was defined as the reimbursement for a procedure according to DRG-grouping minus variable costs divided by the average calculated length of the surgical procedure.[6] Fixed costs are those that do not vary with outputs, such as equipment, buildings, and salaries. Variable costs, which change proportionally to output, were defined in this case as operating room costs directly attributable to the patient such as test reagents, medications and disposable materials and supplies (non-fixed costs). The length of the surgical procedure was defined as the time between the onset of anesthesia in the operating suite and the entrance in the recovery room at the end of the surgical intervention; it was rounded to the closest quarter of hour. Over a two months period, we quantified the portion of total staffed operating room time represented by the unused operating room time. Such time could can be reallocated to elective surgical activity with a minimal risk of overrun. The unutilized total staffed operating room time was defined as the total time with planned personnel in a day or week that was not exploited for surgery (for example in the case of a cancelled operation or procedures ending earlier than planned). The minimum risk of overrun was defined as the occupation as close as possible to 80% of available elective slots on a given day.[12]

Data simulation

We eventually calculated the cumulative CMH for every surgical intervention as the total CMH obtained with a reallocation of the unexploited operating room time on a first-come first-served basis among the waiting list of surgical operations at our institution. Finally, we ran a simulation calculating the cumulative CMH over that period with a simulated reallocation of the unexploited operating room time by prioritizing procedures with a higher CMH from the waiting list. All financial data is expressed in United States dollars (USD): Swiss Franc to USD exchange rate = 1.05 (last updated on 06.29.2020).

Statistical analysis

We used MedCalc Statistical Software version 19.2.6 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2020). Descriptive statistics were presented as a mean with standard deviation (SD) for continuous variables. The average reimbursement of CMH and the total CM were calculated for the ten most commonly performed surgical operations during the study period and for the simulation. The Student's *t*-test assuming independent variable was applied to evaluate CMH differ-

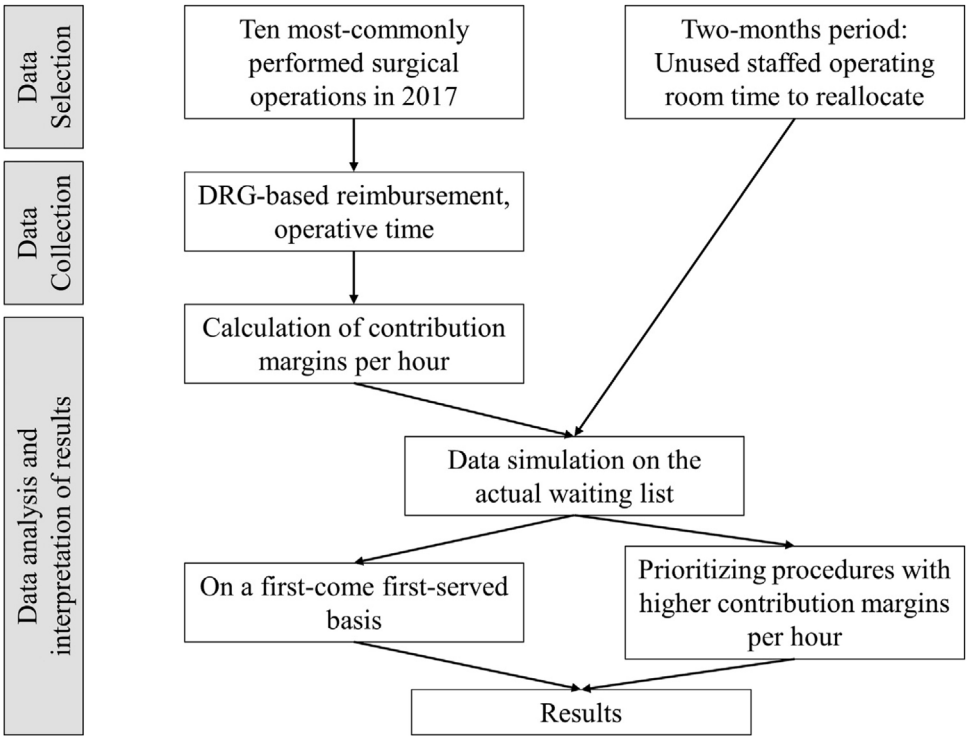

Figure 1 Flow chart of the study design.

ences between the groups (first come–first served group vs. higher CMH group). The threshold of statistical significance was set at $p < 0.05$.

Results

The CMH of the ten most-commonly performed elective surgical operations are reported in Table 1. Soft tissue operations (e.g., skin lesions, skin transplants), trans-urethral resection of the prostate and total hip replacement yielded a contribution margin between 9,000 and 10,500 USD per hour.

As second step of the analysis, we identified 14.5 hours of unused operating room time over a two-month period that could be reallocated with a minimum risk of overrun according to Green L et al.[12] According to the simulation, while the actual cumulative CMH was USD 87,117 (Table 2), the hypothetical cumulative CM achievable by prioritizing procedures with the highest CMH of operating room time would have been USD 140,444 (mean CMH over the study period = USD 5,989 ± 1,857 vs. mean CMH of the simulation = USD 9,406 ± 2,814, $p < 0.001$). Since only elective procedures were prioritized according to this criterion, access to urgent surgery was not jeopardized. Therefore, the CMH of operating room time-based approach was applied to elective surgical cases on the waiting list to reallocate the unutilized operating room time. Details are reported in Table 3.

Discussion

The potential economic impact of CMH of operating room time, to rationally reallocate unexploited operating room time to elective procedures on the waiting list, may be enormous. In fact, during the 2-months simulation period described in the present study, the actual cumulative CMH (USD 87,117) could be increased by 61% (hypothetical cumulative CMH: USD 140,444).

Effective reallocation of unutilized operating room time is a convenient tool to improve global cost-effectiveness of the operating theatre and has therefore strong strategical implications. Ideally, the allocation of staffed operating room time should fit exactly with the requirements of surgical services.[13,14] Although different techniques exist to allocate surgical slots and to minimize under-used operating room time, given the nature itself of the surgical activity, operating room managers always have to administer some unutilized operating room time.[15–17]

CM may be a straightforward criterion to incorporate economic ponderations into clinical and managerial decision-making by simply prioritizing reallocation of unexploited operating room time among surgeons and surgical services.[18] However, CM can be a misleading concept: a single operation, in fact, may have a very high absolute CM, but, in parallel, be very time consuming. Thus, reallocating unused operating room time to procedures with a high absolute CM could also represent a loss in terms of cost-opportunity. Time may be employed more effectively if redistributed to other different shorter procedures with a higher CM related to the effectively needed operating room time.[12,18] This specific issue raises the problem of opportunity costs; in fact, all reasonable alternatives should be examined before making a decision that involves resource allocation, since opportunity costs represent the profit lost when one alternative is selected over another. In fact, identifying and reallocating unutilized staffed operating room time with a minimum risk of overrun implies the

Table 1 The ten most-commonly performed surgical operations in 2017 with contribution margin per procedure and contribution margin per hour.

Procedure	Number of operations	Contribution margin per procedure, USD	Length of the surgical procedure, hours (SD)	Contribution margin per hour, USD (SD)
Soft tissue operations	35	18,269	1.75 (0.3)	10,439 (2,026)
Trans-urethral prostate resection	37	7,327	0.75 (0.2)	9,769 (2,699)
Total hip replacement	62	13,627	1.5 (0.4)	9,085 (2,720)
Open inguinal hernia repair	43	6,010	0.75 (0.2)	8,013 (2,409)
Trans-urethral bladder resection	86	5,856	0.75 (0.3)	7,808 (5,292)
Hysteroscopy	30	5,789	0.75 (0.3)	7,719 (5,705)
Laparoscopic cholecystectomy	157	6,184	1.0 (0.3)	6,184 (1,696)
Arthroscopic meniscectomy	31	3,985	0.75 (0.2)	5,313 (1,380)
Laparoscopic ventral hernia repair	104	4,115	1.0 (0.2)	4,115 (748)
Gastric by-pass for morbid obesity	31	10,308	3.0 (0.7)	3,436 (951)

Data is expressed with mean and standard deviation (SD) in parentheses. Financial data is reported in United States dollars (USD).

Table 2 The reallocated surgical operations during the study period with contribution margin per hour on a first-come first-served basis.

Procedure	Number of operations	Cumulative length of the surgical procedure, hours	Cumulative contribution margin, USD
Hemorrhoidectomy	2	2	8,718
Fistula for hemodialysis	1	1.5	11,112
Video-assisted thoracoscopy	1	1.25	9,838
Hysteroscopy	2	1.5	11,578
Tension free obturator tape positioning (TVT-O)	1	1.25	4,955
Arthroscopic meniscectomy	1	1	3,985
Laparoscopic ventral hernia repair	1	1.25	4,115
Laparoscopic ileostomy	1	2	13,333
Trans-urethral bladder resection	1	0.75	5,856
Total hip replacement	1	2	13,627
TOTAL	**12**	**14.5**	**87,117**

Financial values are expressed in United Stated dollars (USD).

Table 3 The simulation of the surgical operations during the study period with contribution margin per hour.

Procedure	Number of operations	Cumulative length of the surgical procedure, hours	Cumulative contribution margin, USD
Soft tissue operations	1	1.75	10,439
Trans-urethral prostate resection	5	3.75	48,845
Total hip replacement	2	3	18,170
Open inguinal hernia repair	3	2.25	24,039
Trans-urethral bladder resection	4	3	31,232
Hysteroscopy	1	0.75	7,719
TOTAL	**16**	**14.5**	**140,444**

Financial values are expressed in United Stated dollars (USD).

opportunity of increasing revenues. In this perspective, the potential choice to not reallocate these resources represents an opportunity cost. Moreover, social and economic costs of a delayed operation that, due to its low CMH, is not prioritized should be considered as well. On the other hand, operations with a high CMH would be prioritized and, despite obvious difficulties in estimating actual costs, opportunity costs may be balanced between delayed/anticipated operations. Another point is represented by unexploited staffed operating room time in a context in which trained personnel is not engaged in clinical activity and can be reallocated to alternative but still necessary tasks, such as inventory, bureaucracy, teaching, etc. This exploitable time would be reduced to the limit of minimum overrun risk and such activities should be redistributed. This would determine a cost opportunity, but being such activities flexible, we could

assume a low (although not neglectable) impact on efficiency. Opportunity costs may represent an important factor to take into account and further studies are needed to assess their relevance.

From an economical point of view, the need for a criterion to prioritize resource allocation in the perioperative setting is prone to many conceptual errors. Each elective adjunctive procedure does not necessarily represent an increase in hospital revenues. A given operation may even have a negative CM when it produces an operating room overrun, thus causing personnel overtime, which can even double the fixed cost of one hour of operating room time. An effective operating room management must therefore aim at minimizing both under-used and over-used operating room time, by implementing both daily tactical decisions and long-term strategic choices such as slot design and allocations.[16]

The systematic application of our allocation criterion on a vast scale could have a significant impact on the cost-effectiveness of operating suites and ultimately on total hospitals revenues. Moreover, the adoption of the concept of CMH in operating room management is not only an effective managerial tool which can contribute to implement the cost-effectiveness, but also a strategic tool for the hospital/clinic as a whole. In fact, through a more cost-effective allocation of its resources, a hospital could also choose to promote a specific sector of its surgical activity, which would contribute the most to the overall structure sustainability.[8,18] On the other hand, the risk of a CMH-based approach in the allocation of healthcare resources such as operating room time would be a potential cream-skimming process, that selects only the most profitable surgical cases within a given case-mix, which would represent a critical ethical issue, particularly for a public hospital. Similarly, hospital administrators/managers may decide to prioritize surgeons who can complete operations faster, but the surgical ability is not the only factor affecting the operative time and CMH. In fact, many time-consuming surgical steps are procedure- and patient-specific, so the risk would be of selecting patients in which a fast and uncomplicated operation can be expected, or even selecting surgeons who select patients. The risk would be again that of a cream-skimming process for surgeons and patients, affecting equal access to healthcare. In our opinion, it is of utmost importance to be as neutral as possible and not to consider surgeons individually, though this model might be prone to such issue. In order to avoid such risks and preserve equal accessibility to the operating suite, the inclusion of CMH among the criteria to allocate operating room time should be reserved exclusively to unused staffed operating room time. It could improve this resource utilization according to a cost-effectiveness criterion, rather than on a simple ''come first–serve first'' basis.[9] Obviously, the most common elective procedures end up occupying the vast majority of the reallocated operating room time, as they are the main constituents of surgical services waiting lists. Only the ten most-commonly performed surgical operations were considered in this study. Rarely performed operation, even with a more profitable CMH, could be difficult to be promptly reallocated and may not contribute to shorten waiting lists.[19] However, this practice may be uneconomical for a public hospital, as giving regular priority to elective procedures with a lower CM has a profound impact on the operating suite cost-effectiveness. On the other hand, the optimization of surgical procedures with a low CM should be considered of primary importance. In this way, as part of the cost-effectiveness analysis of surgical procedures, a low CM could indicate the lack of a cost-effective resource consumption. Although a low CMH is not necessarily associated to inefficient resources' optimization, workflow processes may be evaluated for possible improvements.

Moreover, the allocation of public resources should not be simplistically dismissed as unethical or in some way subordinate to more important clinical considerations. On the contrary, in a context of increasingly limited resources, cost-effectiveness and thus the sustainability of care systems assumes a very strong ethical connotation, as any unnecessary resource consumed for a patient is eventually denied to another in the future. According to Dexter D. et al.,[16] the CM may not be the goal itself, but it is a tool that hospital administrators can use to cover fixed costs and still have sufficient funds remaining for the society's common good. If a hospital plans to expand its services to the poor, fund-increasing research, and so-forth, then it must also identify and maintain an appropriate mix of larger-margin services.[16]

Finally, this is just one aspect of the potential increase in hospital revenues in the long run, in the case such approach to operating room management is systematically applied. In fact, providing incentives such as attribution of more operating room time to a given surgical activity would produce positive consequences, such as the positive impact on the public image of a given hospital or clinic. As a consequence, it could become a referral center for a given surgery and consequently attract more patients suffering from certain conditions, eventually leading to the performance of procedures with a high CMH.

The potential values of this model are its feasibility, reliability and reproducibility among hospitals that adopt a DRG-based reimbursement. Our results are not directly reproducible in terms of economic revenue but they give a potential basis to simply apply this model to other institutions. A retrospective analysis of a 2-months period collecting the DRG-based reimbursements, variable costs and operative times of surgical interventions should be enough. This simple model should easily help in increasing the cost-effectiveness of operating rooms according to specific hospital settings.

Our study has some limitations. Firstly, the analysis was based on data produced by a 2-months study period only in order to provide reproducibility and applicability. Longer data analyses are necessary to validate this model and to test reliability. Secondly, present data were based on a service operating on a DRG system basis and its conclusions might not be directly applicable to all reimbursement systems. Capitation and fee-for-service models are the two main methods of reimbursement. The fee-for-service is divided into cost-based reimbursement, charge-based reimbursement and prospective payment. CMH cannot be applied in the capitation model, while in the fee-for-service models it should be retrospectively possible in the cost-based and the charge-based reimbursements. In the prospective payment, which include DRG-based reimbursement, it should be easier applicable, as demonstrated by our study. In Brazil, the predominant reimbursement model is the fee-for-service and, therefore, CMH may be used.[20] At our

institution, a peculiar type of DRG reimbursement system, called Swiss-DRG,[5] is currently adopted and it shares many similarities to DRGs in other European countries and the United States.[21–23] That being said, even if reimbursements may have a slightly different CMH according to which healthcare systems is considered, results should remain comparable. Moreover, economic data are extremely context sensitive and may change significantly among different countries: for example, reimbursements, costs of personnel, costs per unit of operating room time are extremely different and can change the results accordingly, thus affecting their reproducibility. However, even if the entity of revenues and costs may change in terms of absolute values, the principles according to which the analysis has been conducted remain valid across different contexts: the staffed operating room time is the most relevant surgical fixed cost, affecting the whole economics of the clinical perioperative process. In order to optimize hospital revenues, two options remain valid: on the one hand, the increase in patients' turnover and the performance of more cases in the same available staffed hours; on the other hand, the completion of more cases with a higher CMH of operating room time.[16,17]

Finally, as already mentioned, these economic aspects are not the only criteria according to which the surgical activity of a given hospital should be organized and managed. In fact, more important criteria may be the direct consequences of a hospital's mission and its strategy in the long run. The latter, for example, may contemplate the acceptance of incurring in a temporary loss in cost-opportunity as a form of investment, in order to incentivize a given surgical activity, which is regarded as strategic. In fact, as it usually happens in other contexts with regard to the exploitation of precious resources, also the allocation of the operating room time should be rationally considered as an important strategic asset and used accordingly.[17] Shortening the waiting list of a given surgical service by constantly allocating more operating room time in its favor, in the long run, shapes the image of the hospital in the direction of a referral center in that kind of procedure, with direct positive consequences on outcomes and quality of the services provided. Of course, this cannot be the case for a public hospital, which has specific obligations toward society in providing whatever services are required, independently of their profitability. In this setting, the use of CMH of operating room time of given surgical procedures may also be a helpful tool to contribute to hospital sustainability.

Summary

In conclusion, as complex issues keep seriously jeopardizing the overall sustainability of most healthcare systems in developed countries, economic considerations are assuming a new ethical dimension and are increasingly incorporated into the decision-making process by healthcare managers. Surgical activity may be one of the most profitable activities for hospitals, but a cost-effective management of an operating suite demands a comprehension of its costs profile. To summarize this last aspect, the main factor affecting an operating suite cost-effectiveness is a rational utilization of its staffed total operating room time, in order to maximize occupation while avoiding overruns. Reallocation of unused operating room time should be performed according to ethical and economic principles. CMH may represent a simple, reproducible, and reliable tool in the setting of operating room management. The CMH-based reallocation of unused staffed operating room time to elective cases on a waiting list could improve the operating suite cost-effectiveness. Validation studies are needed to confirm the reliability of our model.

Conflicts of interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.bjane.2021.03.024.

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ORIGINAL INVESTIGATION

Low-cost *versus* high-fidelity pediatric simulators for difficult airway management training: a randomized study in continuing medical education

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Airway management

Abstract
Background: High-fidelity (HF) pediatric patient simulators are expensive. This randomized study aimed to compare the quality and educational impact of a full-scale simulation workshop with an HF infant simulator (SimBaby™, Laerdal) or with a low-cost (LC) simulator composed of an inert infant manikin with SimBaby™ software that displays respiratory/hemodynamic parameters on a monitor for medical education in pediatric difficult airway management.
Methods: After written informed consent, anesthetists and emergency or ICU physicians participated in teams (4 to 6 participants) in a training session that included direct participation and observation of two difficult intubation scenarios. They were randomized into two groups (HF group, n = 65 and LC group, n = 63). They filled out a simulation quality score (SQS, 0 to 50), self-evaluated their anesthetists' non-technical skills (ANTS) score (15 to 60), and an educational quality score (EQS, 0 to 60) immediately (T0, main criteria), as well as 3 (T3) and 6 (T6) months after the training session.
Results: We enrolled 128 physicians. Direct participation SQS (39 ± 5 HF group *versus* 38 ± 5 LC group), observation SQS (41 ± 4 H F group *versus* 39 ± 5 LC group), ANTS scores (38 ± 4 HF group *versus* 39 ± 6 LC group), T0 SQS (44 ± 5 HF group *versus* 43 ± 6 LC group), T3 and T6 SQS were not different between groups.
Conclusion: Our low-cost simulator should be suggested as a less expensive alternative to an HF simulator for continuing medical education in pediatric difficult airway management.

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Introduction

Tracheal intubation is frequently performed in children in anesthesia, intensive care, and emergency medicine. Despite the development of guidelines,[1] difficult intubation remains a major cause of morbidity[2] owing to the physiological characteristics of infants and young children, thereby contributing to the rapid onset of hypoxia during apnea.[3] The incidence of laryngospasm is especially increased when the anesthetist is insufficiently experienced.[4] Continuing education in difficult intubation is more necessary since it is less common in children.[5] High-fidelity simulation (HF) is a positive contribution to the management of pediatric emergencies with scenarios that recreate the clinical context as closely as possible.[6–8] HF patient simulators such as the SimBaby™ (Laerdal, Stavenger, Norway) include electromechanically controlled systems with computer software in order to mimic physiological functions including respiratory, hemodynamic, and pathological events. Multiple studies have demonstrated their interest in initial training and continuing medical education to improve technical and behavioral performance.[9,10] Their major inconvenience is cost, especially since this very fragile equipment requires technical maintenance. We propose a low-cost (LC) alternative consisting of an inert infant manikin with limited functionalities and a monitor which displays the progression of respiratory and hemodynamic parameters using SimBaby™ software.

We aimed to compare whether the quality and the educational efficacy perceived by HF SimBaby™ simulator learners are superior or not to an LC simulator for pediatric difficult airway management simulation training in a continuing medical education course.

Methods

This single-center open randomized study was performed in the High-Fidelity Simulation Center of our University after approval by our Institutional Ethical Committee (February 7, 2012). After informed written consent, all the anesthesiologists and emergency or intensive care physicians (certified health professionals or anesthesiologists, or emergency medicine residents at the end of their training) who participated in pediatric difficult airway management simulation training in 2012 and 2013 were included. None of the participants was at his or her usual hospital workplace. Exclusion criteria were refusal of a physician to participate in the study. In that case, he or she participated in the course without completing the evaluation questionnaires.

Pediatric simulators

Each simulation training session was scheduled for a team of 4 to 6 participants from the same medical specialty. The random allocation sequence was generated using a random-number table with three equilibrated blocks. Only one investigator generated the random allocation sequence, enrolled and assigned the teams as HF or LC groups. Allocation was implemented using sequentially numbered envelopes which were opened immediately before the simulation session.

In the HF group, the simulator was a SimBaby™. Briefly, airway configuration, pulmonary and cardiac auscultation, thoracic movements could be modified in order to simulate lingual or pharyngeal edema, difficult or accidental selective right main bronchus intubation, closed vocal cords, laryngospasm, bronchospasm, or acute respiratory distress. It was possible to mobilize the head in extension and rotation, jaw trust, insert a stomach tube and use all of the airway devices. If insufflation pressure was excessive, stomach dilatation occurred and facial mask ventilation became difficult. Peribuccal cyanosis appeared when SpO_2 was below 85%. A microphone built into the simulator made it possible to hear prerecorded sounds (screaming, crying, moaning, complaining, and vomiting). The evolution of events (dyspnea, apnea, obstruction, thoraco-abdominal asynchrony, laryngospasm, bronchospasm) and the monitor display of hemodynamics (electrocardiogram, blood pressure) and ventilation (respiratory rate, cyanosis, SpO_2, capnogram, O_2, N_2O, sevoflurane, and CO_2 inspiratory and expiratory fractions) was controlled by an instructor using predefined scenario scripts.

In the LC group, the simulator consisted of an inert infant manikin (Stat Baby, Simulaids Ltd, Leicestershire, United Kingdom) with non-movement and limited functionalities. There was no spontaneous ventilation or color change. The stomach could not be insufflated. It was only possible to close the vocal cords or generate labial edema using a pneumatic system by air through a 50-ml syringe in a long tube connected to the manikin. All the airway management devices described above were usable. The manikin was not connected to a computer system. However, the changes in physiological parameters displayed on the monitor were also controlled by an instructor with SimBaby™ software in the same manner as in the HF group.

Proceedings of the simulation session

The environment, equipped according to the scenario (at the patient's home, operating room, or pediatric emergency room and progression of the simulation was strictly identical whatever the simulator. The simulation was preceded by a briefing with presentation of the educational objectives, simulator, equipment, and environment. To ensure the reproducibility of simulation training, the briefing, control of the simulation software, and debriefing were always carried out by the same instructor. The facilitator's role was always performed by one of the three investigators. His or her mission was to provide the participants with additional information to manage the case and help them with the environment. In the LC group, the facilitator communicated clinical data that could not be transmitted by the manikin (cyanosis, apnea, thoraco-abdominal asynchrony, auscultation characteristics).

Physicians participated in the workshop in groups of 4 to 6 in the same specialty. Half of the group was equipped with microphones and participated directly in the first scenario while the other half observed the scenario in another room with simultaneous audio–video retransmission. The reverse procedure was applied to the second scenario. Each learner

was directly involved in one scenario and was an observer for the second. After each scenario, the debriefing was carried out with the entire group. The total duration of the simulation session was 60–70 minutes, with two 10-to-15-minute scenarios and two 20-minute debriefings.

Scenarios

Two scenarios were used for the anesthesiologist sessions and two others for the emergency and intensivist physicians. For each scenario, technical and non-technical educational objectives, briefing elements, script, information given to the learners, initial state of the simulator, standardized evolution of the simulator's behavior according to learner actions, and facilitator role were specified. The educational objectives of the scenarios were the evaluation and anticipation of difficult intubation, ventilation and oxygenation, the appropriate choice of anesthetic agents and intubation technique, equipment preparation task prioritization, and distribution and communication within the team.

For the anesthesiologists, the first scenario was a 12-month-old infant with 50% burned body surface and moderate cervical edema who had undergone a first dressing with surgical debridement under general anesthesia with tracheal intubation in the operating room of a regional pediatric burn center. Participants were informed of milk ingestion just before the accident and a slight inspiratory draw with tachypnea possibly due to moderate cervical edema. SpO_2 was 100% with a high concentration oxygen mask. The expected actions were preoxygenation, rapid sequence induction, and orotracheal intubation. The oropharyngeal sphere was slightly edematous and laryngoscopic view of the glottis was grade 3 according to the Cormack-Lehane classification system. Intubation was supposed to be performed using a long gum elastic bougie. The second case was a planned difficult intubation in a 9-month-old infant with Pierre Robin syndrome, undergoing surgical treatment of cleft lip and palate. Expected management was induction of general anesthesia by inhalation of sevoflurane with spontaneous ventilation and fiberoptic intubation with local glottic anesthesia.

For emergency room and intensivist physicians, the first scenario took place at the patient's home with a 12-month-old boy without difficult intubation who was found unconscious in his grandparents' bathroom after accidental ingestion of a sedative. The second scenario was, as above, a 12-month-old child with 50% burned body surface in the emergency room of a general hospital. Participants had to intubate the child in anticipation of a long transfer to a specialized burn center.

Evaluation

Participants evaluated their educational experience with three surveys that included Simulation Quality Score (SQS), Anesthetists' Non-Technical Skills (ANTS) score,[11] and Education Quality Score (EQS). SQS and EQS were derived from the French College of Anesthesia and Resuscitation questionnaire for evaluation of continuous medical education. ANTS score was described by Fletcher et al. for evaluation of non-technical performances.

The SQS questionnaire was a 5-item survey (realism of the patient simulator and the scenario, relevance of the medical crisis, participant comfort, and appreciation of the scenario. The participants filled out the SQS at time 0 (T0) immediately after the workshop for simulation direct participation (direct SQS) and simulation observation (observation SQS). Each item was rated using a modified Likert scale graded from 1 (poor) to 10 (excellent). The SQS, graded from 10 to 100, was the sum of the direct SQS and observation SQS.

The EQS was self-evaluated by the participants with six questions on the acquisition of new data, the correlation between the announced and processed objectives, the quality of teaching materials and teaching resources, the interest of the subject and the intended changes by the participant for his or her subsequent clinical practice. The answers were also given using a modified Likert scale graded from 1 to 10. EQS graded from 6 to 60 was the sum of scores for each of its 6 items. In addition, the magnitude of subsequent intended clinical practice changes was also rated on a scale from 1 (slight) to 10 (radical).

ANTS score was self-evaluated by the participants at T0.[11] This score included 15 items classified into four categories: task management (planning and preparing, prioritizing actions, providing and maintaining standards, identifying and utilizing resources), teamwork (coordinating activities with team members, exchanging information, using authority and assertiveness, assessing capabilities, supporting others), situation awareness (gathering information, recognizing and understanding, anticipating), decision-making (identifying options, balancing risks and selecting options, re-evaluating). Each item was graded from 1 (poor) to 4 (excellent) and ANTS score ranged from 15 to 60.

Finally, EQS was also evaluated by the participants 3 (T3) and 6 (T6) months after the workshop. T3 and T6 questionnaires were sent by e-mail. If there was no response, reminders were sent 2 and 4 weeks after the initial message.

Information on the study, the obtaining of informed consent and collection of questionnaires and demographic data (age, medical specialty, workplace, professional status, duration of practice, frequency of pediatric activity, and previous experience in simulation training) were carried out by a single investigator.

Statistical analysis

Statistical analysis was performed using Statview® 5 software (Abacus Concept, Inc. Berkeley, CA). The T0 EQS was the primary outcome. The other scores were secondary endpoints. T0 EQS was 46 $\pm$ 6 for 107 participants between 2008 and 2011 in similar pediatric difficult airway workshops with a SimBaby™ simulator (unpublished personal data). The number of participants needed to objectify a 4-point score variation with a 0.05 α risk and a 0.9 power with a two-tailed test was 33 participants per group. Given the potential of a high number of refusals to participate in the study and participants lost to follow-up, we chose to include all the participants in a pediatric difficult airway management workshop organized in our simulation center between January 2012 and April 2013. Data are expressed by medians and percentiles 25–75% or number (percentage) of parti-

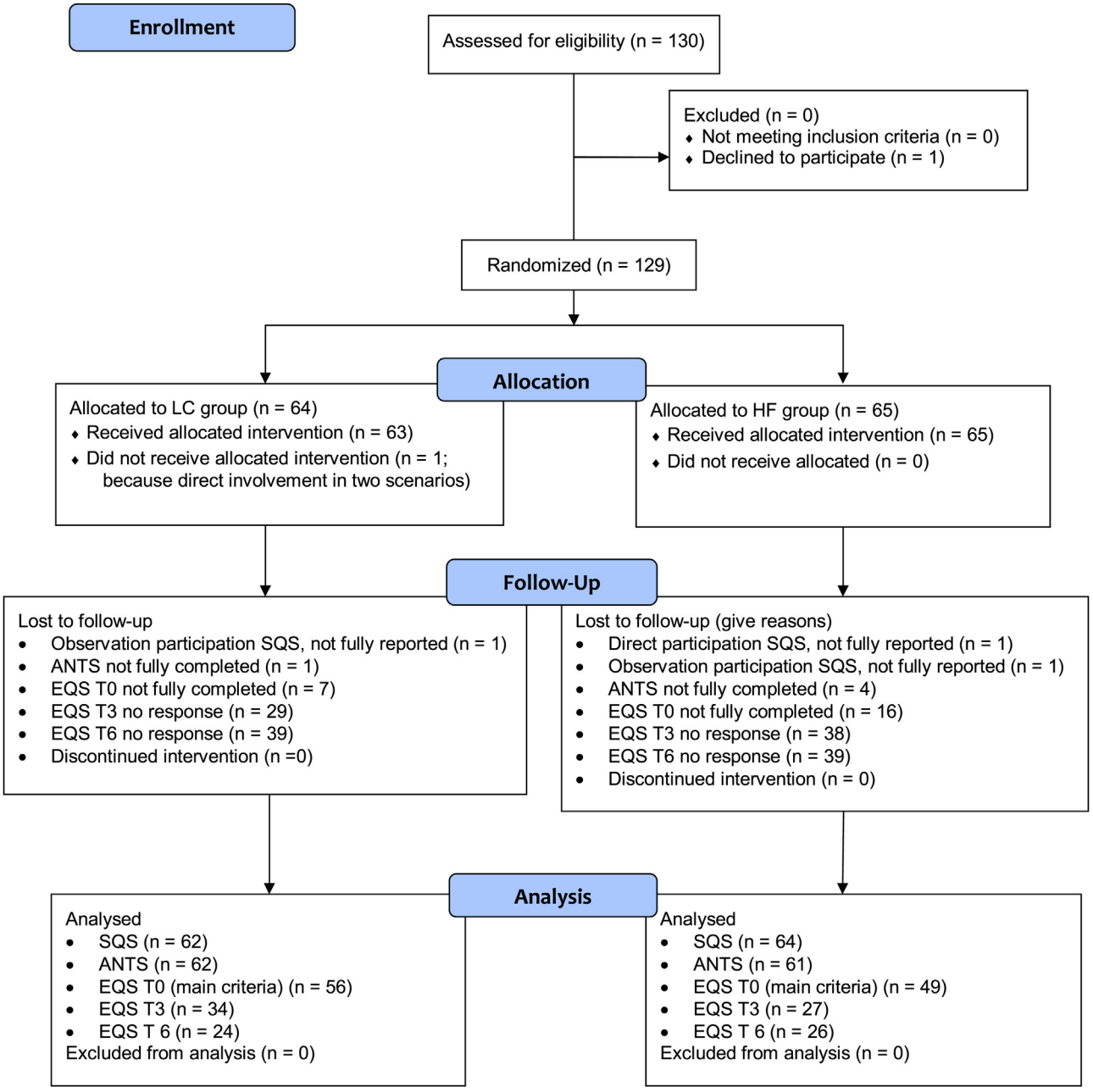

Figure 1 Consort Flow diagram.

cipants. Comparisons of demographic data and T0 scores between the LC and HF groups were performed with a Mann-Whitney U test or Chi-square as appropriate. A $p < 0.05$ was considered significant. Comparison of T0, T3, and T6 EQS between groups was performed using a repeated variance analysis followed by Bonferroni-Dunn tests.

Results

During the 13-month inclusion period, 130 participants attended pediatric difficult airway management workshops at our high-fidelity simulation center and were invited to join the study (Fig. 1). Only one participant, who did not sign the informed consent form, was not included. Another was excluded owing to direct involvement in two scenarios. Finally, 128 participants were enrolled, of whom 72.6% had been graduates for a median of 9 (4–17) years (Table 1). Response rates at T0, T3 and T6 to the EQS questionnaire (respectively 82.0%, 47.6%, and 39.1%) decreased over time in a comparable manner in the LC and HF groups (Fig. 2). EQS could be analyzed at T0 for 56 and 49 of the participants respectively in the LC and HF groups (Table 2). The EQS of the other participants could not be analyzed because some of the items had not been completed.

There was no difference in T0, T3, and T6 between LC and HF groups for the primary and secondary endpoints. An analysis of variance for repeated measures followed by the Bonferroni-Dunn test was made possible only for the

Table 1 Demographic characteristics and previous pediatric experience of the participants (n = 128).

Simulation group	Low-cost (n = 63)	High-fidelity (n = 65)	*p*
Medical discipline (%)			0.029
anesthesia	43 (68.2)	41 (63.1)	
intensive care medicine	5 (7.9)	0 (0)	
emergency room	15 (23.8)	24 (36.9)	
Age, years	36 (31–44)	33 (29–41)	0.0952
Sex ratio, F/M, n (%)	36 (57.1)/27 (42.9)	35 (53.8)/30(46.2)	0.7255
Graduate/fellow n (%)	13 (20.6)/50 (79.4)	22 (33.8)/43 (66.2)	0.1140
Previous simulaition experience, n (%)	36 (57.1)	37 (56.9)	> 0.999
Structure, n(%)			0.1628
University hospital	35 (58.3)	42 (64.6)	
General hospital	22 (36.7)	14 (21.5)	
Private hospital	1 (1.6)	(9.2)	
Mixed	2 (3.2)	1 (1.5)	
Pediatric practice, n (%)			0.3291
exclusive	3 (4,8)	1 (1.5)	
mixed with adult	41 (65.1)	38 (58.5)	
none	19 (30.2)	26 (40)	
Pediatric practice < 1 year, n (%)			0.4965
frequent	6 (9.5)	6 (9.2)	
occasional	9 (14.3)	6 (9.2)	
rare	19 (30.2)	15 (23.1)	
exceptional	28 (44.4)	38 (58.5)	
Pediatric practice 1 to 3 years, n (%)			0.5604
frequent	13 (20.6)	11 (16.9)	
occasional	20 (31.7)	15 (23.1)	
rare	14 (22.2)	19 (29.2)	
exceptional	16 (25.4)	20 (30.8)	
Pediatric practice > 3 years, n (%)			0.5000
frequent	19 (30.2)	13 (20.0)	
occasional	21 (33.3)	21 (32.3)	
rare	12 (19.0)	15 (23.1)	
exceptional	11 (17.5)	16 (24.6)	

Data are expressed as medians and percentile 25–75% or number (percentage) of participants.
Comparison of low-cost *versus* high-fidelity groups by Chi^2 or Mann-Whitney U test, as appropriate.
$p < 0.005$ was considered as significant.

Table 2 Educational Quality score (EQS) immediately (T0), 3 months (T3), and 6 months (T6) after the workshop.

Simulation group	Low-cost (n = 63)			High-fidelity (n = 65)			*p*[a]
	T0 (n = 56)	T3 (n = 34)	T6 (n = 24)	T0 (n = 49)	T3 (n = 27)	T6 (n = 26)	T0
Acquisition of new data	8 (7–9)	8 (6–8)	8 (5–8)	8 (8–9)	8 (7–8)	7 (6–8)	0.2058
Agreement of objectives with those announced	9 (8–10)	9 (8–9)	9 (7–9)	8 (8–10)	8 (8–9)	8 (8–9)	0.6712
Educational material quality	9 (8–10)	8 (7–9)	8 (7–9)	9 (8–9)	8 (7–9)	8 (7–9)	0.9263
Educational resource quality	9 (8–9)	9 (8–9)	8 (8–9)	9 (8–10)	9 (8–9)	9 (7–9)	0.2271
Level of interest of subject	9 (8–10)	9 (8–9)	9 (8–9)	9 (9–10)	9 (7–10)	8 (7–9)	0.4903
Learners who want to change their practices, n (%)	51 (91.1)	28 (82.3)	18 (75.0)	59 (90.8)	25 (92.6)	21 (80.8)	> 0.9999
Amplitude of change in practices	8 (5–8)	5 (4–7)	6 (0–8)	7 (6–8)	6 (5–7)	6 (5–7)	0.8830
EQS	49 (45–54)	47 (41–50)	45 (39–50)	50 (47–54)	47 (42–51)	45 (41–49)	0.3940

Data are expressed as medians and percentiles 25–75% or number (percentage) of responder participants.
EQS is the sum of the scores assigned to the 6 items.
[a] T0 comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test, *ns*.

Table 3 Simulation quality score (SQS) evaluated by the participants during direct participation and observation.

Simulation	Low-cost	High-fidelity	*p*
Direct participation SQS	(n = 63)	(n = 64)	
Simulator realism	7 (5–8)	8 (7–9)[a]	< 0.0001[a]
Scenario realism	9 (8–10)	9 (8–10)	0.5990
Relevance of the critical situation	8 (7–9)	8 (8–9)	0.2955
Participant comfort	7 (5–8)	5 (4–6)[a]	0.0020[a]
Appreciation of the scenario	9 (8–10)	9 (8–10)	0.7084
Total	38 (35–41)	39 (37–42)	0.2617
Observation SQS	(n = 62)	(n = 64)	
Simulator realism	7 (5–8)	8 (7–9)[a]	< 0001[a]
Scenario realism	9 (8–10)	9 (8–9)	0.6317
Relevance of the critical situation	8 (8–9)	9 (8–10)	0.1959
Participant comfort	7 (6–8)	7 (5–8)	0.1121
Appreciation of the scenario	9 (8–10)	9 (8–10)	0.5643
Total	39 (35–43)	40 (38-44)	0.0850
SQS	(n = 62) 77 (73–83)	(n = 64) 80 (75–6)	0.1517

Data were expressed as median and percentiles 25–75%.
A direct participation SQS not completely filled in the HF group was not analyzed.
An observation SQS, not fully reported in each group, was not analyzed.
SQS being the sum of the participation and direct observation SQS, it was only analyzed when both of its components were reported.
Comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test.
[a] $p < 0.05$ was considered as significant.

Table 4 Anesthetists' Non-Technical Skills (ANTS) core self-evaluated by the participants.

Groups	Low-cost (n = 62)	High-fidelity (n = 61)	*p*
Task management	11 (10–12)	11 (9–11)[a]	0.0195[a]
Teamwork	14 (12–15)	14 (13–15)	0.5257
Situational awareness	9 (8–9)	9 (8–9)	0.6220
Decision making	8 (7–9)	9 (7–9)	0.3508
ANTS score	42 (38–45)	41 (38–43)	0.4452

Data were expressed as median and percentiles 25–75%.
The ANTS score is the sum of the 4 items.
The ANTS score was not fully completed by one participant in the low-cost group and by 4 participants in the High-fidelity group and was not analyzed.[a]
Comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test.
[a] $p < 0.05$ was considered as significant.

participants who completed all of the T0, T3, and T6 EQS questionnaires, i.e., 18 in the LC group and 12 in the HF group. No group effect was noted ($p = 0.6624$). In contrast, a time effect was observed ($p = 0.0001$) with a T0 EQS higher than the T3 and T6 EQS. T3 and T6 EQS were not different (Fig. 2). SQS (Table 3) were not different between the groups regardless of the component (direct participation or observation) and their items except for two of them. Realism of the manikin was higher and participant comfort was lower in the HF group. The ANTS score (Table 4) was not different between either group. It was the same for all of its items *except for ẗask managementc̈onsidered easier in the LC group with a slightly higher score* (*p= 0.0195*).

Discussion

The main finding based on our results is that the quality of the simulation and educational impact of our low-cost pediatric simulator evaluated by the participants was not different from that of a high-fidelity patient simulator when used for training in pediatric difficult airway management in continuing medical education.

The originality of this study lies in its design and theme. Randomization and participants of diverse origins reinforce our findings. Some studies have concluded that the efficacy of high-fidelity simulation is not systematically higher than a well-built low-fidelity simulation,[12–15] but this has never been shown in the management of pediatric airways. Owing to the high incidence of respiratory complications, intubation remains a challenge for anesthesiologists and emergency physicians who only occasionally have pediatric practice.[4] The very heterogeneous prior experience of our participant population underlines the need for simulation training in this field of activity.[16]

Analysis of the questionnaires identified only a difference for two EQS items. The realism of SimBaby™ was obviously higher. The lower participant comfort score in the HF group could be related to the greater vulnerability of the SimBaby™ and fear of damaging it during intubation maneu-

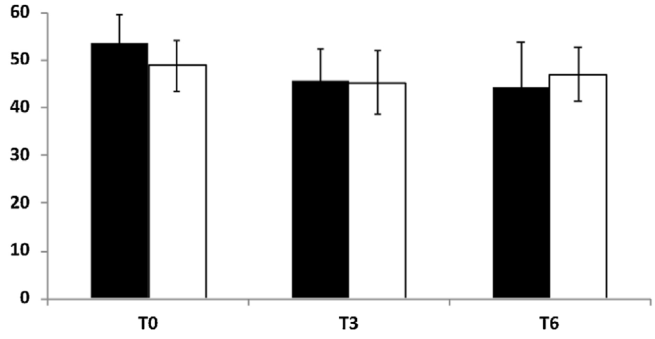

Figure 2 Comparison of the Educational Quality (EQS) score immediately (T0), 3 (T3) and 6 months (T6) after the training sessions for the participants of the HF group (n = 12) (■) and LC groups (n = 18) (▭) who responded to the survey 3 times. Variance analysis for repeat measurement, group effect ns, time effect with T3 and T6 versus T0, $p < 0.0001$. Data are mean ± SD.

vers – leading to overprotection of the simulator by the instructor. Another explanation is that the HF group participants had to see some medical simulation change (cyanosis, apnea), interpret it and act on it, whereas in the LC group these modifications were described by the instructor. The higher comfort score in the LC group may be related to an easier task. Lower comfort in the HF group may also reflect higher anxiety. The pedagogical impact of stress in simulation is controversial. While a moderate level of stress can facilitate the mobilization of mental capacities, an excessive level is deleterious.

These low simulation quality differences did not influence the perceived efficacy. As Seropian et al. pointed out, simulation cannot be reduced to a manikin.[17] Multiple factors are likely to influence the quality of a simulation such as the reliability of the equipment, the environment, the relevance of the script, or the quality of the briefing and debriefing. The contribution of these elements to the fidelity of the simulation probably has a greater amplitude than the technical features of the manikin itself. Individual and team reflective feedback is strongly responsible for the passage of concrete experience to abstract conceptualization and is the main component of cognitive memory processes.[18]

Iterative laryngoscopy exposes SimBaby™ airways to irreversible damage in the glosso-epiglottitis folds and corners of the mouth. The relative cost ratio between low and high-fidelity simulators is approximately 1 to 10.[19] The maintenance of an infant HF simulator includes regular replacement of vulnerable airways while the maintenance cost of a low-fidelity patient simulator is insignificant. Our results confirm that the absence of an HF simulator should not hinder the implementation of a pediatric difficult airway management program. The objectives of simulation training in crisis resource management are not limited to the development of technical skills. A meta-analysis emphasized its interest in improving behavioral skills in airway management.[20] The performances described in the ANTS score significantly contribute to the favorable outcome of a life-threatening situation.[21]

Limitations should be discussed. Our results are valid only for the described scenarios. Facilitation should be carried out by an experienced trainer with sufficient knowledge of the scenario to communicate additional information about the patient's condition (e.g., respiratory arrest, cyanosis). However, once apnea occurs, whatever the mechanism, the only difference between the two simulators is the appearance or not of cyanosis. Visualization of the evolution of SpO_2 on the monitor compensates for it and the capnogram keeps track of the quality of ventilation. A relevant rating of the ANTS score requires training.[22] To the best of our knowledge, self-assessment in such situations has never been described. In the same manner, SQS and EQS have not been validated. Finally, evaluation of the efficacy of the workshop was only based on self-assessment by the participants and not on their clinical practice. This first level analysis according to the Kirkpatrick pyramid does not prejudge the acquisition of new skills in clinical practice, but it is nevertheless necessary to verify that the learner favorably reacts to the pedagogical technique.

HF simulators probably have a place for training participants who already have a certain expertise. A randomized study on peripheral venous catheter management highlighted the positive impact of a gradual increase in the fidelity of simulation tools on the performances of workshop participants.[23]

A low response rate is commonly observed in surveys several months after training. The decrease over time of the perceived educational impact is inevitable regardless of the teaching method used. The persistence of a long-term effect passes exclusively through regular training.[24,25]

Finally, various studies have demonstrated the interest of high-fidelity simulators in adults as well as in pediatrics for the development of technical and non-technical skills. However, our study is the first to propose and evaluate an alternative to a high-fidelity simulator for pediatric airway management scenarios. A very large number of anesthesiologists and emergency physicians have no access or access only with insufficient frequency to pediatric high-fidelity simulation training owing to the cost, especially in developing countries, but this is also true in all countries. The major contribution of our article is to propose a less expensive alternative that is easily accessible.

The substitution of an HF simulator with a low-cost device in a full-scale HF accredited continuous medical education workshop did not affect learner perception of the quality and impact of difficult pediatric airway simulation training.

Ethical approval

Approval by our Institutional Ethical Committee (Groupe Nantais d'Ethique dans le Domaine de la Santé) on February 7, 2012 and written informed consent of all participants.

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Conflicts of interest

The authors declare no conflicts of interest.

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ORIGINAL INVESTIGATION

Patient satisfaction in ambulatory anesthesia assessed by the Heidelberg Peri-anaesthetic Questionnaire: a cross-sectional study

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Ambulatory surgical procedures;
Patient satisfaction;
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Professional-patient relations;
Quality management;
Surveys and questionnaires

Abstract

Background: Service quality in anesthesiology has been frequently measured by morbidity and mortality. This measure increasingly considers patient satisfaction, which is the result of care from the client's perspective. Therefore, anesthesiologists must be able to build relationships with patients, provide understandable information and involve them in decisions about their anesthesia. This study aimed to evaluate the peri-anesthetic care provided by the anesthesia service in an ambulatory surgery unit using the Heidelberg Peri-anaesthetic Questionnaire.

Methods: This cross-sectional study used the Heidelberg Peri-anaesthetic Questionnaire to evaluate 1211 patients undergoing ambulatory surgery. We selected questions that showed a greater degree of dissatisfaction and correlated them with patient characterization data (age, sex, education, and ASA physical status), anesthesia data (type, time, and prior experience), and surgical specialty.

Results: Questions in which patients tended to show dissatisfaction involved fear of anesthesia and surgery, feeling cold, the urgent need to urinate, pain at the surgical site, and the team's level of concern and speed of response in relieving the patient's pain.

Conclusion: The Heidelberg Peri-anaesthetic Questionnaire proved to be a useful tool in identifying points of dissatisfaction, mainly fear of anesthesia and surgery, feeling cold, the urgent need to urinate, pain at the surgical site, and the team's level of concern and speed of response in relieving the patient's pain in the population studied. These were correlated with patient, anesthesia, and surgical variables. This allows the establishment of priorities at the different points of care, with the ultimate goal of improving patient satisfaction regarding anesthesia care.

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Introduction

Modern medicine cannot be dissociated from the concept of quality, which promotes and improves habits and actions in the healthcare system as a whole. This concept is not universally understood, and many consider it to be vague and difficult to define. Some may argue that when there is competence and expertise, quality naturally follows, obviating the need for conceptualization. Donabedian,[1] however, said that despite these difficulties, it is possible to analyze the concept of quality in healthcare. The study of patient-oriented quality implies a need for constant evaluation of structure, processes, and results.

The development of access to information, especially since the 1990s, has led us to the "client era". The previous concept of the patient as passive and uninformed has changed to one of a patient/client who is demanding, critical, and a better evaluator, who interacts in ways to defend their interests. Evaluation of results has traditionally focused on measures of morbidity and mortality and taken less into account measurements based directly on patient observations.[2]

In modern anesthesia, the anesthesiologist should be capable of building relationships with patients, providing understandable information, involving patients in decisions about their anesthesia, and clarifying their concerns.[3,4]

In February 2012, the Royal College of Anaesthetists issued a position statement endorsing the view that all anesthesiologists should seek patient feedback using questionnaires, and should strive to improve relations with patients, as most complaints involve claims of poor communication.[5] The quest for feedback has become a routine part of our work, indicating a future in which anesthesiologists are valued not only for their excellence in practical and theoretical knowledge, but also for their effective skills in communication with patients.

In the literature, satisfaction is presented as an indicator of healthcare quality, correlated with patient behavior, particularly in relation to treatment adherence.[6] In anesthesiology, a specialization increasingly involved in perioperative care, there is a need to establish new measures for evaluating patient satisfaction.[7]

In the classic definition, satisfaction is ascertained as being based on the degree of congruence between the patient's expectations and what is achieved. The authors are aware that this is a subjective measurement, and difficult to evaluate.[8] However, the importance of satisfaction in anesthesiology is recognized, and several questionnaires to address this metric have been published.[9-16]

Schiff et al.[14] developed and validated a psychometric questionnaire designed to evaluate patient satisfaction in the peri-anesthetic experience: the Heidelberg Peri-anaesthetic Questionnaire. These authors considered that identifying dissatisfied patients is even more important than determining levels of satisfaction with the service. They therefore built and developed a multidimensional questionnaire that covers different phases of anesthesia care and seeks to address possible causes of patient dissatisfaction. The study was validated for use in the Portuguese language by Moura et al.[17]

The questionnaire is considered a valid and reliable instrument. It is easy to apply at the end of the postoperative period and is designed to be used in cross-sectional studies.[14]

This study aimed to evaluate the peri-anesthetic care provided by the anesthesia service in an ambulatory surgery unit, based on the opinion of patients, by using the Heidelberg Peri-anaesthetic Questionnaire to identify points of dissatisfaction at each stage of care, and correlated them with some patient, anesthesia, and surgery variables.

Methods

This work was submitted for approval by the Medical School (FMB) of the Universidade Estadual de São Paulo (Unesp) Ethics Committee, Botucatu Campus, on February 2, 2016, and received certificate (CAAE) number 52457915.6.0000.5411 from Conep (Brazil's National Committee for Ethics in Research). After obtaining written informed consent from all study participants, we conducted a cross-sectional study applying a questionnaire to 1.211 patients undergoing surgery, in an outpatient unit between March 30 and July 31, 2016. In a pre-anesthetic consultation, the anesthesiologists screened patients who would undergo surgery at the unit, performed the anesthesia, and assessed (nonsurgical) postoperative clinical events.

A psychometric questionnaire developed and validated by Schiff et al.,[14] the Heidelberg Peri-anesthetic Questionnaire, which had been translated into and validated in Portuguese by Moura et al.[17,18] was applied. The data were collected by a nurse of the research team, who was appropriately trained not to interfere with patients' responses. Data characterizing each patient, and their anesthesia and surgery (by surgical specialty) were recorded. The data were collected when patients were awake at their hospital bed and approaching the time of discharge.

The questionnaire comprises 38 items, in which the patient assigns a degree of agreement on a four-point Likert scale (strongly disagree, disagree, agree, strongly agree), making it impossible to choose a central response. The items are placed in chronological order according to the following phases of the service provided by the anesthesiologist: pre-anesthetic consultation, the perioperative period and post-anesthetic recovery. The questions covered five aspects: trust and atmosphere; fear; discomfort; treatment by personnel; and information and waiting.

The sample size was determined with reference to what is described in the literature,[14,17] and was intended to be representative of the hospital in full operation, considering the total number of surgeries carried out in the period of the investigation, their distribution by specialty, and the

demographic characteristics of each patient. The Heidelberg Peri-anaesthetic Questionnaire was organized as shown in Figure 1.

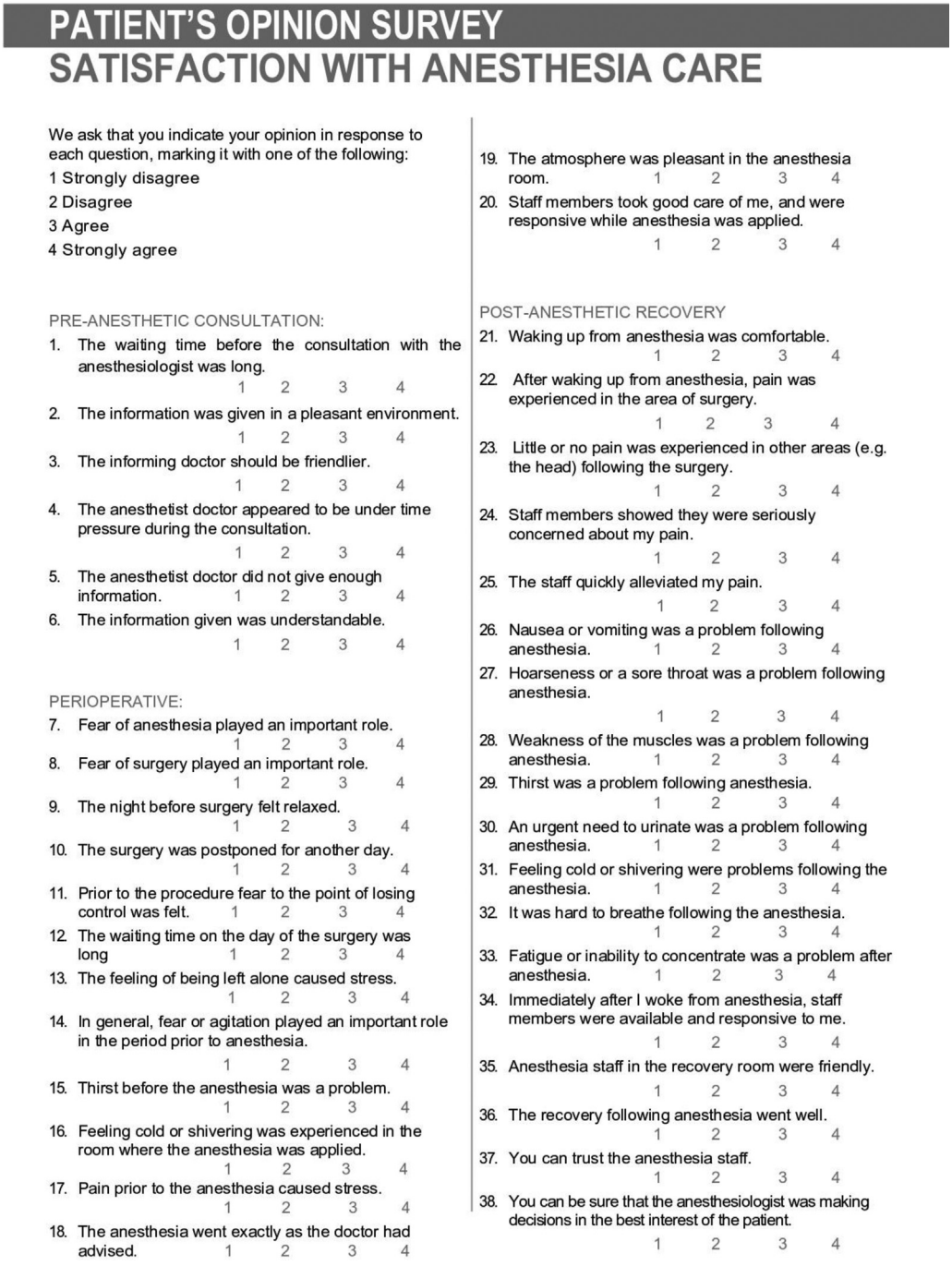
The inclusion criteria were age 18 or over; elective surgery; surgery with discharge expected on the same day; and absence of neuropsychiatric disease. The exclusion criteria were patients with cognitive impairment in communication; and refusal answer the questionnaire.

The following variables were also evaluated for each patient: age; sex; education; ASA (American Society of Anesthesiologists) physical status;[19] type of surgery; type of anesthesia; duration of anesthesia; and prior anesthesia.

Statistical analysis

Categorical variables are described by their absolute and relative frequencies. Continuous variables with normal distribution are described by their mean and Standard Deviation (SD), and variables with non-normal distributions are described by their median and quartiles.

Mean satisfaction scores were calculated for each question. Since the perception of satisfaction on the Likert scale differs according to each question, for standardization, the scores of questions that were asked in the negative format were reversed (a score of 1 was converted to 4, and vice



PATIENT'S OPINION SURVEY
SATISFACTION WITH ANESTHESIA CARE

We ask that you indicate your opinion in response to each question, marking it with one of the following:
1 Strongly disagree
2 Disagree
3 Agree
4 Strongly agree

PRE-ANESTHETIC CONSULTATION:

1. The waiting time before the consultation with the anesthesiologist was long. 1 2 3 4
2. The information was given in a pleasant environment. 1 2 3 4
3. The informing doctor should be friendlier. 1 2 3 4
4. The anesthetist doctor appeared to be under time pressure during the consultation. 1 2 3 4
5. The anesthetist doctor did not give enough information. 1 2 3 4
6. The information given was understandable. 1 2 3 4

PERIOPERATIVE:

7. Fear of anesthesia played an important role. 1 2 3 4
8. Fear of surgery played an important role. 1 2 3 4
9. The night before surgery felt relaxed. 1 2 3 4
10. The surgery was postponed for another day. 1 2 3 4
11. Prior to the procedure fear to the point of losing control was felt. 1 2 3 4
12. The waiting time on the day of the surgery was long 1 2 3 4
13. The feeling of being left alone caused stress. 1 2 3 4
14. In general, fear or agitation played an important role in the period prior to anesthesia. 1 2 3 4
15. Thirst before the anesthesia was a problem. 1 2 3 4
16. Feeling cold or shivering was experienced in the room where the anesthesia was applied. 1 2 3 4
17. Pain prior to the anesthesia caused stress. 1 2 3 4
18. The anesthesia went exactly as the doctor had advised. 1 2 3 4
19. The atmosphere was pleasant in the anesthesia room. 1 2 3 4
20. Staff members took good care of me, and were responsive while anesthesia was applied. 1 2 3 4

POST-ANESTHETIC RECOVERY

21. Waking up from anesthesia was comfortable. 1 2 3 4
22. After waking up from anesthesia, pain was experienced in the area of surgery. 1 2 3 4
23. Little or no pain was experienced in other areas (e.g. the head) following the surgery. 1 2 3 4
24. Staff members showed they were seriously concerned about my pain. 1 2 3 4
25. The staff quickly alleviated my pain. 1 2 3 4
26. Nausea or vomiting was a problem following anesthesia. 1 2 3 4
27. Hoarseness or a sore throat was a problem following anesthesia. 1 2 3 4
28. Weakness of the muscles was a problem following anesthesia. 1 2 3 4
29. Thirst was a problem following anesthesia. 1 2 3 4
30. An urgent need to urinate was a problem following anesthesia. 1 2 3 4
31. Feeling cold or shivering were problems following the anesthesia. 1 2 3 4
32. It was hard to breathe following the anesthesia. 1 2 3 4
33. Fatigue or inability to concentrate was a problem after anesthesia. 1 2 3 4
34. Immediately after I woke from anesthesia, staff members were available and responsive to me. 1 2 3 4
35. Anesthesia staff in the recovery room were friendly. 1 2 3 4
36. The recovery following anesthesia went well. 1 2 3 4
37. You can trust the anesthesia staff. 1 2 3 4
38. You can be sure that the anesthesiologist was making decisions in the best interest of the patient. 1 2 3 4

Figure 1 Adapted from the Heidelberg Peri-anaesthetic Questionnaire.

versa, and a score of 2 was converted to 3, and vice versa). These are questions 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 22, 26, 27, 28, 29, 30, 31, 32 and 33: they are marked with an "X" in Figure 2. Questions with a mean score of satisfaction below the overall mean minus 1 SD were selected for further evaluation as potential factors associated with dissatisfaction. Below, where convenient, we refer to the questions by their numbers, e.g., "Q7", "Q8".

Multivariate logistic regression analysis was used to identify the variables associated with dissatisfaction in the selected questions. Dissatisfaction was defined as a score of 1 (strongly disagree) or 2 (disagree).

All the tests were two-tailed, and final results with $p \leq 0.05$ were considered statistically significant. The data were analyzed using the Statistical Package for Social Sciences software (version 20.0, SPSS, Chicago, IL, USA) and registered on a Microsoft Excel database (version 16.47.1). We followed STROBE guidelines to report this trial.

Results

The variables studied, together with the respective results, are shown in Table 1. Only 8 (0.66%) patients refused to answer all the questions. Questions with mean satisfaction minus 1 SD are shown below in Figure 2.

Questions 24 and 25, which were below mean satisfaction minus 1 SD (3.70 to 0.63), are shown in Tables 2 and 3, respectively.

In Question 24, compared to female patients, male patients had a 2.11 times higher tendency toward dissatisfaction in this question (95% CI 0.995—4.475, $p = 0.051$). This means that men more often felt that staff members were not seriously concerned about their pain. Patients who had undergone prior general anesthesia were more likely to show dissatisfaction, with an Odds Ratio (OR) of 1.68

Table 1 Data on patient characterization, anesthesia, and surgery by specialty (n = 1211).

Variables	Values
Age (mean ± standard error)	44.8 ± 15.4
Female	990 (81.8)
Education	
Illiterate or incomplete primary	9 (0.8)
Complete elementary	23 (1.9)
Complete high school	286 (24.0)
Incomplete or complete college	876 (73.4)
Prior anesthesia	
General	675 (55.7)
Spinal block	569 (47.0)
Local and sedation	252 (20.8)
Peripheral block	4 (0.3)
ASA	
I	553 (45.7)
II	644 (53.3)
III	12 (1.0)
Type of anesthesia	
General	995 (82.2)
Local and sedation	161 (13.3)
Peripheral block	53 (4.4)
Spinal block	2 (0.2)
Anesthesia time (min) (median and quartiles)	50 (45—75)
Surgical specialty	
(1) Gynecological	551 (45.5%)
(2) Vascular	207 (17.1%)
(3) Dermatological	101 (8.3%)
(4) Ophthalmic	99 (8.2%)
(5) Orthopedic	125 (10.3%)
(6) Urological	51 (4.2%)
(*) Other	77 (6.4%)

The data are presented as valid n (%), unless specified.

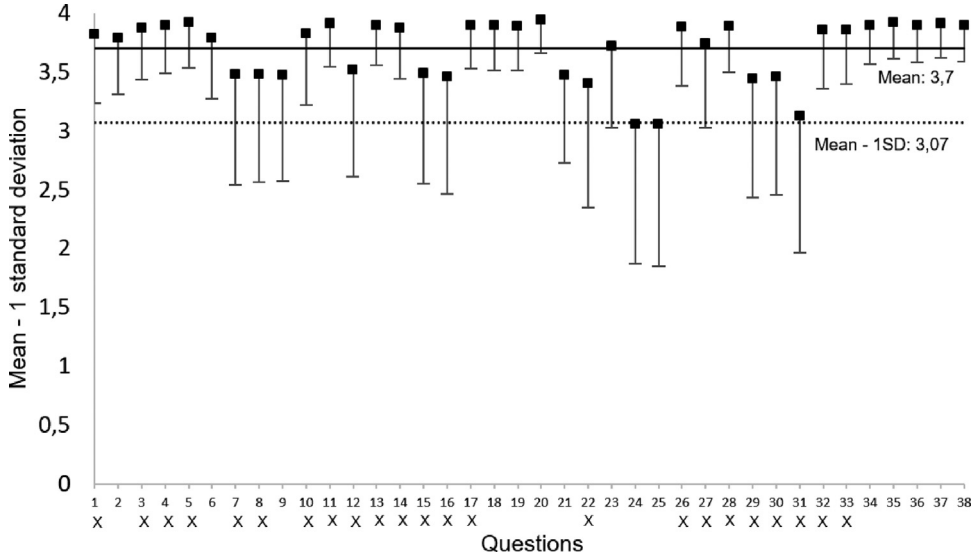


Figure 2 Mean — 1 standard deviation of satisfaction scores for each item. Mean satisfaction scores were calculated for each question. Questions that were asked in the negative nature are marked with an "X". Questions below the satisfaction average are represented in Tables 2 and 3. Questions with a high internal SD are analyzed in Table 4.

Table 2 Q24: "Staff members showed they were seriously concerned about my pain".

	Coefficient	SE	Wald	OR	CI 95%	*p*-value
Age (each additional year)	-0.004	0.010	0.178	0.996	0.976–1.016	0.673
Male	0.747	0.384	3.792	2.110	0.995–4.475	0.051
Education (ref.: Complete college)			2.703			0.259
Complete elementary	0.799	0.604	1.748	2.223	0.680–7.269	0.186
Complete high school	0.333	0.286	1.356	1.395	0.797–2.443	0.244
ASA (ref.: ASA I)			0.032			0.984
ASA II	0.045	0.257	0.031	1.046	0.632–1.731	0.860
ASA III	0.075	1.058	0.005	1.078	0.135–8.583	0.943
Anesthesia Type (ref.: General)			0.551			0.759
Local and sedation	-0.328	0.732	0.200	0.721	0.172–3.027	0.655
Peripheral block	0.405	0.736	0.302	1.499	0.354–6.343	0.582
Total anesthesia time (minutes)	-0.009	0.005	3.034	0.991	0.981–1.001	0.082
Prior anesthesia						
General	0.518	0.261	3.943	1.678	1.007–2.796	0.047
Local and sedation	-0.107	0.309	0.120	0.899	0.491–1.646	0.729
Spinal block	-0.065	0.265	0.060	0.937	0.557–1.576	0.806
Surgical specialty			19.705			0.003
(1) Gynecological	-0.622	0.352	3.126	0.537	0.269–1.070	0.077
(2) Vascular	0.303	0.359	0.710	1.354	0.669–2.737	0.399
(3) Dermatological	1.173	0.652	3.231	3.231	0.899–11.604	0.072
(4) Ophthalmic	-1.700	0.928	3.358	0.183	0.030–1.125	0.067
(5) Orthopedic	0.146	0.460	0.101	1.157	0.470–2.850	0.751
(6) Urological	1.217	0.533	5.203	3.376	1.187–9.603	0.023

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval.

Table 3 Q25: "The staff quickly alleviated my pain".

	Coefficient	SE	Wald	OR	95% CI	*p*-value
Age (each additional year)	-0.013	0.011	1.548	0.987	0.967–1.008	0.213
Male	0.782	0.402	3.793	2.187	0.995–4.806	0.051
Education (ref.: Complete college)			2.276			0.320
Complete elementary	0.592	0.644	0.844	1.807	0.511–6.391	0.358
Complete high school	0.379	0.287	1.742	1.460	0.832–2.562	0.187
ASA (ref.: ASA I)			0.189			0.910
ASA II	-0.087	0.261	0.111	0.917	0.549–1.530	0.739
ASA III	0.214	1.030	0.043	1.239	0.165–9.329	0.835
Anesthesia type (ref.: General)			1.305			0.521
Local and sedation	-0.615	0.860	0.511	0.541	0.100–2.918	0.475
Peripheral block	0.717	0.832	0.744	2.049	0.402–10.455	0.388
Total anesthesia time (minutes)	-0.006	0.005	1.376	0.994	0.985–1.004	0.241
Prior anesthesia						
General	0.616	0.266	5.354	1.852	1.099–3.122	0.021
Local and sedation	-0.057	0.311	0.033	0.945	0.513–1.739	0.855
Spinal block	-0.181	0.271	0.448	0.834	0.491–1.418	0.503
Surgical specialty			17.954			0.006
(1) Gynecological	-0.684	0.353	3.750	0.504	0.252–1.008	0.053
(2) Vascular	0.129	0.372	0.120	1.138	0.548–2.360	0.729
(3) Dermatological	1.554	0.766	4.119	4.733	1.055–21.236	0.042
(4) Ophthalmic	-1.503	0.943	2.542	0.222	0.035–1.411	0.111
(5) Orthopedic	0.049	0.484	0.010	1.050	0.406–2.714	0.919
(6) Urological	1.089	0.543	4.030	2.973	1.026–8.611	0.045

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval.

(95% CI 1.01−2.80, p = 0.047). In the multivariate analysis of question 24, patients who had undergone urological surgery (category 6) had a higher chance of dissatisfaction, compared to the mean general dissatisfaction value, with an OR of 3.38 (95% CI 1.19−9.60, p = 0.023). Patients who underwent dermatological surgery (category 3) also showed a tendency toward increased chance of dissatisfaction, with an OR of 3.23 (95% CI 0.90−11.60, p = 0.72), compared to the mean general dissatisfaction value. Patients who had undergone gynecological surgery (category 1) and ophthalmologic surgery (category 4) showed a tendency toward a decreased chance of dissatisfaction in relation to concern of the staff with patient pain, with ORs of 0.54 (95% CI 0.27−1.07, p = 0.77) and 0.18 (95% CI 0.30−1.13, p = 0.67), respectively.

The likelihood of dissatisfaction with the speed with which members of the anesthesia team relieved the patient's pain was higher in patients with a prior history of general anesthesia (OR = 1.85, 95% CI 1.09−3.12, p = 0.021) and tended to be higher among men (OR = 2.19, 95% CI 0.995 −4.80, p = 0.051). Thus, being male and having a history of prior general anesthesia were factors associated with dissatisfaction in this question (i.e., negative response to the question "The staff quickly alleviated my pain").

Patients who underwent dermatological surgery (category 3) and urological surgery (category 6) were more likely to be dissatisfied with the speed of team members in easing their pain, with ORs of 4.73 (95% CI 1.055−21.236, p = 0.42) and (OR = 2.97, 95% CI 1.30−8.61, p = 0.45), respectively. Patients undergoing gynecological surgery (category 1) showed a tendency toward decreased chance of dissatisfaction with the speed of team members in easing their pain, with an OR of 0.50 (95% CI 0.25−1.01, p = 0.053).

We noted that a relatively high number of patients did not respond to questions 24 (59.6%) and 25 (62.8%) due to the condition established in the question, which was having felt postoperative pain.

In our study, advanced age and prior experience of general anesthesia were correlated with patients being less afraid of undergoing further anesthesia (Q7), and older patients were also found to be less afraid of surgery (Q8). We conclude that in relation to fear, there is a need to improve care for patients who have never undergone anesthesia and for younger patients.

In relation to another question involving anxiety (Q9), specifically regarding the night before surgery (Q9), there was a tendency for older patients to be more relaxed, supporting the concept of eliminating the use of anxiolytics as premedication in the cases of some of these patients.

There were a few questions that had a higher satisfaction mean than the mean minus 1 SD, but with a high internal SD among the results, indicating a great deal of heterogeneity among the answers. Although a high mean was maintained, many individuals had poor experiences and were dissatisfied. The questions in which means were good but internal SDs were high are indicative of points in anesthetic care with the potential for improvement in terms of greater uniformity in care quality. These were questions Q7 (SD = 0.936), Q8 (SD = 0.918), Q9 (SD = 0.895), Q12 (SD = 0.906), Q15 (SD = 0.945), Q16 (SD = 0.998), Q21 (SD = 0.747), Q22 (SD = 1.051), Q29 (SD = 1.005), Q30 (SD = 1.004) and Q31 (1.169), as shown in Table 4.

Discussion

In this study, using the Heidelberg Peri-anaesthetic Questionnaire, patients tended to show dissatisfaction related to fear of anesthesia and surgery; feeling cold; urgent need to urinate; pain at the surgical site; and the level of the team's concern and speed of response in relieving their pain.

The questionnaire makes it possible to evaluate the quality of the peri-anesthetic care in an outpatient surgery unit, in the various stages of care in which the anesthetist is directly involved. This makes this tool more appropriate for an identification of dissatisfied patients than others widely cited in the literature, such as the QoR-40 questionnaire developed by Myles et al.[10] and the QoR-15 questionnaire developed by Stark et al.[16] in which evaluation is limited to the quality of post-anesthetic recovery.

In contrast to the original method developed by Schiff et al.[14] in which the questionnaire was distributed to patients and data collected subsequently, we applied the questionnaire in the form of a standardized interview. We chose this method because patients undergoing ophthalmic surgery could not read the questionnaire in the immediate postoperative period and would therefore have been excluded from the study. We chose a team member to conduct all the interviews and, similarly to Bauer et al.[20] we achieved surprisingly high patient acceptance and questionnaire completion rates.

Our mean satisfaction results were high compared to other studies on the subject in the literature.[14,17,20] Since patients tend to give positive answers to questions, the analysis gave priority to questions in which dissatisfaction was higher, irrespective of absolute values.

There was a tendency for older patients to feel less afraid of undergoing further anesthesia (Q7) and surgery (Q8), and to feel more relaxed the night before surgery (Q9). Celik et al.[21] evaluated preoperative anxiety and fear of anesthesia at a university hospital using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) score and did not find a significant correlation between anxiety scores and age. They observed, though, that as patients get older, their desire for information decreases. Data in the literature on correlation between anxiety and advanced age are divergent.

The waiting time on the day of surgery (Q12) was an area in which younger patients and those undergoing dermatological surgery had a higher chance of dissatisfaction.

We also analyzed dissatisfaction with thirst before anesthesia (Q15). We found that older patients had a tendency to complain less of thirst before surgery. Patients with prior experience of local anesthesia and sedation were more likely to be dissatisfied, possibly due to prolonged preoperative fasting time. On waking from anesthesia, thirst (Q29) continued to be an important factor of dissatisfaction, and elderly patients, again, were least likely to complain. Patients with a high school education were less likely to complain of thirst than patients with a college degree. As the thirst sensation decreases with age,[22] the elderly are more prone to dehydration; this group therefore requires special attention in this regard.

Feeling cold or shivering in the room where the patients were anesthetized (Q16) and after anesthesia (Q31) was a cause for dissatisfaction, especially among female patients,

Table 4 Variables associated with dissatisfaction in the questions analyzed.

	OR	95% CI	*p*-value
Q7. Fear of anesthesia played an important role.			
Age (each additional year)	0.990	0.978–1.003	0.082
Prior general anesthesia	0.751	0.544–1.035	0.080
Q8. Fear of surgery played an important role.			
Age (each additional year)	0.985	0.973–0.997	0.015
Q9. The night before surgery felt relaxed.			
Age (each additional year)	0.987	0.973–1.001	0.071
Q12. The waiting time on the day of the surgery was long			
Age (each additional year)	0.981	0.967–0.994	0.006
Dermatological surgery	1.769	1.091–2.867	0.021
Ophthalmic surgery	0.265	0.095–0.740	0.011
Q15. Thirst before the anesthesia was a problem.			
Age (each additional year)	0.986	0.975–0.999	0.028
Prior local and sedation anesthesia	1.446	1.008–2.078	0.045
Q16. Feeling cold or shivering was experienced in the room where the anesthesia was applied.			
Age (each additional year)	0.989	0.978–1.001	0.081
Male	0.592	0.380–0.922	0.020
Complete college	2.293	0.894–5.877	0.083
Q21. Waking up from anesthesia was comfortable.			
Male	0.477	0.226–1.004	0. 051
Local anesthesia and sedation	0.312	0.078–1.246	0.099
Prior local and sedation anesthesia	1.575	1.009–2.457	0.046
Gynecological surgery	1.561	0.931–2.617	0.091
Dermatological surgery	0.227	0.055–0.946	0.042
Q22. After waking up from anesthesia, pain was experienced in the area of the surgery			
Age (each additional year)	0.998	0.976–1.001	0.075
Male	0.484	0.294–0.797	0.004
Complete high school	0.672	0.463–0.975	0.036
Spinal block	0.638	0.454–0.897	0.010
Gynecological surgery	3.010	1.907–4.750	0.000
Dermatological surgery	0.220	0.066–0.738	0.014
Ophthalmic surgery	0.354	0.132–0.952	0.040
Q29. Thirst was a problem following anesthesia.			
Age (each additional year)	0.988	0.976–1.000	0.046
Complete high school	0.707	0.493–1.013	0.059
Q30. An urgent need to urinate was a problem following anesthesia.			
Age (each additional year)	0.983	0.968–0.997	0.020
Female	0.432	0.236–0.791	0.007
Anesthesia time (every single minute)	1.011	1.005–1.016	0.000
Urological surgery	2.236	1.149–4.349	0.018
Gynecological surgery	1.443	0.951–2.191	0.085
Orthopedic surgery	0.472	0.219–1.017	0.055
Q31. Feeling cold or shivering were problems following the anesthesia.			
Age (each additional year)	0.980	0.968–0.991	0.001
Male	0.496	0.320–0.769	0.002
Anesthesia time (every single minute)	1.005	1.001–1.010	0.020
Ophthalmic surgery	0.582	0.321–1.058	0.076

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval.

and was directly related to duration of anesthesia. Older patients were less likely to be dissatisfied due to feeling cold before being anesthetized, likely because it is characteristic of advancing age to be less sensitive to variations in room temperature.[23] We conclude that these patients should be given special attention in regard to prevention and treatment of perioperative hypothermia.[24] Compared to patients with a high school education, patients with a college

education had a greater tendency to be dissatisfied due to feeling cold in the operating room.

Regarding pain at the surgical site on waking from anesthesia (Q22),[25-28] our results are similar to those found by Stark et al.[16] and Gerbershagen et al.[25] in equivalent samples. It can be concluded that young, female patients, those with a college education and those undergoing gynecological surgery under general anesthesia had a greater chance of dissatisfaction due to pain at the surgical area.

The questions that addressed satisfaction with care in the case of postoperative pain (Q24 and Q25) were those for which the lowest mean satisfaction scores were found, and these mean scores were also lower than those found by Moura et al.[17] We observed that the number of individuals who did not answer the two questions (Q24, 59.6% and Q25, 62.8%) was very high due to a characteristic of the method — since having felt pain in the postoperative period was a prerequisite for answering the question. Male patients were more likely to be dissatisfied than women. There was also a greater tendency toward dissatisfaction among patients who had undergone prior general anesthesia. Being male, having a history of prior general anesthesia and having undergone urological surgery were factors associated with dissatisfaction in response to these questions.

Elderly patients were less likely to experience an urgent need to urinate (Q30), which is expected, given that the sensation of having a full bladder decreases with advancing age.[29] Compared with male patients, female patients were more likely to feel an urgent need to urinate. It can be concluded that patients undergoing local anesthesia, sedation and spinal block were less likely to experience an urgent need to urinate than those who underwent general anesthesia. Moreover, the longer the duration of anesthesia, the greater was the likelihood of the patient experiencing an urgent need to urinate after surgery. This result is expected due to the longer period of hydration without the possibility of emptying the bladder.

There were significant correlations between higher satisfaction and older age and lower education level. Our results resemble those found in a meta-analysis performed by Hall et al.[30] where older patients were observed to generally report less pain, nausea, and vomiting, and were likely to score more positively in level of satisfaction.

Limitations of this study include the fact that it was carried out at a single hospital, and that the questionnaire was applied as an interview. The fact that the study was carried out in an autonomous outpatient surgery unit represented a limiting factor for the inclusion of surgical risk in the multivariate analysis. The high level of education of the studied population proved to be a possible limitation since it does not correspond to the average level of education of the population of the country (Brazil). The short period between the end of anesthesia and the interview may also have been a limiting factor, as these patients might still have been under the influence of drugs, and thus possibly with an altered mood, influencing their responses. A possible alternative to this problem would be to conduct a second interview, after hospital discharge. The fact that females were 81.8% of the population of this study could also have been a limiting factor since females may have different levels of satisfaction or dissatisfaction than males.

Conclusion

The Heidelberg Peri-anaesthetic Questionnaire proved to be a useful tool in identifying points of patient dissatisfaction, mainly fear of anesthesia and surgery, feeling cold, the urgent need to urinate, pain at the surgical site, and the team's level of concern and speed of response in relieving the patient's pain in the population studied. These were correlated with patient variables as age, sex, education level, ASA physical status, prior anesthesia, anesthesia type and duration and surgical specialty. This allows the establishment of priorities at the different points of care, with the ultimate goal of improving patient satisfaction in relation to anesthesia care.

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Conflicts of interest

The authors declare no conflicts of interest.

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ORIGINAL INVESTIGATION

Multitasking in postanesthesia care unit following nurse interruptions, an analysis of the causes and consequences using classification tree: an observational prospective study

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Abstract
Background: Postanesthesia Care Unit (PACU) is an environment associated with an important workload which is susceptible to lead to task interruption (TI), leading to task-switching or concurrent multitasking. The objective of the study was to determine the predictors of the reaction of the nurses facing TI and assess those who lead to an alteration of the initial task.
Methods: We conducted a prospective observational study into the PACU of a university hospital during February 2017. Among 18 nurses, a selected one was observed each day, documenting for each TI the reaction of the nurse (task switching or concurrent multitasking), and the characteristics associated with the TI. We performed classification tree analyses using C5.0 algorithm in order to select the main predictors of the type of multitasking performed and the alteration of the initial task.
Results: We observed 1119 TI during 132 hours (8.5 TI/hour). The main reaction was concurrent multitasking (805 TI, 72%). The short duration of the task interruption (one minute or less) was the most important predictor leading to concurrent multitasking. Other predictors of response to TI were the identity of the task interrupter and the number of nurses present. Regarding the consequences of the task switching, long interruption (more than five minutes) was the most important predictor of the alteration of the initial task.

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Conclusions: By analysing the predictors of the type of multitasking in front of TI, we propose a novel approach to understanding TI, offering new perspective for prevention strategies.

Introduction

Twenty years ago, the *To err is human* report lifted the veil off the medical error by pointing out that nearly 100,000 patients die every year from medical errors into the United States.[1] This led to an awareness of the healthcare professional on their impact on patient safety, and opened a new opportunity for research to improve patient care. James Reason in *Human error* (1990) suggested that task interruption (TI) may induce lapses of attention and cause a specific type of error called omission. Interruption is a frequent event during everyday activities in healthcare.[2] While operating rooms, intensive care units or emergency departments were studied as healthcare settings favouring task interruption, only one study evaluated task interruptions during patient handover in the PACU.[3] Still, the PACU is an environment associated with an important cognitive load for the nurses considering rapid patient turnover, monitoring and alarms, drug administration, and multiple caregiver interactions as part of the workload. This environment is similar to that of an intensive care unit or emergency department both of which are propitious to task interruption.

The healthcare professional experiencing task interruptions reacts inexorably with multitasking. Pashler et al.[4] defined two types of multitasking: the task switching, where the primary task switches to a new one, and the concurrent multitasking where both tasks are performed simultaneously. Those two processes rely on different neuronal pathways and induce different consequences.[5] Multitasking is a frequent event. In more than 1000 hours of observation, Walter et al. estimated its incidence to be from 9 to 17 times per hour in an emergency department.[6] Interruptions leading to multitasking are associated with an increase in error rate,[7,8] procedure failure, and clinical errors.[9]

Numerous studies focused on describing the characteristics of the interruptions and their consequences.[10] Still, knowledge is lacking regarding the factors that may influence the type of response triggered by an interruption and its negative effect on interrupted task.

Our hypothesis is that task switching or concurrent multitasking may occur differently according to the characteristics of the interruption, like the task interrupted (related to patient care or not), the characteristics of the interrupter (colleague, patient), the duration of the interruption, and its context. We therefore prospectively studied tasks interruptions and multitasking during nurse activity in a university hospital PACU.

Methods

Study design

We conducted a prospective observational study in the anesthetic department of a French university hospital in the PACU from the 8th of February to the 1st of March 2017. This paper was written according to the STROBE statement. The study has been submitted and approved by our local ethics board.

Setting

The PACU has a capacity of 12 patients for visceral, endocrinologic, urologic, and gynecologic procedures. During the daytime activity, from 8:10 AM to 8:00 PM, 4 nurses and 2 nursing assistants work in the PACU with a 30-minute lunch break. Each nurse is in charge of a maximum 4 patients. Day shifts are scheduled as follow: one nurse from 8:00 AM to 06:30 PM, two nurses from 9:00 AM to 07:30 PM and one from 11:40 to 07:30 PM. The 2 nursing assistants' day shifts are 8:00 AM to 4:00 PM, and 12:30 to 8:00 PM.

Data collection

Each day for 16 days, a unique and different nurse pertaining to the PACU was observed. A rotation of four observers was organized with one per day observing one randomly selected nurse. The four observers were anesthetic nurse trainees. These trainees were former nurses with several years of experience in emergency care, intensive care, or in PACU. All the observers were trained to detect and characterize task interruptions. The information and consent of the observed nurse were obtained at the beginning of the day, and from the patient at the beginning of the procedure. There were no refusals to participate. Then, the observer took place in a corner of the room with a laptop and stayed there as discreetly as possible, with no direct contact with the observed nurse. The data was collected using an Excel spreadsheet designed for the study.

Variable

The investigator reported data using a standardized checklist adapted from an evaluation tool issued by the French National Authority for Health (Haute Autorité de Santé, HAS).

Table 1 Definition used for Task interruption, Task switching, and Concurrent multitasking.[23]

	Definition
Task interruption	Task interruption if defined by a break in performance, provisional or definitive, of human activity. The source of the task interruption is internal or external to the recipient. The task interruption causes a break in the workflow, a disturbance of the concentration of the operator, and an alteration of the performance of the act. The possible realization of secondary activities completes to thwart the smooth running of the initial activity.
Concurrent multitasking	Concurrent multitasking (or dual-task interference, dual-tasking, dual-task performance) is the performance of two or more actions simultaneously.
Task switching	Task switching is the management of multiple tasks in which there is switching between tasks that are progressing in parallel.

Table 2 Data collected for each interruption observed.

Workload	Step of care	Interrupter	Interruption source
Number of healthcare professionals present	Patient admission	Oneself	Human direct interaction
Number of patient present	Drug preparation	Patient	Noise
	Nursing care	Healthcare professional	Phone
	Patient record filling	*Authority: Medical Doctor, Chief nurse, Anesthesiologist resident*	Alarm
	Patient monitoring	*Nurse/Anesthetist nurse*	Other
	Patient set-up	*Nurse assistant*	
	Nurse shift	*Other caregivers: SB, Regulator*	
		Other: Non-human interruption	
Subject of the task interruption	Duration of the interruption	Type of multitasking	Consequences of the multitasking
Social interaction	< 1 min	Task switching	Resumption of the initial task with no alteration
Seek information	1–5 min	*Withholding of the initial task*	Alteration of the initial task
Provide information	> 5 min	*Transfer the task to another caregiver*	*Cancellation*
Asking for help		Concurrent	*Alteration*
Logistic			Start over
Other (Supervision, Reminder...)			Resumption lag
			Other

The definitions used for the task interruption, task switching, and concurrent multitasking are described in Table 1. The data collected for each interrupted task were:

- The workload at the time of the task interruption characterized by the number of healthcare professionals present and the number of patients present;
- The step of care of the initial task out of seven predefined steps of the PACU care process;
- The caracteristics of the interruption: source, topic, duration defined as the time between the interruption of the initial task, and the end of the interrupting task;
- Nature of the interrupter: Patient, Healthcare professional, or Non-human interruption. The Healthcare professional was stratified according to the hierarchy of the hospital as Authority: medical doctor, chief nurse, resident; Colleague: nurse or anesthetist nurse; Nurse assistant, or the interrupter could also be identified as the Nurse (self-interruption);
- Type of multitasking: concurrent multitasking or task switching. In the case of task switching, the transfer of the task to another colleague or withholding of the initial task were documented;
- The consequences of multitasking: resumption of the initial task or the alteration of the initial task. The alteration of the initial task was defined as the cancellation of the task or the delaying of the task (starting over, resuming lag, etc.).

The detailed data collected are described in Table 2.

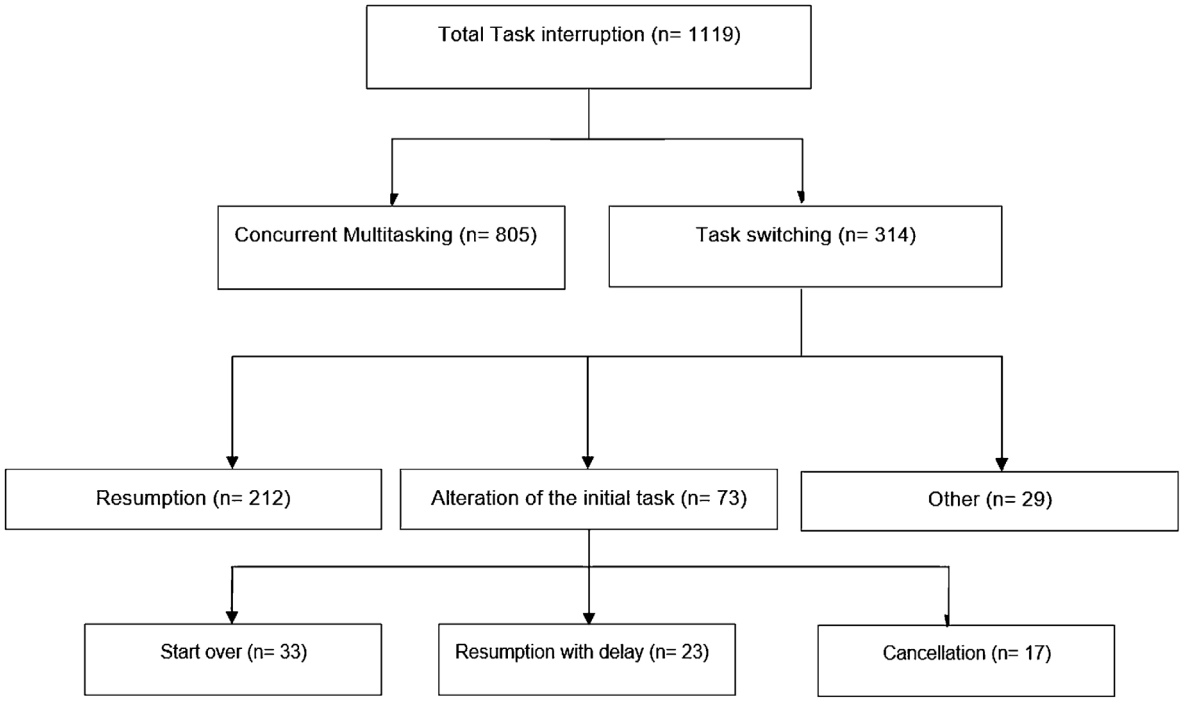

Figure 1 Flow chart of the reaction in front of a task interruption.

Objective

The primary objective of the study was to focus on the predictors of the reaction of the observed nurse (task switching or concurrent multitasking).

Our second objective was to select the predictors, in case of concurrent multitasking, leading to an alteration of the initial task.

Statistical analysis

Quantitative variables were presented with their median associated with their interquartile range. Qualitative variables were presented using numbers and proportions. The homogeneity between classes was evaluated using Pearson's Chi-square tests and Fisher Exact test (qualitative variable) and Welch *t*-test (quantitative variable).

In order to select and represent variables of importance for the description of the outcomes, classification tree analyses were computed using the C5.0 algorithm. The C5.0 algorithm is used to create a classification tree by selecting the most important variable for each node in order to lower the entropy among the different leafs created. Two classification trees were computed in order to explain (1) the choice of the nurse between concurrent multitasking or task switching, and in case of task switching (2), the resumption or alteration of the task. The predictor variables used for the analysis were the number of healthcare professionnals in the PACU, the number of patients in the PACU, the interrupter, the duration of the interruption, and the step of care.

Finally, in order to determined the stability of the first variable selected into the classification trees, we used 1000 bootstrap iteration to determined the percentage of selection of the first selected variable and confirmed his importance.

In all statistical tests (two-tailed), *p*-values smaller than 0.05 were considered as significant. Statistical analyses were performed using R version 3.4.3 (package C50 0.1.2).

Results

From the 8th of February to 1st of March 2017, we reported 1119 TI during 132 hours of observation (8.5 TI/hour), from 18 observed nurses. The main reaction was concurrent multitasking (805 TI, 72%). The task switching led to an alteration of the initial task in 73 TI (23%), with cancellation (17 TI, 23%), a resumption lag (23 TI, 32%), or starting over the task (33 TI, 45%). Among the 314 task switching, 291 result in witholding the initial task (93%), while 23 leaded to the transfer of the new task to another caregiver (8%). The repartition of the reaction and consequences of the TI are represented in the Figure 1.

Table 3 describes the characteristics of the task switching and concurrent multitasking. Task switching was preformed preferentially when the interruption source was a direct human interaction or a noise, and among interrupters, self-interruption, or patient interruption led to task switching (Table 3). During the patient monitoring or the nurse shift, the task interruption resulted principally in task switching. Task switching was also the main reaction when the subject of the task interruption was logistic reason or asking for help.

The practice of concurrent multitasking was predominant during the short interruptions (less than one minute), and when the task interrupter was a nurse assistant or another caregiver.

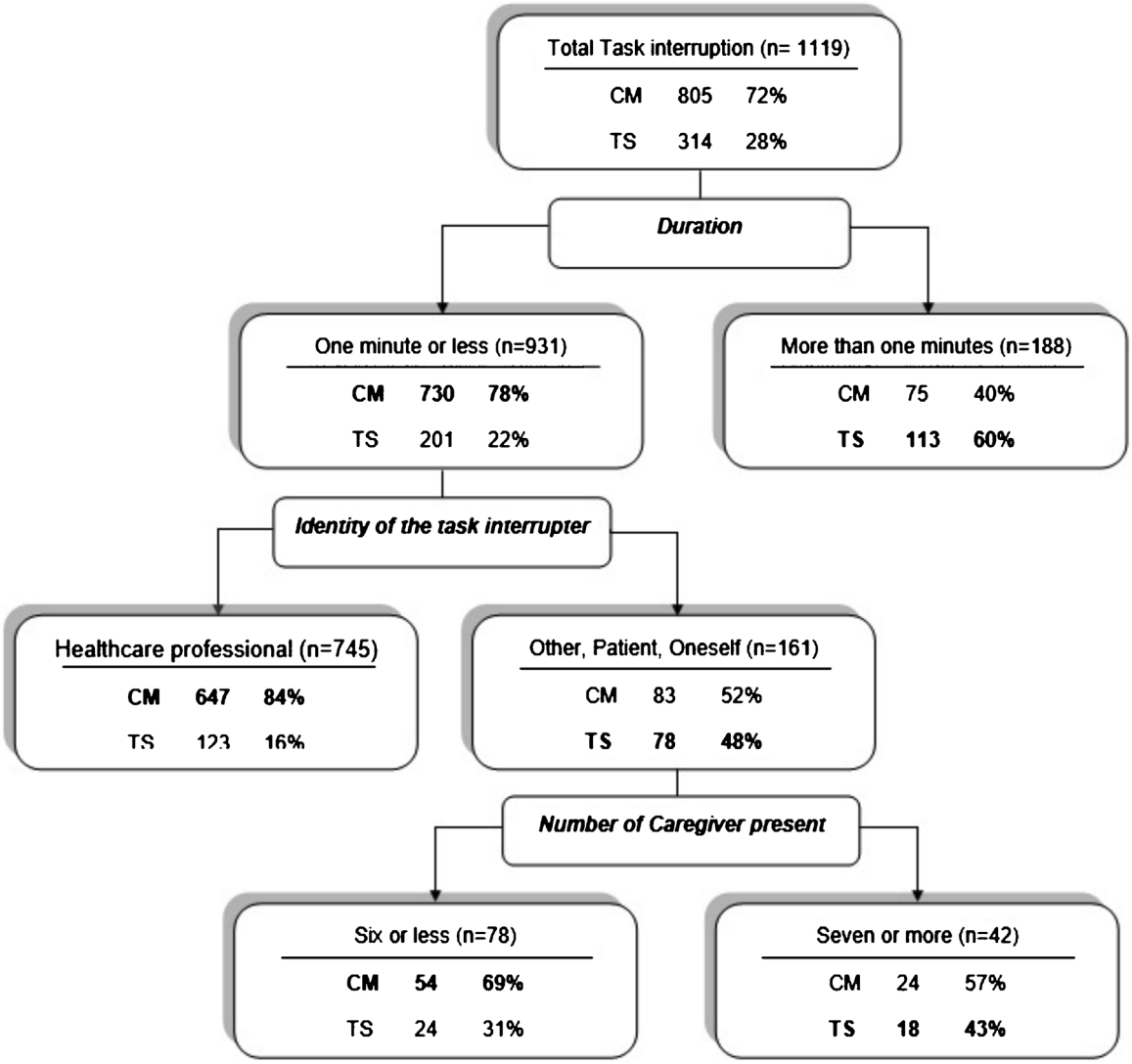

Figure 2 Classification Tree for the Task switching and Concurrent Multitasking. TS, task switching; CM, concurrent multitasking.

There was no difference in the mean number of patients in the PACU or of healthcare professionals for the two types of multitasking.

Considering the choice of task switching or concurrent multitasking, the most important associated factor was the duration of the task which interrupted the nurses. The short tasks (one minute or less) were significantly associated with the choice of concurrent multitasking, while longer tasks were associated with task switching. The other factors associated with the type of multitasking were the interrupter, the subject of the task interruption, and, less significantly, the number of nurses present (Fig. 2). Concerning the stability analysis, the duration was the most frequent variable selected (89.4%), followed by the identity of the task interrupter (9.8%).

Regarding the consequence of the task switching on the initial task, we documented more alteration of tasks during longer periods of time (Table 4). While the duration was still the main characteristic to determine the resumption or the alteration of the initial task, the step of care and the number of patient present were the two other associated factors (Fig. 3). Concerning the stability analysis, the duration was the most frequent variable selected (75.7%), followed by the step of care (12.7%).

Discussion

This study identified several important findings. First, to our knowledge, we conducted the first study to provide a description of a large number of task interruptions and its consequences in a PACU. Frequency of the TI is similar to those previously reported in ICU, emergency rooms and operating rooms.[11–13] Second, it highlights the variety of reactions of the nurse facing a task interruption, and describes two possible outcomes (task switching and concurrent multitasking). These reactions are associated with factors that may negatively influence concurrent multitasking.

In this work, we confirm that concurrent multitasking is far more frequent than the task switching. This reaction occurs when the nurses face human interaction or when the

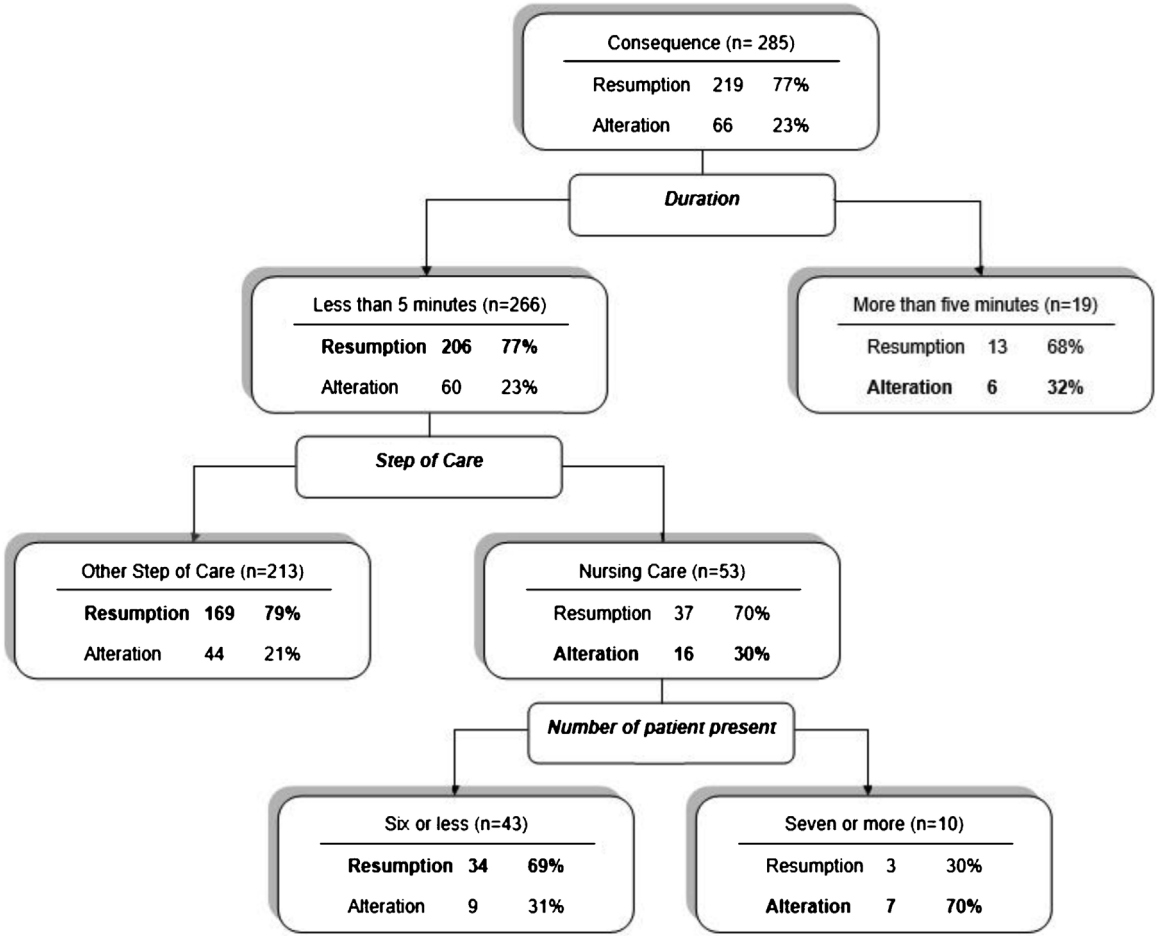

Figure 3 Classification Tree for the consequence of the task switching (Alteration or Resumption).

interruption is a short-lived task (less than one minute). We suppose that the nurses are able to assess the duration of the interruption and evaluate the feasibility of their original task. The duration of interruption seems to be the major parameter of multitasking time, as a longer interruption leads to task switching.

The concurrent multitasking seems commonly preferred when a task is not complex and the duration of the interruption is short.[6] Interestingly, it has been shown that the people who will most likely engage in concurrent multitasking have poor actual concurrent multitasking ability.[14] Moreover, multitasking lowers IQ and productivity by 40%,[15] decreases accuracy,[16] and increases reaction time in response to environmental stimuli.[17] The ''Bottleneck effect'' appears when cognitive capacities are overwhelmed by intense workload, a consequence of concurrent multitasking.[18]

We chose to study the consequences of the task switching on the initial task by dividing them as follows: either there is a resumption or an alteration of the initial task (starting over of the task, resumption with delay, or cancellation). When the nurses are interrupted in their task, we can observe a shift in attention from the initial process to the new one with a decay of the memory of the initial process. When the interrupting task is handled, the nurse moves back to the original task, but the step of the process when interrupted may be lost. Then, the interrupted nurse may start over the initial task, or even cancel it.[10] Task switching activates an internal task set reconfiguration inducing an increase in response time to the new task and therefore the likelihood of errors.[16,19] Similarly, we found that the duration of the interruption was the major factor leading to the alteration of the initial task, and among the different steps of care, nursing care interruption was significantly associated to a higher rate of alteration of the initial task.

Moreover, the number of patients in the PACU is another significant factor associated to the alteration of the initial task, confirming that a higher workflow of patients probably favours the negative effect of the interruption.

The workload is a debated factor for the influence on the error rate. Weigl et al. investigated the impact of interruption and multitasking on patient care quality in an emergency department and reported that workflow interruptions were positively associated with patient-related information on discharge and overall quality of transfer.[20] On the other hand, Westbrook et al. found no association between workload and error rate.[7] In our study, there seems to be a negative (but modest) impact of the workload on the resumption of the initial task during task switching, leaving the discussion open for future research.

Table 3 Descriptive characteristics of the task switching and concurrent multitasking.

	Total 1119–*100%*	Task switching 314–*28%*	Concurrent 805–*72.0%*	*p-value*
Number of patients during the interruption	6 [5;7]	6 [5;6]	6 [5;7]	0.211
Number of healthcare professionals during the interruption	6 [5;8]	6 [5;8]	6 [5;8]	0.077
Interruption source				< 0.001
Human direct interaction	964–*86.1%*	233–*74.2%*	731–*90.8%*	
Noise	71–*6.3%*	17–5.4%	54–6.7%	
Phone	38–*3.4%*	30–*9.6%*	8–*1.0%*	
Alarm	25–*2.2%*	17–*5.4%*	8–1.0%	
Other	21–*1.9%*	17–*5.4%*	4–*0.5%*	
Duration				< 0.001
< 1 min	931–*83.2%*	201–*64.0%*	730–*90.7%*	
1–5 min	152–*13.6%*	91–*29.0%*	61–*7.6%*	
> 5 min	36–*10.4%*	22–*7.0%*	14–*1.7%*	
Interrupter				< 0.001
Nurse	392–*35.0%*	79–*25.2%*	313–*38.9%*	
Nurse anesthetist	126–*11.3%*	31–*9.9%*	95–*11.8%*	
Authority	98–*8.8%*	34–*10.8%*	64–*8.0%*	
Nurse assistant	78–*7.0%*	10–*3.2%*	68–*8.4%*	
SB, Regulator, OC	227–*20.3%*	54–*17.1%*	173–*21.5%*	
Oneself	113–*10.1%*	60–*19.1%*	53–*6.6%*	
Other	44–*3.9%*	27–*8.6%*	17–*2.1%*	
Patient	41–*3.7%*	19–*6.1%*	22–*2.7%*	
Step of care				0.002
Patient admission	82–*7.3%*	18–*5.7%*	64–*8.0%*	
Drug preparation	65–*5.8%*	15–*4.8%*	50–*6.2%*	
Nursing care	281–*25.1%*	62–*19.8%*	219–*27.2%*	
Patient record filling	474–*42.4%*	147–*46.8%*	327–*40.6%*	
Patient monitoring	99–*8.8%*	40–*12.7%*	59–*7.3%*	
Patient set-up	68–*6.1%*	14–*4.5%*	54–*6.7%*	
Nurse shift	50–*4.5%*	18–*5.7%*	32–*4.0%*	
Subject of the interruption				< 0.001
Provide information	208–18.6%	52–16.6%	156–19.4%	
Asking for help	59–5.3%	36–11.5%	23–2.9%	
Seek information	319–28.5%	106–33.7%	213–26.5%	
Social interaction	131–11.7%	24–7.6%	107–13.3%	
Logistic	85–7.6%	48–15.3%	37–4.6%	
Other	317–28.3%	48–15.3%	269–33.3%	

SB, stretcher bearer; OC, other caregiver.
Results are expressed in number of interruption and percentages for qualitative variable and median with their interquartile range for quantitative variable. *p*-value represents the *p*-value of a chi-squared test of the class between task switching and concurrent multitasking.

In a global approach regarding the flow of disruption and interruption in clinical practice, it is important to recall that the interruption and multitasking is not always harmful: not to mention the interruption in order to alert another healthcare professional of a safety problem, even the social interactions are also a necessity for human beings, and to provide a social environment improving communication.[21]

In our study, we did not compare the consequences of concurrent multitasking and task switching, and our design was not intended to extrapolate this conclusion. There are probably specific consequences for each multitasking choice. We chose to focus only on the consequences of task switching because of a simple, clear, and reproducible method. For logistical reason, we also did not choose the video recording tool to document the task interruption, which allows microanalysis of the footage and lead to a better investigation of adverse events.[22] This allowed us to document a bigger number of interruptions, at the cost of using a simple classification and simpler analysis. In most categories, we successfully managed to classify each interruption, but regarding the subject of the interruption, we had 28% of the interruption classified as ''other''. Furthermore, we did not study the impact of the personality or the intrinsic factor depending of the observed nurse, leading to potentially large unmeasured effect of observed nurse. The variability of the observed result related to the observed nurses need to be investigated in future study, as well as another classification for the subject of the interruptions might be used, more suitable to the PACU.

Table 4 Descriptive characteristic of the consequence of the task switching on the interrupted task.

	Alteration 73–*24.6%*	Resumption 212–*74.4%*	*p-value*
Number of patient during the interruption	6 [5;6]	6 [5;7]	0.415
Number of healthcare professionals during the interruption	5 [4;6]	5 [4;7]	0.327
Trigger			0.790
Human direct interaction	57–*78.0%*	157–*74.0%*	
Noise	3–*4.1%*	14–*6.6%*	
Phone	5–6.9%	22–*10.4%*	
Alarm	3–*4.1%*	9–*4.3%*	
Other	5–*6.9%*	10–*4.7%*	
Duration			< 0.001
< 1 min	37–*50.7%*	145–*68.4%*	
1–5 min	23–*31.5%*	61–*28.8%*	
> 5 min	13–*17.8%*	6–*2.8%*	
Interrupter			0.114
Nurse	28–*38.3%*	44–*20.7%*	
Nurse anesthetist	5–*6.9%*	24–*11.3%*	
Authority	6–*8.2%*	23–*10.9%*	
Nurse assistant	2–*2.7%*	7–*3.3%*	
SB, Regulator, OC	13–*17.8%*	36–*17.0%*	
Oneself	8–*11.0%*	47–*22.2%*	
Other	7–*9.6%*	18–*8.5%*	
Patient	4–*5.5%*	13–*6.1%*	
Step of care			0.016
Patient admission	6–*8.2%*	9–*4.3%*	
Drug preparation	2–*2.7%*	11–*5.2%*	
Nursing care	21–*28.8%*	37–*17.6%*	
Patient record filling	30–*41.1%*	106–*50.0%*	
Patient monitoring	9–*12.3%*	24–*11.3%*	
Patient set-up	5–*6.9%*	8–*3.7%*	
Nurse shift	0–*0%*	17–*8.0%*	
Subject of the interruption			0.410
Provide information	16–21.9%	35–16.5%	
Asking for help	5–6.9%	23–10.9%	
Seek informations	25–34.2%	71–33.5%	
Social interaction	5–6.9%	19–9.0%	
Logistic	15–20.5%	30–14.1%	
Other	7–9.6%	34–16.0%	

SB, stretcher bearer; OC, other caregiver.
Results are expressed in number of interruption and percentages for qualitative variable, and median with their interquartile range for quantitative variable. *p*-value represents the *p*-value of exact fisher test for the homogeneity of the class.

Conclusion

In this study, we selected the main predictor of the task switching and concurrent multitasking in order to improve our understanding in the health care setting. This encourages future research on flow disruption and multitasking, regarding the variability of the negative effect of each reaction (task switching or concurrent multitasking) caused by an interruption, the exploration of adapted prevention strategies, and confirm that the PACU is a suitable environment to document and investigate task interruption.

Conflicts of interest

The authors declare no conflicts of interest.

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ORIGINAL INVESTIGATION

Mobile phones of anesthesiologists as reservoirs of nosocomial bacteria in a quaternary teaching hospital: an observational study

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KEYWORDS
Bacterial colonization;
Infection prevention;
Patient care;
Quality measures

Abstract

Background: Mobile phones in hospital settings have been identified as an important source of cross-contamination because of the low frequency with which mobile phones are cleaned by health workers and cyclical contamination of the hands and face. The aim of this study was to investigate whether the mobile phones of the anesthesia team at a teaching hospital are potential reservoirs of nosocomial bacteria. In addition, differences in device sanitization and hand hygiene habits between attending and resident anesthesiologists were correlated with mobile phone colonization.

Methods: A prevalence study was conducted over a 6-month period from 2017 to 2018 that involved the collection of samples from the mobile phones of the anesthesiology team and culturing for surveillance. A questionnaire was administered to assess the mobile phone sanitization and hand washing routines of the anesthesia team in specific situations.

Results: Bacterial contamination was detected for 86 of the 128 mobile phones examined (67.2%). A greater presence of *Micrococcus* spp. on devices was correlated with a higher frequency of mobile phone use ($p = 0.003$) and a lower frequency of sanitization ($p = 0.003$). The presence of bacteria was increased on the mobile phones of professionals who did not perform handwashing after tracheal intubation ($p = 0.003$).

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Conclusion: Hand hygiene and device sanitization habits were more important than the use behavior, as a higher presence of bacteria correlated with poorer hygiene habits. Furthermore, handwashing is the best approach to prevent serious colonization of mobile devices and the possible transmission of pathogens to patients under the care of anesthesiologists.

Introduction

Portable electronic devices are increasingly present in the daily lives of individuals and in the medical environment. Positive impacts of these devices among medical professionals with regard to communication, productivity and doctor-patient relationships have been reported.[1] Nonetheless, since the beginning of the 21st century, the use of mobile phones in hospital settings has been considered dangerous due to electromagnetic interference with equipment such as infusion pumps, ventilators, and pacemakers.[2]

Another concern with these devices derives from a pioneering study on the collection of hand and mobile phone swabs that correlated the presence of *Acinetobacter* spp. in these samples with the potential of future patient transmission.[3] Since then, these devices have been identified as potential reservoirs of nosocomial bacteria,[4–7] viruses,[8] and fungi.[9] Indeed, a review published in 2009 indicated that the rate of mobile phone contamination with pathogenic bacteria was between 9 and 25%.[6]

Furthermore, it is believed that mobile phones may be more problematic for cross-contamination than the inanimate objects of hospital settings. The reasons for this include the low frequency with which mobile phones are cleaned by health workers and the cyclical contamination of the hands and face, as well as the close contact with areas of the body that exhibit a high incidence of bacterial colonization, such as the ears, nose, and mouth.[5,7,8,10–12]

Although it has been established that the use of mobile phones by anesthesiologists can result in hand contamination,[12] few studies on this population related to this issue have been specifically conducted.

Given the above information, the aim of this study was to investigate whether the mobile phones of anesthesia teams at a teaching hospital are potential reservoirs of nosocomial bacteria. Additionally, differences in device sanitization and hand hygiene habits between the attending and resident anesthesiologists were investigated and correlated with mobile phone colonization.

Methods

After approval by the institutional Research Ethics Committee, this cross-sectional study was conducted over a 6-month period from 2017 to 2018. This study was based on the collection of samples from the mobile phones of the anesthesiology team of the surgical centers of the Hospital Central da Santa Casa de Misericórdia de São Paulo and microbial culturing for surveillance purposes.

The time spent in data collection should not influence the result of the collected data, as the colonization of mobile phones would be hypothetically related to the habits of hand hygiene and sanitization of devices. For example, the possibility of response bias due to change in behavior (such as more frequent and thorough cleaning of mobile phones), from the perspective of the Hawthorne Effect,[13] would be more likely in a short period (such as 1 month) for a person to attempt to reduce the amount of bacteria cultured from their sample. Ideally, collection on a single day would be the best option for such surveillance, but not all anesthesiologists work on the same day.

Therefore, 10–15 mobile phones belonging to the anesthesiologists were analyzed every two weeks, excluding those who refused to participate, those who did not carry mobile phones in the surgical center, those who were absent on their working days when the samples were collected and those with mobile phones in use for less than three months. Each device was only analyzed once by the investigators. As the surveillance involved convenience sampling, the sample size was determined by based on the population of attending and resident anesthesiologists.

Two trained investigators performed swab sample collections using the appropriate aseptic technique. For each mobile phone, swabbing of the entire screen, back portion, and side buttons was performed for approximately 30 seconds. The swab technique was chosen, which is the most commonly used technique.[5] Unique samples from different anesthetists were transported to the laboratory in Amies medium within 4 hours. A non-validated questionnaire adapted from Ulger et al.,[10] Sadat-Ali et al.,[11] Mark et al.,[14] and Cavari et al.[8] was given to the participants to identify their device sanitization and hand hygiene behaviors, and signed informed consent was obtained.

In the laboratory, the samples were spread onto blood agar plates and incubated at $35 \pm 2\,^{\circ}C$ for up to 48 hours. Colonies that grew on the plates were identified according to conventional biochemical laboratory techniques, and the antimicrobial resistance profiles of the isolates were determined according to the criteria of the Clinical and Laboratory Standards Institute.[15]

An external collaborator was responsible for correlating the questionnaire data with the microbiological results, maintaining confidentiality. All samples were paired with the questionnaires using identification codes such that only individual mobile phone owners could identify their culture analysis results using their personal codes at the end of the study, if interested. This study adhered to the applicable STROBE guidelines.[16]

Quantitative variables were analyzed using Student's *t*-test, and the results are expressed as the mean and standard

Table 1 Distribution of participants according to mobile phone usage habits in the surgical center. Values are reported as the number (percentage).

		Overall n = 126	Attendings n = 78	Residents n = 48	p[c]
Frequency of mobile phone use in a single day[a]	1–5 times	17 (13.5)	13 (16.6)	4 (8,3)	**0.173**
	6–10 times	34 (27)	24 (30.8)	10 (20.8)	
	11–20 times	25 (19.8)	12 (15.4)	13 (27.1)	
	> 20 times	50 (39.7)	29 (37.2)	21 (43.8)	
Types of activities performed with mobile phones[b]	Communication	110 (87.3)	72 (92.3)	38 (79.2)	**<0.001***
	Medical practice	103 (81.7)	59 (75.6)	44 (91.7)	**0.036***
	News	87 (69.0)	50 (64.1)	37 (77.1)	0.15
	Social networks	77 (61.1)	34 (43.6)	40 (83.3)	**<0.001***
	Games	27 (21.4)	13 (16.7)	14 (29.2)	0.102

[a] Only one answer was allowed for this habit. A chi-square test was performed on a 4×2 contingency table.
[b] Participants could choose more than one activity.
[c] A chi-square test was performed between the groups, yielding the p values listed in the table.

deviation. Qualitative variables were analyzed using the chi-square test, and the results are expressed as absolute and relative frequencies. All analyses were performed with the help of the Statistics Service of Santa Casa de São Paulo School of Medical Sciences using SPSS 13.0. The significance level adopted was $p < 0.05$.

For missing data analysis, missing completely at random (MCAR) assumptions were applied. We used pairwise deletion for one participant in sex analysis, one participant in mobile phone brand compilation and two participants in protective cover analysis.

Results

Of 163 potential participants among the attending and resident members of the anesthesia team, 129 met the inclusion criteria for study participation. Of these, only one refused to participate in the study. A total of 128 participants (69 males and 59 females) who carried their mobile phones in the surgical center were selected for participation in this study. The mean age (MA) of the participants was 37.5 (11.2) years, and the mean number of years of anesthesiology experience (MNYAE) was 10.8 (11). Of these 128 participants, 49 were anesthesiology residents (25 males and 24 females; MA: 28.3 [2.2] years; MNYAE: 1.8 [0.83] year) and 79 attending anesthesiologists (44 males and 35 females; MA: 43.4 [10.7] years; MNYAE: 16.1 [10.8] years).

Of 128 participants, one attending and one resident reported that despite carrying the device they did not use their mobile phone inside the surgical center. Of the 126 respondents who responded about their frequency of mobile phone use, only 13.5% reporting minimal use (1–5 times/day) of the device. Protective cases were used on the mobile phones of 115 anesthesiologists (91.3%). When asked about the types of activity performed on their mobile phone, Communication and Medical Practice were the most frequently mentioned activities. When comparing attendings and residents, there was greater use of mobile phones among the latter for Medical Practice ($p = 0.036$) and for Social Networks ($p < 0.001$). The results are summarized in Table 1.

Sanitization habits

We observed that the frequency of reported device cleaning differed between attendings and residents: only 2% of the residents reported cleaning their device every day (vs. 32.9% of the attendings). The results are summarized in Table 2.

Although only 59.4% of the participants performed routine mobile phone cleaning (daily or weekly), 93.8% believed that their mobile phones could be contaminated with bacteria when asked about the subject.

Among the participants who performed mobile phone cleaning, 70% ethanol was the most frequently mentioned agent used, at 88 responses (68.8% of the total). Alcoholic chlorhexidine was stated by 13 participants (10.2%). More than one response was allowed per participant.

Bacterial contamination

Of 128 mobile phones analyzed, 86 (67.2%) showed the presence of bacteria based on culturing. Coagulase-negative staphylococci (CoNS) were the most common bacteria detected, present in 67 samples of which 19 strains were found to be oxacillin-resistant to antimicrobials. *Staphylococcus aureus* was detected in 6 samples (4.7%), with one yielding a methicillin-resistant (MRSA) isolate. Three sample with *Streptococcus* spp. and a single sample with vancomycin-resistant *Enterococcus* (VRE) were also detected, as shown in Fig. 1.

No significant associations were observed when evaluating the presence of bacteria related to the use of protective covers ($p = 0.777$) and the sex ($p = 0.169$) and resident status ($p = 0.976$) of the participants.

Considering the sum of all bacteria in the analysis of the frequency of use and cleaning of mobile phones, no differences were observed in contamination related to better hygiene habits ($p = 0.148$) or higher frequency of use ($p = 0.722$). However, in the analysis of the presence of each bacterium, we observed that *Micrococcus* spp. correlated with both a higher frequency of use and a lower frequency of device sanitization, as illustrated in Table 3.

Table 2 Distribution of participants according to sanitization habits of mobile phones. Values are reported as the number (percentage).

		Overall n = 128	Attendings n = 79	Residents n = 49	*p*
Frequency of mobile phone cleaning[a]	Daily	27 (21.1)	26 (32.9)	1 (2)	**<0.001**
	Weekly	49 (38.3)	30 (38)	19 (38.8)	
	Monthly	21 (16.4)	10 (12.7)	11 (22.5)	
	Never	31 (24.2)	13 (16.4)	18 (36.7)	
		n = 97[c]	n = 66	n = 31	
Motivation for cleaning[b]	Patient contamination	40 (41.2)	26 (39.4)	14 (45.2)	0.591
	Children	21 (21.6)	20 (30.3)	1 (3.2)	**0.003***
	Personal hygiene	81 (83.5)	55 (83.3)	26 (83.9)	0.947
	Fear of disease	7 (7.2)	7 (10.6)	0	0.060

A chi-squared test was performed, yielding the *p* values listed in the table.
[a] Only one answer was allowed for this question. A chi-square test was performed on a 4 × 2 contingency table.
[b] Participants could choose more than one motivation.
[c] Participants who never sanitized their devices were excluded.

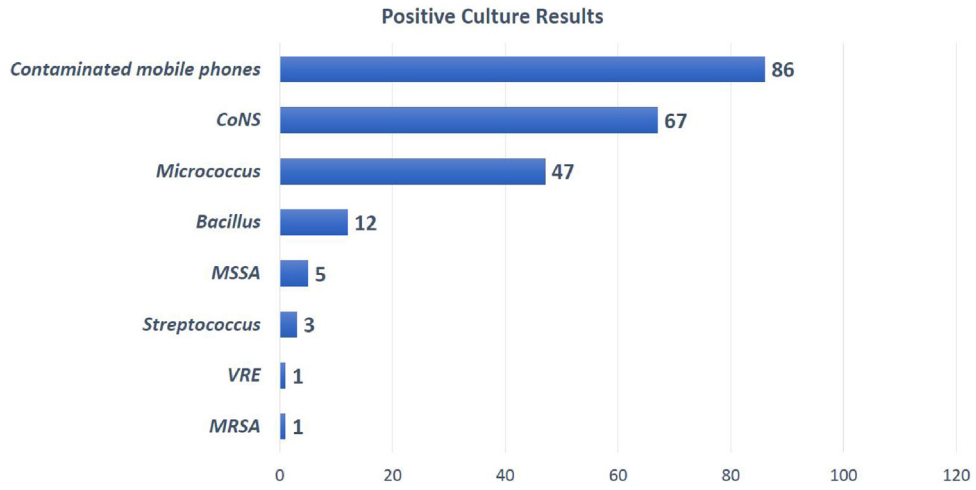

Figure 1 Positive culture results of swab samples from the mobile phones of anesthesiologists in absolute numbers. CoNS, coagulase-negative *Staphylococcus*; MSSA, methicillin-sensitive *Staphylococcus aureus*; MRSA, methicillin-resistant *S. aureus*; VRE, vancomycin-resistant *Enterococcus*.

Regarding contamination of the devices sanitized with cleaning products compared to that of the devices not cleaned with these products, no significant differences in device contamination were observed when using 70% ethanol (65.9% vs. 70.0%, respectively; $p = 0.648$) or Alcoholic Chlorhexidine (53.8% vs. 68.7% contamination, $p = 0.28$). When examining the presence of each bacterial group with respect to the use of each cleaning product, we observed lower contamination of *Micrococcus* spp. on devices cleaned with 70% ethanol compared to other sanitation methods or unsanitized devices (29.5% vs. 52.5% with $p = 0.013$).

Hand hygiene

Each anesthesiologist was asked to indicate when they washed their hands at the surgical center during determined situations of their routine practice. Before central venous line placement and after contact with biological material were the moments in which the most hand washing occurred. For peripheral venipuncture, prior hand washing was not performed by most of the professionals as shown in Fig. 2.

The presence of bacteria was analyzed for each of the situations in which the anesthesiologist performed hand washing, and the results showed a lower percentage of bacteria for almost all situations. Except for the situation of tracheal intubation (TI) ($p = 0.003$), this reduction was not significant as shown in Table 4.

A deeper analysis of handwashing after TI revealed a greater prevalence of *Micrococcus* spp. ($p = 0.003$; 50.7% [95% CI 38.5–63.0%] vs. 21.3% [95% CI 10.7–31.9%]) and CoNS ($p = 0.005$; 64.2% [95% CI 52.4–76.0%] vs. 39.3% [95% CI 26.7–52.0%]) in the device sample cultures for those who did not perform hand washing in this situation.

Table 3 Relationship between the presence of bacteria in swab sample cultures from devices and a) the frequency of mobile phone use in the surgical center in a single day and b) frequency of mobile phone cleaning. Values are reported as the percentage (95% confidence interval).

		Micrococcus	CoNS	*Bacillus*	*Streptococcus*	*S. aureus*	*Enterococcus*	Bacteria
a) Daily usage	1 to 5	5.9 (0–18.4)	58.8 (32.7–84.9)	5.9 (0–18.4)	11.8 (0–28.8)	11.8 (0–28.8)	0	70.6 (46.4–94.7)
	6 to 10	24 (8.5–38.6)	47.1 (29.4–64.7)	11.8 (0.4–23.2)	0	2.9 (0–8.9)	0	58.8 (41.4–76.3)
	11 to 20	48 (27.0–69.0)	60 (39.4–80.6)	8.0 (0–19.4)	0	4.0 (0–12.3)	0	68.0 (48.3–87.7)
	> 20 times	48 (33.7–62.3)	48 (33.7–62.3)	10.0 (1.4–18.6)	2.0 (0–6)	4.0 (0–9.6)	2.0 (0–6)	70.0 (56.8–83.2)
	p	**0.003***	0.659	0.93	0.549	0.228	0.369	0.722
b) Cleaning frequency	Daily	18.5 (2.9–34.2)	63.0 (43.5–82.4)	11.1 (0–23.8)	3.7 (0–11.3)	7.4 (0–18.0)	0	77.8 (61–95)
	Weekly	28.6 (15.5–41.7)	42.9 (28.5–57.2)	10.2 (1.4–19.0)	4.1 (0–9.8)	8.2 (0.2–16.1)	0	57.1 (43–72)
	Monthly	42.9 (19.8–65.9)	42.9 (19.8–65.9)	9.5 (0–23.2)	0	0	0	61.9 (39–85)
	Never	61.3 (43.1–79.5)	64.5 (46.7–82.4)	6.5 (0–15.6)	0	0	3.2 (0–9.8)	77.4 (62–93)
	p	**0.003***	0.134	0.93	0.549	0.228	0.369	0.148

A chi-square test was performed, with $p < 0.05$ indicating significance.

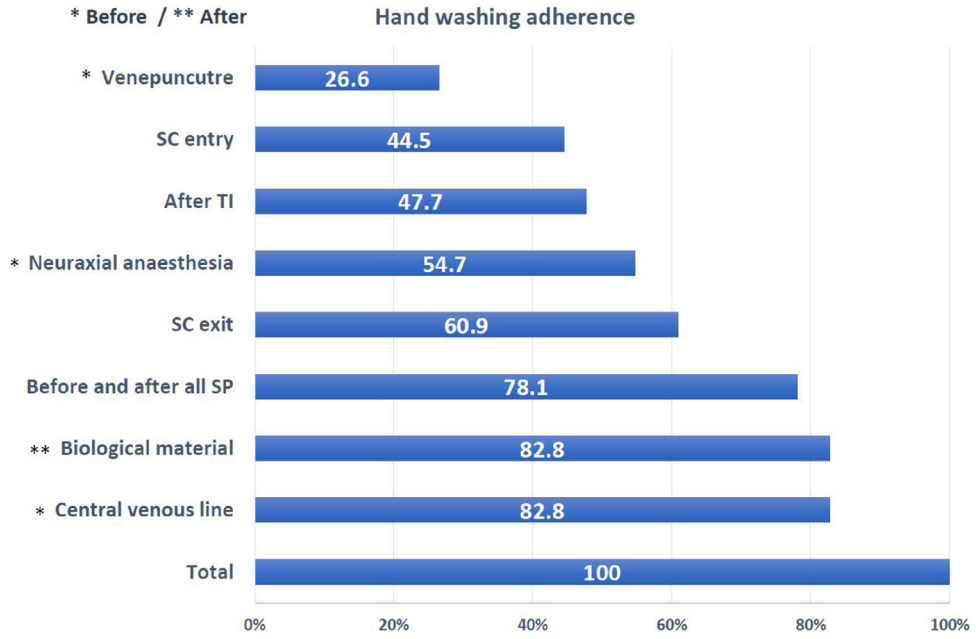

Figure 2 Occurrences of hand washing during routine practices by anesthesiologists, reported in percentages. TI, tracheal intubation; SC, surgical center; SP, surgical procedures.

Table 4 Analysis of the presence of bacteria on mobile phones related to the habit of washing hands or not in specific situations of the routine practice of anesthesiologists. Values are reported as the percentage (95% confidence interval).

Situation	Washes hands	Does not wash hands	*p*
After TI	54.1 (41.2–67.0)	79.1 (69.1–89.1)	**0.003**
SC exit	61.5 (50.5–72.6)	76.0 (63.7–88.3)	0.089
SC entry	59.6 (46.5–72.8)	73.2 (62.7–83.8)	0.104
Central venous line	64.2 (54.9–73.4)	81.8 (64.3–99.3)	0.108
Venipuncture	58.8 (41.4–76.3)	70.2 (60.8–79.6)	0.225
Before and after all SP	65.0 (55.5–74.5)	75.0 (57.9–92.1)	0.319
Neuraxial anesthesia	64.3 (52.8–75.8)	70.7 (58.6–82.8)	0.442
Biological material	67.0 (57.9–76.1)	68.2 (47.0–89.3)	0.913

*A chi-square test was performed, with $p < 0.05$ indicating significance.
TI, tracheal intubation; SC, surgical center; SP, surgical procedures.

Discussion

The present study evaluated the extent to which anesthesiologists' mobile phones can be reservoirs of pathogenic, potentially pathogenic and antibiotic-resistant bacteria. We decided not to divide the bacteria into groups according to their pathogenicity due to the imprecision of the terms "pathogenic" and "non-pathogenic". All bacteria found in the study may cause diseases in humans, varying only in their pathogenic potential.[17] Despite our knowledge of the possible major impact pathogenic bacteria would have on a patient's condition, we preferred not to use this classification in order not to mitigate the anesthesiologists' responsibility with respect to their hygiene habits.

A bacterial contamination rate of 67.2% was observed on mobile phones, which is lower than that described in other studies.[4,10] A review from 2015 indicates that the prevalence of bacteria can vary from 10–100%, with *S. aureus* being the most frequently isolated bacterium.[5] However, our bacterial profile indicated that CoNS was predominant relative to other bacteria, which is similar to the results of a study conducted by Tekerekoğlu et al.[4] This difference might be explained by the progressive decrease in the presence of keyboards and grooves in mobile phones over the years, which previously allowed for bacterial storage and hindered cleaning.[14,18] Furthermore, contamination rates vary according to the country of origin and the hospital setting studied,[6] as well as by the habit of using the devices in specific places, such as restrooms.[19]

In a study that evaluated adherence of anesthesiologists to hand washing, procedures such as peripheral venipuncture and TI were associated with the lowest rate of hygienic adherence, below 25% (vs. 26.6% for venipuncture and 47.7% for TI in our study). In contrast, central venous line placement and neuraxial anesthesia showed the highest rates of hygienic adherence.[20] Therefore, detection of a greater presence of *Micrococcus* spp. and CoNS on the mobile phones of the participants who do not wash their hands after TI is

not surprising, as this practice is recommended by the WHO in its primary hand washing guidelines.[21] A minority of anesthesia professionals are well aware of these guidelines, and the low handwashing adherence observed may be justified by a failure by these professionals to recognize potential contamination situations.[22]

We did not detect any complex dynamics related to the microbiomes of mobile phones with respect to different cleaning strategies, identifying only reduced contamination by *Micrococcus* spp. when 70% ethanol was used and when the mobile phone was frequently sanitized. This lack of impact may reflect the limitations of using self-declared questionnaires and their response biases, which might restrict the extent of the conclusions on which they are based. In addition, the heterogeneity of cleaning methods in terms of scrubbing time, pressure, and area covered among the different participants may have contributed to these results. Thus, the need for studies focused on cleaning techniques and the elimination of bacteria may be of great value to guide these practices and identify the most appropriate technique to lower the bacterial colonization of mobile phones.

From the perspective of the patients, the exploration of possible alterations of patients' flora, to investigate the link between the lack of hand hygiene after intubation and increase of *Micrococcus*, could be the subject of future research to better understand this relationship.

Conclusions

Although device microbiomes are local specific and vary according to the cleaning habits of the owners of the devices, our findings regarding the importance of hand washing to limit potential contamination are likely replicable because the hygiene habits of physicians tend to be precarious. More important than the use profile were the device sanitization and hand hygiene habits, with a higher presence of bacteria correlating to poorer hygiene habits. Limiting the use of mobile phones is not an appropriate strategy, as their benefit in intrahospital or emergency situations would be lost if their use is prohibited. Therefore, hand washing remains the best approach to prevent serious colonization of mobile devices and the possible transmission of pathogens to patients under the care of anesthesiologists.

Conflicts of interest

The authors declare no conflicts of interest.

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ORIGINAL INVESTIGATION

Comparison between oral midazolam versus oral ketamine plus midazolam as preanesthetic medication in autism spectrum disorder: double-blind randomized clinical trial

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KEYWORDS
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Dental care;
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Midazolam;
Preanesthetic medication

Abstract

Background: Conventional dental care is often impossible in patients with Autism Spectrum Disorder (ASD). Non-collaborative behaviors, sometimes associated with aggressiveness, are usual justifications for premedication in this population. Thereby, this research focuses on the effects of oral midazolam versus oral ketamine plus midazolam as preanesthetic medication in ASD.

Methods: The sample included 64 persons with ASD, aged 2-59 years, scheduled for dental care under general anesthesia. The primary objective of this study was to compare degrees of sedation between two parallel, double-blinded, equally proportional groups randomized to receive oral midazolam (0.5 mg.kg^{-1}, maximum 15 mg) or oral midazolam (0.5 mg.kg^{-1}) associated with oral *S*(+)-ketamine (3 mg.kg^{-1}, maximum 300 mg). The secondary outcomes were the need of physical stabilization to obtain intravenous line, awakening time, and occurrence of adverse events.

Results: According to the dichotomous analysis of sedation level (Ramsay score 1 and 2 *versus* Ramsay $\geq$ 3), oral association of *S*(+)-ketamine and midazolam improved sedation, with increased probability of Ramsay $\geq$ 3, Relative Risk (RR) = 3.2 (95% Confidence Interval [95% CI] = 1.32 to 7.76) compared to midazolam alone. Combined treatment also made it easier to obtain venous access without physical stabilization, RR = 2.05 (95% CI = 1.14 to 3.68). There were no differences between groups regarding awakening time and the occurrence of adverse events.

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Conclusion: The association of oral *S*(+)-ketamine with midazolam provides better preanesthetic sedation rates than midazolam alone and facilitates intravenous line access in patients with autism.

Introduction

In 2016, the United States Centers for Disease Control monitoring system estimated the prevalence of Autism Spectrum Disorder (ASD) at 18.5/1000 children by the age of eight.[1] This was 175% higher than the results from 2000 and 10% higher than the results from 2014 using the same database. In Northern Ireland, in 201920, the prevalence rate was 4.2% in school-age children.[2] This increased prevalence may be related to broader diagnostic criteria, public awareness of ASD and improved diagnostic tools. ASD is defined as persistent deficits in social communication and social interaction in multiple contexts.[3] Due to these traits, persons with ASD may not cooperate during regular dental care, whether children or adults. In a sample of individuals with neurological disabilities who required general anesthesia for dental treatment, 30% had ASD.[4]

Midazolam is the most commonly used drug as preanesthetic,[5] especially by the oral route, which is better tolerated than the nasal or intramuscular routes in non-cooperative patients. Although not available in oral formulation, parenteral formulation of *S*(+)-ketamine has been used as preanesthetic by oral or nasal route,[6,7] and more recently by fogging.[8] Despite an obvious and increasing demand, the literature provides little data on preanesthetic medications in the autistic population.[9] Premedication makes the experience less unpleasant for the patient and family members, decreases the possibility of physical stabilization, and facilitates multiprofessional management to the individual with ASD.[10]

We hypothesized that adding oral *S*(+)-ketamine to oral midazolam would lead to a better premedication state, compared to oral midazolam alone, when administered as preanesthetic in patients with ASD. Thus, the primary endpoint was to observe the degree of sedation in groups receiving oral midazolam alone *versus* oral midazolam plus oral *S*(+)-ketamine.

Methods

This study was approved by the ethics committee of Faculdade de Medicina da Universidade Estadual Paulista — Campus de Botucatu (CAAE 65117917.1.3001.5411). The trial was registered prior to patient enrollment in REBEC (ensaiosclinicos.gov.br, code RBR-8ttw3f). This parallel, double-blind, controlled, randomized clinical trial was conducted between September 2018 and January 2021 with individuals who had been previously diagnosed with ASD by a neuropsychiatrist and were referred for dental care under general anesthesia. At least 15 days before the procedure, the written informed consent to participate in the study was presented to the next of kin of potential participants during the preanesthetic consultation. Direct patient assent was waived due to their impaired verbal and non-verbal communication. The research was conducted according to the CONSORT statement.

The primary outcome was the degree of sedation in the oral midazolam *vs* the oral midazolam plus oral *S*(+)-ketamine groups. Reaction to peripheral venous access, interference in awakening time and occurrence of agitation, nystagmus, sialorrhea, and postoperative vomiting were secondary outcomes.

To calculate the sample size, a 50% sedation rate in the desired range (Ramsay sedation score $\geq$3) for midazolam alone was considered, with an absolute increase of 35% (h = 0.775) for midazolam plus *S*(+)-ketamine. A total of 27 participants were required in each group for detection power of 80% and 5% tolerance interval of error. We added five individuals to each group to compensate for any losses due attrition. The sample included males and females between two and 59 years of age, previously diagnosed with ASD, American Society of Anesthesiologists (ASA) physical status II, who required preanesthetic medication and were undergoing general anesthesia for dental assistance at the Hospital Geral de Goiânia Alberto Rassi, or at the Hospital Santa Terezinha in Goiânia, GO, Brazil. The non-inclusion criteria were prediction of difficult airway, renal dysfunction, heart disease, history of allergy or adverse reaction to the study drugs. Exclusion criteria after enrollment were inadequate intake and vomiting after drug administration, as well as major bleeding during surgery or any other significant surgical complication that could interfere in postoperative recovery. The degrees of autism were considered as stratified by the American Psychiatric Association: 1 = requires support, 2 = requires substantial support, 3 = requires very substantial support.[3] The analysis was performed per-protocol to assess the effect of treatment under ideal conditions.

On the day of the procedure, the head nurse in the inpatient ward received, in writing, the weight adjusted dose for one or both medications for each individual participant and administered the premedication according to group determination. Allocation was performed with opaque envelopes numbered from 1 to 64, each containing one of the proposed intervention options (32 envelopes for each group). The envelopes were then drawn in a random order determined by a simple randomization process with the aid of specific software (www.randomization.com). Neither the participants nor their tutors were aware of the intervention group.

The fasting period was 6 hours for light solid foods and 2 hours for clear liquids. If the participants routinely used psychotropic medications, their administration was scheduled to no less than two hours prior to the surgical procedure. The participants received the designated medication while in the inpatient ward. In the Midazolam group,

midazolam dose was 0.5 mg.kg^{-1} (maximum 15 mg), while in the Midazolam/Ketamine group, midazolam dose was 0.5 mg.kg^{-1} (maximum 15 mg) plus *S*(+)-ketamine dose 3 mg.kg^{-1} (maximum 300 mg), diluted in the oral midazolam solution. The formulation of midazolam was in original manufactured formulation syrup with sweet taste (2 mg.mL^{-1}) and *S*(+)-ketamine was in parenteral formulation (50 mg.mL^{-1}), both manufactured by Cristalia® pharmaceutical industry. The doses were calculated based on actual body weight within a limit of 15 mg for midazolam and 300 mg for *S*(+)-ketamine to avoid major collateral effects in accordance with previously published studies.[5,11]

Thirty minutes after ingestion, the anesthesiologist, who was blinded to the allocation group, assessed the degree of sedation using the Ramsay scale (1: anxious, agitated; 2: awake, cooperative, calm; 3: asleep, awakens to low auditory stimulus; 4: asleep, reacts briskly to light glabellar tap or loud auditory stimulus; 5: asleep, reacts slowly to vigorous painful stimulus or loud auditory stimulus; 6: asleep, unresponsive to vigorous painful stimulus or loud auditory stimulus).[12] The sedation level was dichotomized into Ramsay scores 1 and 2 vs. ≥3. The participants were separated from their parents or tutors at entering in the surgical theater.

In the operating room, the reaction prior to peripheral venous access was stratified into four degrees (1: pharmacological intervention; 2: protective physical stabilization; 3: minimal reaction; 4: no reaction). Pharmacological intervention involved protective physical stabilization plus inhalation of sevoflurane and 100% O_2 through a face mask, or intramuscular administration of ketamine (3 mg.kg^{-1}). Protective physical stabilization involved careful stabilization by nursing professionals. Minimal reaction consisted in minimal stabilization only of the limb to be punctured. No reaction represented immobility. The reaction to vascular access was dichotomized as either with stabilization (score 1 and 2) or without stabilization (score 3 and 4).

Intraoperative monitoring consisted of continuous electrocardiogram, noninvasive blood pressure, peripheral oxygen saturation, capnometry ($EtCO_2$), and axillary temperature. Preoxygenation was given for three minutes, and anesthesia was induced with propofol (3 mg.kg^{-1}), fentanyl (2 μg.kg^{-1}), and cisatracurium besylate (0.15 mg.kg^{-1}). Trachea was intubated through nasal route and after waiting for the maximum effect of the neuromuscular blocker. Mechanical ventilation was initiated according to the following parameters: tidal volume 6 mL.kg^{-1} (peak airway pressure limited in 30 cm H_2O) and age-appropriate respiratory rate for a target $EtCO_2$ between 35 to 45 mmHg with a FiO_2 of 80% and positive end-expiratory pressure of 5 cm H_2O. Anesthesia was maintained with sevoflurane, within the minimum alveolar concentration of 2%, with increments of 0.5% based on cardiovascular parameters. If the required dose of sevoflurane reached 4%, incremental boluses of fentanyl (1 μg.kg^{-1}) were administered up to a maximum dose of 5 μg.kg^{-1}. When endodontic treatment and/or tooth extraction were indicated, local anesthesia was performed by the surgical team with 2% lidocaine with vasoconstrictor. During the intraoperative period, the anesthesiologist was blinded to the participant's intervention group.

At the end of the procedure, metamizole (30 mg.kg^{-1}) and ondansetron (0.15 mg.kg^{-1}) were administered. Controlled ventilation was continued until there were signs of swallowing and respiratory movement, at which point neuromuscular blockade was reversed with atropine (0.02 mg.kg^{-1}) and neostigmine (0.04 mg.kg^{-1}). The tracheal tube was removed when the neuromuscular blocker had been completely reversed, with the patient showing signs of adequate spontaneous ventilation and attempts at self-extubation. The awakening time was measured in minutes from the moment that inhalation anesthetic was interrupted until removal of endotracheal tube. Participants remained in the postanesthetic care unit until they had returned to their usual neuropsychological condition with a score of seven or more on the Aldrete and Kroulik scale. They were still observed for the occurrence of agitation, nystagmus, sialorrhea, vomiting, and signs of postoperative pain. The hospitalization regime planned was ambulatorial.

In the statistical analysis, qualitative variables were expressed as sample proportions and 95% Confidence Intervals (95% CI) of the percentage differences and Relative Risks (RR). For comparison between groups, chi-square test with Yates correction and Fisher's exact test were used when applicable. For quantitative variables, the Shapiro-Wilk test and histogram analysis were performed to assess the normality of distribution. Since continuous variables were normally distributed, they were expressed as mean and standard deviation, and the groups were compared using an unpaired Student's *t*-test. Differences in awakening time was assessed using the Kaplan-Meier survival curve; *p*-values < 0.05 were considered statistically significant. The analyses were carried out in the R environment.[13]

Results

To evaluate and compare the degree of sedation between midazolam and the combination of midazolam plus *S*(+)-ketamine as oral premedication in patients with ASD, a total of 64 participants were recruited and randomly allocated in two equal groups. Four participants in the combined treatment group, 6.25% of the total sample, did not ingest the premedication and were excluded from the study (Fig. 1).

The groups were similar in terms of patient characteristics, preoperative conditions, and duration of the procedures (Table 1). All participants were considered ASA physical status II, mainly due to autism. In children and adolescents, obesity was considered a z-BMI score ≥ 2 according to World Health Organization score curves adjusted for sex and age group.[14,15] In adults, a BMI ≥ 30 was used to diagnose obesity.[16]

Regarding the primary outcome, the degree of sedation differed between the two groups, with Ramsay score 2 predominating in the Midazolam group. There was a significant difference between the groups overall, with *p*-value = 0.02 (Table 2). Dichotomous analysis of the degree of sedation (Ramsay score 1 and 2 vs. Ramsay score ≥ 3) showed a significant difference between groups, as well. In the Midazolam group, the occurrence of Ramsay score ≥ 3 was 15.6%, while in the Midazolam/Ketamine group this same score was observed in 50% of the participants, which bestows a

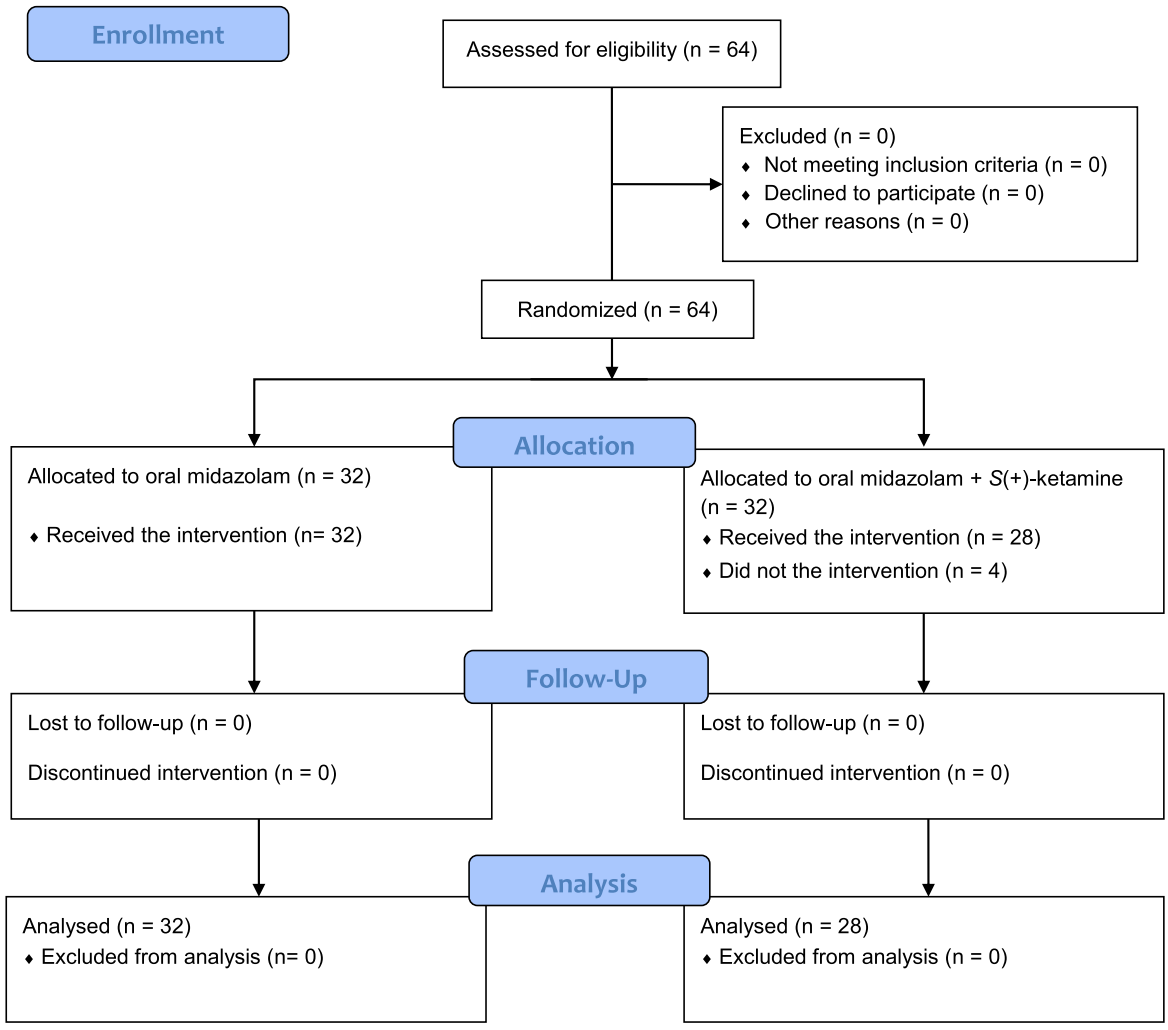

Figure 1 Clinical trial flow diagram (CONSORT).

RR = 3.2 (95% CI = 1.32 to 7.76 with *p*-value = 0.01) for this degree of sedation.

Venous access was significantly easier in the combined treatment group (*p*-value = 0.01), with a higher relative frequency of physical stabilization required in the Midazolam group (Table 3). Dichotomous evaluation of venous access revealed that adding *S*(+)-ketamine to midazolam facilitated venous access without resorting to restraint (64.2%) when compared with midazolam alone (31.2%) with a RR = 2.05 (95% CI = 1.14 to 3.68) and *p*-value = 0.02.

Regarding awakening time, the groups did not differ significantly in a time to event analysis as shown in the Kaplan-Meier curve (Fig. 2). None of the participants in both groups needed additional boluses of opioids, however about 30% in each group required minimum alveolar concentration of sevoflurane up to 3%, without significant differences between them (Table 1).

Concerning secondary outcomes in the Midazolam group and Midazolam/Ketamine group, the respective occurrences of adverse effects were as follows: agitation 9.3% vs. 7.1% (RR = 0.76 [95% CI = 0.13 to 4.23] *p*-value = 0.75), nystagmus 3.1% vs. 0% (RR = 0.37 [95% CI = 0.01 to 8.95] *p*-value = 0.54), sialorrhea 21.8% vs. 17.8% (RR = 0.81 [95% CI = 0.29 to 2.28] *p*-value = 0.69), and vomiting 0% vs. 3.5% (RR = 3.41 [95% CI = 0.14 to 80.58] *p*-value = 0.44). None of the participants required additional analgesia.

All patients from both groups had acquired conditions of being released from the postanesthetic care unit within 60 minutes, and of hospital discharge within two hours after leaving the surgical theater.

Discussion

Among the many challenges faced by autistic patients, difficulty in social communication and low adaptability to non-routine sensory experiences are particularly frequent. Non-collaborative behaviors and high occurrence of anxiety in the perioperative period are key justifications for preanesthetic medication in this specific population, especially in those individuals who exhibit aggressive behaviors. It not only helps all procedures related with anesthetic induction, but also facilitates amnesia, favoring non-memorization of triggering events that could lead to worse behaviors in

Table 1 Patients' characteristics, preoperative conditions, anesthesia duration and minimum alveolar concentration of sevoflurane in Midazolam group and Midazolam + Ketamine group (η = 60).

Variable	Midazolam group (η = 32)	Midazolam + ketamine group (η = 28)
Age (years)[a]		
< 12 years	16 (50%)	11 (39.3%)
12 to 19 years	5 (15.6%)	4 (14.3%)
> 19 years	11 (34.4%)	13 (46.4%)
Male[a]	25 (78.1%)	20 (71.4%)
Body mass index ($kg{\cdot}m^{-2}$)[b]	22.0 ±6.0	21.8 ±5.0
Degree of autism[a,c]		
1	4 (12.5%)	4 (14.3%)
2	12 (37.5%)	9 (32.1%)
3	16 (50%)	15 (53.6%)
Comorbidities[a]		
None	8 (25%)	6 (21.5%)
Epilepsy	10 (31.2%)	10 (35.6%)
Obesity	8 (25%)	8 (28.5%)
Other	7 (21.9%)	5 (17.9%)
Medications[a]	24 (75%)	22 (78.5%)
Anticonvulsants	11 (34.4%)	13 (46.4%)
Antipsychotics	20 (62.5%)	15 (53.6%)
Antidepressants	3 (9.4%)	3 (10.7%)
Benzodiazepines	6 (18.8%)	8 (28.6%)
Anesthesia duration (minutes)[b]	149.5 ± 66.0	143.3 ± 66.4
Minimum alveolar concentration of sevoflurane		
2%	22 (68.7%)	19 (67.8%)
2.5%	5 (15.6%)	3 (10.7%)
3%	5 (15.6%)	6 (21.4%)

[a] Values expressed in absolute numbers and relative frequency (in parentheses).
[b] Values expressed as mean and standard deviation.
[c] Degree of Autism: 1 = requires support; 2 = requires substantial support; 3 = requires very substantial support.

Table 2 Sedation levels in Midazolam group and Midazolam + Ketamine group according to Ramsay scale.

Variable	Midazolam group (η = 32)	Midazolam + ketamine group (η = 28)	Difference between percentages (95% CI of differences)	p[c]
Ramsay scale[a]				0.02
1	6 (18.8%)	5 (17.9%)	+0.9% (−18.7 to +20.7)	
2	21 (65.6%)	9 (32.1%)	+33.5% (+9.6 to +57.4)	
3	3 (9.4%)	8 (28.6%)	−19.2% (−38.7 to +0.3)	
4	2 (6.2%)	2 (7.1%)	−0.9% (−13.6 to +11.8)	
5	0	4 (14.3%)	−14.3%[b]	

[a] Values expressed in absolute numbers and relative frequency (in parentheses).
[b] Impossible to calculate the difference between percentages.
[c] Chi-square test for independence; significance level: $p < 0.05$

future interventions. Perioperative management should be individualized according to clinical manifestations, autism degree, and associated comorbidities.[10]

The oral route of premedication seems to be less invasive, nonetheless 6.25% of our sample did not accept the proposed preanesthetic and showed uncollaborative behaviors before even tasting the formula (original manufacturer's formulation syrup with sweet taste). Regarding the primary outcome, 81.2% of the participants in the Midazolam group and 82.1% in the Midazolam/Ketamine group had a Ramsay score ≥ 2, which can be interpreted as an anxiolysis state. The low oral bioavailability of S(+)-ketamine, estimated between 8% and 11%,[17,18] may have contributed to the fact that only 50% of participants in the Midazolam/Ketamine group presented a Ramsay score ≥3 (drowsy, asleep, or sedated). Nevertheless, this rate was three times higher than in the Midazolam group, whose rate was 15.6%.

Our sample characteristics were compatible with previous studies, which indicate that the incidence of ASD is approximately three times higher in males than in females.[19] Neuropsychologic behaviors in ASD are similar despite age and merging different age groups in studies with this

Table 3 Comparison of difficulty in obtaining intravenous access between Midazolam group and Midazolam + Ketamine group.

Variable	Midazolam group (η = 32)	Midazolam + ketamine group (η = 28)	Difference between percentages (95% CI of differences)	p^b
Ease of obtaining[a]				0.01
No reaction	1 (3.1%)	7 (25%)	−21.9% (−39.0 to +4.7)	
Minimal reaction	9 (28.1%)	11 (39.2%)	+11.2% (−35.0 to +12.7)	
Physical stabilization	19 (59.4%)	5 (17.9%)	+41.5% (+19.4 to +63.7)	
Pharmacological intervention	3 (9.4%)	5 (17.9%)	−8.5% (−25.9 to +8.9)	

[a] Values expressed in absolute numbers and relative frequency (in parentheses).
[b] Chi-Square test for independence; significance level: $p < 0.05$

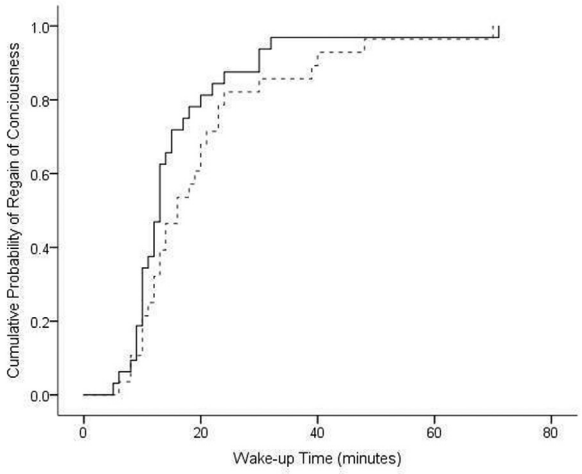

Figure 2 Kaplan-Meier survival analysis for wake-up time in minutes. Midazolam group: continuous line, Midazolam + Ketamine group: dashed line. Log rank test with p = 0.221.

population is not uncommon among published papers related to the matter, since in the real-world scenario a large age range can be observed in referral services for this condition. Regarding comorbidities associated with ASD, epilepsy was present in 33.4% of the participants, which was higher than the proportion found in a systematic review (12.1%).[20] The prevalence of obesity in the general Brazilian population is approximately 14% in children and adolescents and 26% in adults.[21] The prevalence in our sample, which included children, adolescents and adults, was 26.7%. A meta-analysis on the association between ASD and obesity showed an Odds Ratio of 1.84 for the prevalence of obesity in persons with ASD compared to non-autistic individuals.[22]

Almost four-fifths of our sample (76.6%) used psychotropic medications, which is higher than the 63.6% reported in a United States study.[23] The ASD severity distribution of our participants, according to the American Psychiatric Association, showed a predominance of level 3 (requires very substantial support), which comprised more than half of the participants, followed by level 2 (requires substantial support) in more than a third. This is to be expected since those patients are more likely to be referred to a specialized service. A previous study comparing the necessity of premedication in children with ASD, found an odds ratio of 2.70 and of 5.50 for this intervention when ASD level one was compared to level two and to level three respectively, which was similar to our findings.[24]

A clinical trial in non-autistic children that compared midazolam alone and midazolam plus ketamine at the same doses used in our study found an anxiolysis rate of 90% in the combined group and 75% with the midazolam group. This study reported a Ramsay score ≥3 in 70% of the combined group and less than 60% in the midazolam group.[11] Another clinical trial comparing different doses of midazolam in non-autistic children found that a dose of 0.5 $mg.kg^{-1}$ resulted in a sedation level comparable to Ramsay ≥3 in 15% of the sample.[25]

The chronic use of psychotropic medications among our sample, which can alter the functioning of the hepatic cytochrome P450 system,[26] as well as the genetic variability of cytochrome P450,[27] specifically CYP2B6 (involved in the metabolization of ketamine),[28] may have influenced the lower rates of anxiolysis and drowsy or sleeping status in our study. The difference in rates may be attributed to the use of racemic ketamine in previous studies, which has greater bioavailability than oral *S*(+)-ketamine.[17,18,29]

Venous access was a relevant aspect of our trial; in 64.2% of the combined treatment group and 30.3% of the midazolam group, peripheral venous access did not require physical stabilization. This difference could be due to the analgesic properties of ketamine, which acts on NMDA and opioid receptors.[30] A previous publication by Funk et al. used a scale identical to ours to assess the reaction to venous access[11] and showed better venipuncture scores with midazolam/ketamine association in pediatric anesthesia among non-autistic children, however, topical anesthetic at the puncture site was used, which may muddle analogies to our study.

The awakening time analysis with the Kaplan-Meier curve showed no difference between the groups in the present study. Previous studies using the same dosages also found no significant differences between groups.[11,31]

There was a low incidence of agitation, nystagmus, and sialorrhea in both intervention groups and the rates did not differ significantly between them in our research. These results are of an exploratory nature and must be analyzed with due caution, since the sample size was calculated as a function of the primary objective; our detection power for other events is underestimated. We chose to compare only midazolam and the association of midazolam and ketamine due to the lower sedation rates reported with ketamine alone seen in a previous paper,[11] which also found higher rates of

nausea, vomiting, and psychomimetic effects in children that received ketamine alone at a higher dosage (6 $mg.kg^{-1}$).[11]

Since no randomized clinical trials have been conducted on the use of oral midazolam and oral ketamine as preanesthetic in autistic persons, our study is both relevant and unprecedented. Our results can contribute to improve perioperative management in this population. Certain limitations are inherent to this study, such as the per-protocol analysis itself. This type of assessment was used to register the effectiveness of combined treatment in an ideal situation due to the scarcity of clinical data in the literature. Potential exclusion biases could compromise the effectiveness of the intervention, for which an intention-to-treat analysis would be more appropriate. Since it is assumed that ketamine can compromise the individual's sociobehavioral aspects beyond the hospitalization period, the lack of data in this topic could be considered as another limitation, as well as the non-evaluation of parent's anxiety, age difference between groups, non-monitoring of neuromuscular blockade and anesthesia depth. Also, the occurrence of adverse events must be seen with caution due to its inherent exploratory nature, which could lead to type 2 error related to insufficient detection power.

We conclude that the association of oral *S*(+)-ketamine and midazolam provides higher rates of a satisfactory preanesthetic sedation state than oral midazolam alone in patients with ASD. Combined treatment facilitates peripheral venous access without increasing awakening time or the incidence of adverse events.

Conflicts of interest

The authors declare no conflicts of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sector.

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ORIGINAL INVESTIGATION

Cardiopulmonary effects of prolonged surgical abdominal retractors application during general anesthesia: a prospective observational comparative study

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KEYWORDS
Cardiac output;
Dynamic Compliance;
Static Compliance;
Cancer bladder;
Ring self-retaining retractor

Abstract
Introduction: Increasing abdominal pressures could affect pulmonary compliance and cardiac performance, a fact based on which the aim of the present study to detect the cardiopulmonary burden of multiple retractors application during supine versus lateral abdominal surgeries. We hypothesized that surgical ring multiple retractors application would affect the pulmonary and cardiac functions during both lateral and supine abdominal surgeries.
Methods: Prospective observational comparative study on forty surgical patients subdivided into two groups twenty each, comparing pulmonary compliance and cardiac performance before, during and after retractors application, group (S) supine position cystectomy surgery, and group (L) lateral position nephrectomy surgery under general anesthesia, Composite 1ry outcome; dynamic compliance C-dyn and cardiac index CI and Other outcome variables ICON cardio-meter were also recorded.
Results: C-dyn and C-stat were significantly decreased late during retractor application in lateral compared to supine surgery with significant decrease compared to basal values all over the surgical time. CI was significantly increased after retractor removal in both of the study groups compared to basal values. PAWP was significantly increased in -lateral compared to supine surgery -with significant increase compared to basal value all over the surgical time in both of the study groups. significant increase in DO2I compared to basal value during both supine and lateral positions.
Conclusion: Surgical retraction results in a short-lived significant decreases in lung compliance and cardiac output particularly during the lateral-kidney position than the supine position compliance.

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Introduction

Normal pulmonary compliance ranging between 60–100 mL.cm^{-1} H_2O with normal in-between gradient nearly 10 mL.cm^{-1} H_2O. Increasing abdominal pressures would affect both dynamic compliance (Cdyn) and static compliance (Cstat).[1]

Postoperative cardiac and pulmonary complications after general anesthesia is not uncommon with incidence range between 3–7.9%.[2,3] The highest incidence is mostly reported in pulmonary operations[4] in the form of re-intubation, pulmonary failure, edema, infection, and collapse. Postoperative respiratory failure after abdominal operations increases early perioperative mortality by approximately 10-folds.[5] Incriminated predictors include airway edema, obesity, tumors, supine position, and prolonged surgical retractors application.[6]

Prolonged application of surgical retractors has been identified as a risk factor for postoperative pulmonary complication. It may induce diaphragmatic cephalic displacement and chest wall restriction with subsequent compromise gas exchange and pulmonary mechanics.[6,7]

Pulmonary atelectasis has been identified as a major cause of respiratory failure. It starts minutes after induction of general anesthesia due to decrease regional trans-pulmonary pressure in dependent lung areas and worsen by stress response to surgical incision. Decreased compliance in de-recruited areas causes over-inflation of aerated lung tissue in nondependent areas associated with larger trans-pulmonary pressure (volu-trauma), cyclic lung de-recruitment causes low-volume lung injury (atelecto-trauma), release of local pro-inflammatory mediators from surgical incision stress response, tissue trauma by surgical retractors, and infection contribute to pulmonary injury (bio-trauma).[8]

It is still unclear whether self-retaining multiple abdominal retractors would have an impact on cardiac and pulmonary function during lateral and supine surgical positions or no? Finding an answer to this question would illuminate the view for the anesthesiologist's decision on evaluating degree for anesthetic risk, ventilatory and fluid management during different surgical positions while self-retaining multiple abdominal retractors are applied.

We hypothesized that surgical ring multiple retractors application would affect the pulmonary and cardiac functions during both lateral and supine abdominal surgeries.

The study aimed to study the changes in dynamic and static lung compliance, cardiac index (CI), PAWP, oxygen delivery (DO2), and peripheral oxygen saturation (SpO_2) before, during, and after applying the surgical ring multiple retractors in the lateral-kidney and supine positions during open abdominal surgery for nephrectomy and cystectomy, respectively.

Methods

After obtaining approval from institutional research ethical committee IRB code: R.18.11.337, clinical trial registration number NCT03776292, this prospective, observational, comparative study was carried on 40 patients aged 18-65 years. Informed consent was obtained from all patients.

Patient refusal, body mass index (BMI) greater than 35 kg.m^{-2}, asthma requiring bronchodilator therapy, chronic obstructive pulmonary disease, severe pulmonary disease, hemodynamic instability (hypotension or tachycardia), history of congestive heart failure, right ventricular dysfunction, severe valvular heart disease, intracardiac shunts, intracranial hypertension, cardiac rhythm other than regular sinus, severe chronic kidney disease (glomerular filtration rate < 30 mL.min^{-1}. 1.73 m^2), liver cirrhosis (Child Pugh class B or C), pregnancy, previous thoracic surgery (lobectomy, bi-lobectomy, or pneumonectomy), lung metastatic surgery, previous-receiving chemotherapy, emergency surgery, preoperative need for invasive mechanical ventilation were excluded from the study.

After detailed history taking and physical examination, attaching all standard monitors (electrocardiogram ECG, noninvasive blood pressure NIBP, pulse oximeter SaO_2, then 20 G intravenous (IV) catheter was inserted, fluid preloading of 500 ml Ringers' solution and midazolam sedation 0.02 mg.kg^{-1} premedication during 20 minutes before induction of general anesthesia, then the routine regional epidural analgesia under strict aseptic conditions with 15 ml bolus of 0.125% bupivacaine plus fentanyl 1 μg.kg^{-1} (via epidural catheter in cancer bladder supine group according to the local hospital policy), then the ICON noninvasive thoracic bioimpedance cardiometer[9] (Osypka medical GmbH-IC.IFU/5M-17-010x-B-06/2015-softwere version 3.9.7) was attached by placement of four skin sensors two on the neck (Äsensor 5 cm above the left base of the neck, Bsensor on the left base of the neck and two on the left side of the thorax Csensor at lower left thorax at level of the xiphoid and Dsensor on lower left thorax10 cm below xiphoid level allow for the continuous measurement of the changes of electrical conductivity within the thorax, then the 4 steps to measuring COP: after Attaching electrodes Press ''Menu'' to access patient management screen, enter the patient's height, weight, age then press ''Measure'' to start (the green button).

Preoxygenation utilizing 80% O_2 mask 6–8 L.min^{-1} then GA was induced using propofol 1–2 mg.kg^{-1}, and fentanyl 1 μg.kg^{-1}. Endotracheal intubation was facilitated using atracurium 0.5 mg.kg^{-1} muscle, the tracheal tube position was confirmed by detection of $EtCO_2$ side stream catheter with bilateral equal air entry chest auscultation. Intraoperative muscle relaxation fifth the original muscle relaxant bolus dose increments of non-depolarizing neuromuscular blocking agents was given at 30-min intervals and when needed until the end of surgery. Normothermia (> 36 °C) was maintained by forced-air warming blanket and fluid warming prior IV infusion.

General anesthesia was maintained using 1 MAC of (sevoflurane) in a 0.4 oxygen-air mixture. A paracetamol 1 g bolus ± fentanyl boluses of (30 μg) was used if additional analgesia was required during the surgery.

The patient's lungs were mechanically ventilated with volume-controlled mode of mechanical ventilation with ventilation parameters tidal volume TV of 8 mL.kg^{-1} of predicted body weight (PBW) using the FLOW-i C40 anesthesia machine (serial no.SN-310412-SN4272-2015-MAQUET GENTING GROUP). The FiO_2 was set at 0.4, Inspiratory to expiratory (I: E) ratio is set between 1:2 and respiratory rate (RR) adjusted to achieve an $ETCO_2$ level of

35–40 mmHg, PEEP: 8 cmH2O). MAQUET FLOW-i C40 anesthesia machine automatically calculate the peak & platue airway pressures, the Cdyn and manually provide the Cstat by pressing the (Cstat) touch button which open a subsidiary window then press ÏNSPtouch button for 5 seconds and then press the ËXPtouch button for another 5 seconds then the Cstat will appear in a number at its screen place (C stat). Pulmonary Compliance Normal values for both dynamic compliance (Cdyn) and static compliance (Cstat) range is 60–100 mL.cm^{-1} H_2O. Equations for calculation of Cdyn calculation [V_T/P_{aw} − total PEEP] and Cstat [V_T/P_{plat} − total PEEP] a gradient > 10 may be secondary to endotracheal tube obstruction, mucous plugging, or bronchospasm.[10]

Surgical incision site

For cystectomy operation, the surgical incision used was midline suprapubic incision with left Para-median extension; for nephrectomy operation the surgical incision used was extra-pleural extra-peritoneal Lumber incision.

Fluid therapy and hemodynamic monitoring

Preoperative fasting replacement calculation by multiplying maintenance fluid requirements (cc. h^{-1}) in preoperative fasting hours, the maintenance fluid requirements follow the 4/2/1 rule. Anticipated surgical fluid losses were calculated according to severe tissue trauma 6 cc kg^{-1} h^{-1}.

Episodes of perioperative

Hypotension is defined as mean arterial pressure (MAP) less than 20% of the baseline value or $\leq$ 65 mmHg, was managed by using fluid bolus of 200 ml colloid starch and blood transfusion according to patient's requirements and if no response bolus doses of ephedrine 5 mg to be giving. Bradycardia is defined as HR less 20% of the baseline value or $\leq$ 50 beat/minute and to be managed by atropine 0.5 mg bolus.

End of surgery, intravenous muscle relaxant reversal drug neostigmine 0.02 mg.kg^{-1} combined with atropine 0.02 mg.kg^{-1} were given to reverse relaxant effect and tracheal extubation after full consciousness and resuming full muscle power, normal the respiratory drive with effective tidal volume and maintaining $SaO_2 \geq$ 95%.

Sample size calculation

This present study sample size calculation was designed up on a previous study[11] resulted in Cdyn- mean & standard deviation of [66 ± 12 mL.cm^{-1} H_2O and 53 ± 8 mL.cm^{-1} H_2O during supine versus lateral position respectively], yielding effect size of 1.27, A Prior G-power analysis was done to estimate the study sample size. Assuming α (type I error) = 0.05 and β (type II error) = 0.2 (power = 80 %), yielding a total sample size of 36 patients increased up to total of 40 patients 20 for each group to compensate for the dropouts.

Statistical analysis

T he collected data was coded, processed, and analyzed using SPSS program statistical package version 16 (SPSS, Inc., Chicago, IL, USA). Normality of distribution was tested by Kolmogorov-Smirnov and Shapiro test. Normally distributed numerical data was presented as mean and standard deviation and their comparison in between groups (inter-group) was performed using Student's *t*-test. Categorical data was presented as frequency and percentage and compared using Chi-square test. Repeated measure analysis (ANOVA) was used for analysis of intragroup data overtime compared to baseline value. Data was considered significant when *p*-value is < 0.05.

Study outcomes

Primary outcome: Composite 1ry outcome Cdyn and Cardiac Index (CI).

Secondary outcome: Cstat, peak airway pressure (PAWP) Cardiac output (COP), stroke volume (SV)-stroke volume variability (SVV)-cardiac performance index (CPI), oxygen delivery index (DIO_2). Noninvasive intraoperative hemodynamic mean arterial pressure (MAP), heart rate (HR), arterial oxygen saturation (SaO_2), and end-tidal Carbon dioxide ($EtCO_2$)].

Outcome parameters recording time specification

First group of data (Baseline recording times): B1, B2, B3 (B. baseline) recorded just after endotracheal intubation and then every 10 minutes.

Second group of data (During Retractor application recording times): R1, R2, R3, R4, R5, R6 (R, retractor) recorded every 10 minutes in Group (S) after Dennis Brown ring retractor and after self-retaining Finochietto abdominal retractor application in Group (L).

Third group of data (post-retractor removal recording times): NR 1, NR2, NR3 (NR, non-retractor) recorded every 10 minutes after retractors removal.

Results

Patient demographic variables such as gender, weight, length, BMI were non-significant, except for the patient age, which was significantly decreased in lateral nephrectomy compared to supine cystectomy group within the study age predefined range (Table1).

The two groups had similar changes in the Cdyn and cardiac output. Compared to baseline values, there was a statistically significant increase in CI in both of the study positions (Table 2). Compared with the lateral position, the Cdyn was statistically significant lower after retractor application in the supine position at R5&R6 time periods (p = 0.043 and p = 0.024, respectively), these changes were statistically significant less than the baseline values in both of the study positions (Table 3).

As regard the COP; Compared to supine position the lateral position was statistically significant lower after

Table 1 Patient demographic data.

	Group S	Group L	*p* value
Age (years)	57.5 ± 10.7	46.3 ± 9.9[a]	0.02
Gender (male/female)	17/3	11/9	0.82
Weight (Kg)	87.7 ± 8.7	79.4 ± 7.6	0.556
Length (cm)	171.7 ± 8.2	168 ± 8.8	0.176
BMI	29.9 ± 3.1	28.3 ± 3.7	0.161

This table shows patient demographic data represented in mean and standard deviation except gender in number ratio.
Group S, supine position group; Group L, lateral position group; BMI, body mass index; kg, kilogram; cm, centimeter. test was used for continuous parametric data statistical analysis which are represented in mean and slandered deviation. Chi-square test was used for categorical data.
Data was significant [(a)] when *p* value < 0.05.
[a] Age was significantly decreased in Lateral nephrectomy compared to supine cystectomy group.

Table 2 COP& CI variables comparison between groups.

	COP			CI		
	Group S	Group L	*P* value	Group S	Group L	*P* value
B1	5.8 ± 1.6	†5.2 ± 1.2	0.167	†3.2 ± 0.74	†2.8 ± 0.6	0.04
B2	†6 ± 1.6	†5.5 ± 1.6	0.348	†3.2 ± 0.67	†3.2 ± 0.67	0.346
B3	†6.1 ± 1.9	†5.7 ± 1.6	0.458	†3.5 ± 1	†3 ± 0.95	0.02
R1	†6 ± 1.9	†5.5 ± 1.7	0.363	†3.5 ± 1.1	†3.1 ± 0.95	0.276
R2	†6.3 ± 1.9	†5.4 ± 1.8	0.148	†3.6 ± 1.1	†3 ± 0.96	0.124
R3	†6.3 ± 1.9	†5.4 ± 1.5	0.113	†3.6 ± 1	†3.1 ± 0.86	0.095
R4	†6.6 ± 1.8	†5.5 ± 1.6*	0.05	†3.8 ± 1.1	†3.3 ± 0.79	0.076
R5	†6.7 ± 1.9	5.4 ± 1.5*	0.024	†3.5 ± 1	†3.1 ± 0.73	0.162
R6	†6.7 ± 1.9	†5.4 ± 1.4*	0.018	†3.6 ± 0.87	†3.1 ± 0.75	0.067
NR1	†7.6 ± 2	†5.9 ± 1.4*	0.004	†4 ± 1	†3.4 ± 0.79	0.051
NR2	†7.7 ± 1.8	†6.3 ± 1.7*	0.003	†4.2 ± 1	†3.5 ± 0.78	0.015
NR3	†7.7 ± 1.8	†6.3 ± 1.7*	0.014	†4.2 ± 1	†3.7 ± 0.9	0.122
ANOVA						
D f	3.4	3.529		3.176	3.496	
F	8.26	3.865		5.051	5.883	
P. value	≤0.001	0.009		0.003	0.001	

This table shows; [(*)] Significant decrease in COP in group L compared to group S at R4 to NR3 reading, Significant decrease in CI at B3 and NR2 readings only in group L compared to group S. [(†)] Intragroup data showed significant increase of both COP and CI compared to the basal value overtime. Group S, supine position group; Group L, Lateral position group; B, basal reading: B1, B2, B3 recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3); R, during retractor application reading; NR, non-retractor = reading after retractor removal; COP, cardiac output; CI, cardiac index; ANOVA, Analysis of variance. T test was used for continuous parametric data statistical analysis which are represented in mean and slandered deviation. ANOVA test was used for analysis of intragroupal data compared to basal value. [(*) & (†)] data was significant with *p* value < 0.05.

retractor application at R5&R6 time records (p = 0.024 and p = 0.018, respectively) and after retractor removal at NR 1, NR2, NR3 time records (p = 0.004, p = 0.003, p = 0.014, respectively) these changes were statistically significant less than the baseline values in both of the study positions (Table 3).

Compared to the supine position, the Cstat decreased significantly following application of the retractor in the lateral position at R5 and R6 time periods (p = 0.01 and p = 0.001, respectively). Compared the baseline values, the two groups showed statistically significant decrease in Cstat and increase in PAWP over the study time periods, PAWP showed statistically significant increase during most of the study time periods in the lateral position than during supine position (Table 3).

The changes in MAP and HR were similar in both of the study groups (Fig. 1), CPI was Significantly decreased in group L compared to group S at all the study reading records except at B2, R1 and NR1 (Fig. 2), DO2I similar in both study groups (Fig. 3), SaO_2 was statistically significant lower during lateral versus supine positions from R2 to NR1 time periods, EtCo2 was similar in both of the study groups (Fig. 4), and SVV was similar in both study groups (Fig. 5).

As regard the study flowchart; fifty patients were enrolled, 10 patients were excluded didn't met inclusion criteria, consequent patient selection of the remaining 40 patients undergoing cystectomy or nephrectomy and then allocated into two equal groups each of 20 patients. supine group (S) underwent radical cystectomy and orthotopic urinary diversion in supine position, while the lateral group

Table 3 Pulmonary variables; (Inter-group and intra-group comparison).

	PAWP			Dynamic Comp.			Static Comp.		
	Group S	Group L	*P* value	Group S	Group L	*P* value	Group S	Group L	*P* value
B1	16.53 ± 3.641.6	18.95 ± 2.1*	0.032	58.74 ± 16.23	61.99 ± 16	0.4	69 ± 17.8	65.2 ± 15.4	0.508
B2	#17.58 ± 3.59	#19.4 ± 1.8	0.097	#56.79 ± 13.9	#60.3 ± 14.47	0.342	#65.9 ± 14.5	#62.6 ± 16.4	0.502
B3	#17.53 ± 2.94	#19.9 ± 2.2*	0.013	#53.63 ± 12.7	#57.3 ± 12.1	0.269	#60.6 ± 15.2	#60.6 ± 16.4	0.826
R1	#20.11 ± 3.2	#21.8 ± 2.9	0.068	#45.21 ± 9.2	#49 ± 11.95	0.293	#51.1 ± 12.9	#48.5 ± 9	0.320
R2	#20.79 ± 2.96	#22.5 ± 3.2	0.072	#44.6 ± 11	#45.8 ± 11.4	0.853	49.7 ± 12.4#	#47.8 ± 11.8	0.731
R3	#20.68 ± 3.1	23.4 ± 1.8*#	0.001	#44.68 ± 10.8	#43.7 ± 8.15	0.637	51.2 ± 12.8#	#45.6 ± 9	0.168
R4	#20.21 ± 2.62	#24 ± 1.86*	0.000	#45.42 ± 9.63	#42.3 ± 8	0.216	50 ± 11.5#	#44.4 ± 8.7	0.098
R5	#20.95 ± 3.29	#24.3 ± 1.4*	0.000	#45.4 ± 10	#40.5 ± 6.6†	0.043	49.5 ± 10.3#	#42.3 ± 7	0.01
R6	#20.79 ± 3.5	#24.45 ± 1.3*	0.000	#44.8 ± 8	#39.9 ± 6.2†	0.024	50.6 ± 10.8#	#41.4 ± 5.5	0.001
NR1	#17.42 ± 3.37	#20.7 ± 3*	0.003	#50.8 ± 9	#51.4 ± 12.8	0.932	58.3 ± 14#	#52.2 ± 14.9	0.148
NR2	#17.74 ± 2.74	#20.65 ± 1.7*	0.000	#53.7 ± 10	#53.6 ± 12.3	0.764	65.1 ± 15.1#	#56.4 ± 13	0.061
NR3	#17.1 ± 2.6	#20.2 ± 1.8*	0.000	#57 ± 9.9	#56.7 ± 14.9	0.709	62.9 ± 10.7#	#58.7 ± 11.1	0.165
ANOVA									
D f	3.063	4.286		3.421	4.129		3.384	4.222	
F	11.384	30.533		21.878	21.878		13.366	23.240	
P value	≤0.001	≤0.001		≤0.001	≤0.001		≤0.001	≤0.001	

This table shows (*) significant increase in PAWP in group L compared to group S at most of the study timed records except at B2, R1 and R2. As regard C-dyn and C-stat there were significant decrease (†) in group L compared to group S only late after retractor application at R5-R6 records. (#) Intragroup data showed significant increase of PAEP, C-dyn., and C-stat compared to the basal value overtime. B, basal reading: B1, B2, B3 recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3); R, during retractor reading; NR, non-retractor reading after retractor removal; PAWP, Peak airway pressure; C-dyn, Dynamic compliance; C-stat, Static Compliance. T test was used for continuous parametric data statistical analysis which are represented in mean and slandered deviation, ANOVA with repeated measures was used for analysis of variance. Data was significant; (*) (†) (#) when *p* value < 0.05.

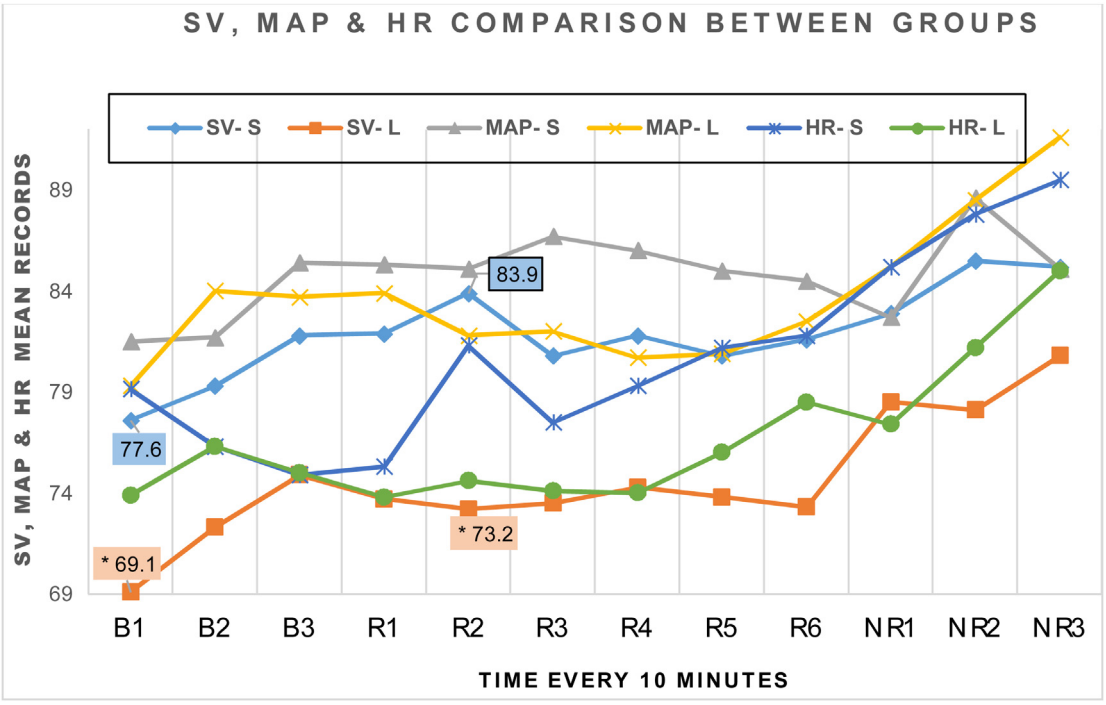

Figure 1 Stroke volume, Noninvasive mean arterial blood pressure, and Heart rate comparison in between groups.
This figure shows * Significant decrease in the SV in group L compared to group S only at B1 (69.1 ± 10.4) Vs (77.6 ± 14.2) with *p* value of 0.037 and R2 73.2 ± 14.4 Vs 83.9 ± 17 with *p* value of 0.048 respectively. No significant difference as regard MAP and HR in Group L compared to group S. T test was used for continuous parametric data statistical analysis represented in mean and standard deviation, and significant data only when *p* value is < 0.05.
B, baseline reading before retractor application recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3)], R (reading during retractor reading), NR (non-retractor = reading after retractor removal), SV (stroke volume), MAP (noninvasive mean arterial blood pressure), HR (heart rate).

(L) underwent open nephrectomy in lateral kidney position under general anesthesia GA (Fig. 6).

Discussion

We reported no statistical important differences between the two surgical approaches before and after applying the surgical retractor in terms of compliance and hemodynamic changes. However, compared with the lateral kidney position, the supine position is associated with favorable higher Cdyn, Cstat, and SaO_2 and less increase in PAWP values.

Abdominal self-retaining retractors application depressive effect on the pulmonary compliance[6,7] can explain our results that both Cdyn and Cstat statistical significant decrease together with statistically significant increase in the PAWP compared to baseline value all over the study time (Table 3), despite no significant intergroup difference between lateral and supine positions as regard Cdyn and Cstat, hence the opinion that only changing the position from supine to lateral even to lateral kidney position is the cause of the pulmonary compliance reduction during abdominal surgery is of no value as it ignores the mechanical effect of abdominal self-retaining retractors application later.

Our findings are similar to Thomas et al. (2007)[12] and Mehdi (2018)[13] who reported statistically significant decreases in lung compliance in the lateral position than during the supine position. That is attributed to concomitant increases in airway pressures. On the other hand, retractors application during supine position is of less burden on oxygen delivery than during the lateral position. Additionally, we reported statistically higher cardiac output values after applying retractor in supine position than the lateral position which could be explained with the concomitant changes in PAWP; a result in line with Raid et al (2018)[14] who found that lateral position was associated with an immediate rise in peak airway pressure as a result of increased airway resistance by 2 cm $H_2O.L^{-1}.s^{-1}$ and in chest wall and lung elastance by 3 and 2 cm $H_2O.L^{-1}$, respectively.

These changes between the two surgical positions were transient and returned to normal after removal of the retractor. Similarly, Yokoyama et al (2000)[15] reported a significant decreases in COP by 20% with changing the position from the supine to the lateral position ($p < 0.01$). These changes were related to the increase in systemic vascular resistance and reduced venous return. In our study, we did not measure these parameters because of local institutional policy for not using invasive pressure monitoring during these surgical procedures except in patients with multiple comorbidities, who were excluded from this study.

Hemodynamically, both CI & COP showed significant elevation after retractor removal compared to baseline values which could be attributed to improvement of venous return.

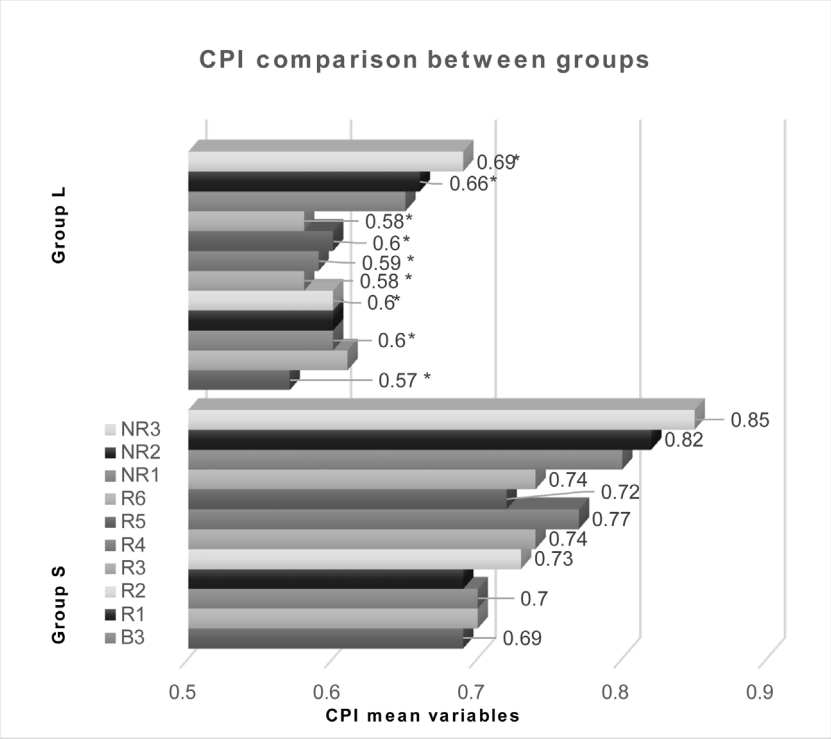

Figure 2 Cardiac performance index comparison in between groups.
This figure shows * Significant decrease in CPI in group L compared to group S at all the study reading records except at B2, R1 and NR1. T test was used for continuous parametric data statistical analysis which are represented in mean and slandered deviation, and significant data only when *p* value is < 0.05. Abbreviations.
B, baseline reading before retractor application recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3)] group L (Lateral position group), group S (Supine position group) B (basal reading), R (during retractor reading), NR (non-retractor = reading after retractor removal), CPI = (cardiac performance index).

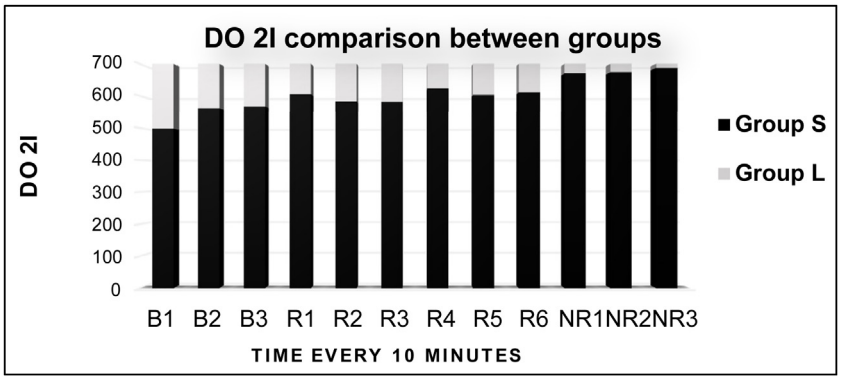

Figure 3 Oxygen delivery index comparison in between groups.
This figure shows no significant difference in DO2I in between Group L compared to group S before, during and after retractor application. T test was used for continuous parametric data statistical analysis represented in mean and slandered deviation, ANOVA analysis of data revealed significant increase in DO2I compared to basal value during both supine and lateral positions (DF, F, *p* value was 2.862, 4.154, 0.011 and 3.980, 2.735, 0.035 respectively). Significant data only when *p* value is <0.05.
B, baseline reading before retractor application recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3)], R (during retractor reading), NR (non-retractor = reading after retractor removal), group L (Lateral position nephrectomy group), group S (Supine position cystectomy group), SV (stroke volume), and DO2I = (oxygen delivery index).

During abdominal retraction as it retracts the abdominal viscera against the abdominal wall sides cephalad compressing indirectly the diaphragm, the base of the lungs and increases the intrathoracic and PAW pressure leading to reduction of the venous return to the heart. In opposition to our results Yokoyama et al (2000)[15] found that position change from supine position to lateral position only without application of ring abdominal retractors has its great hemodynamic burden

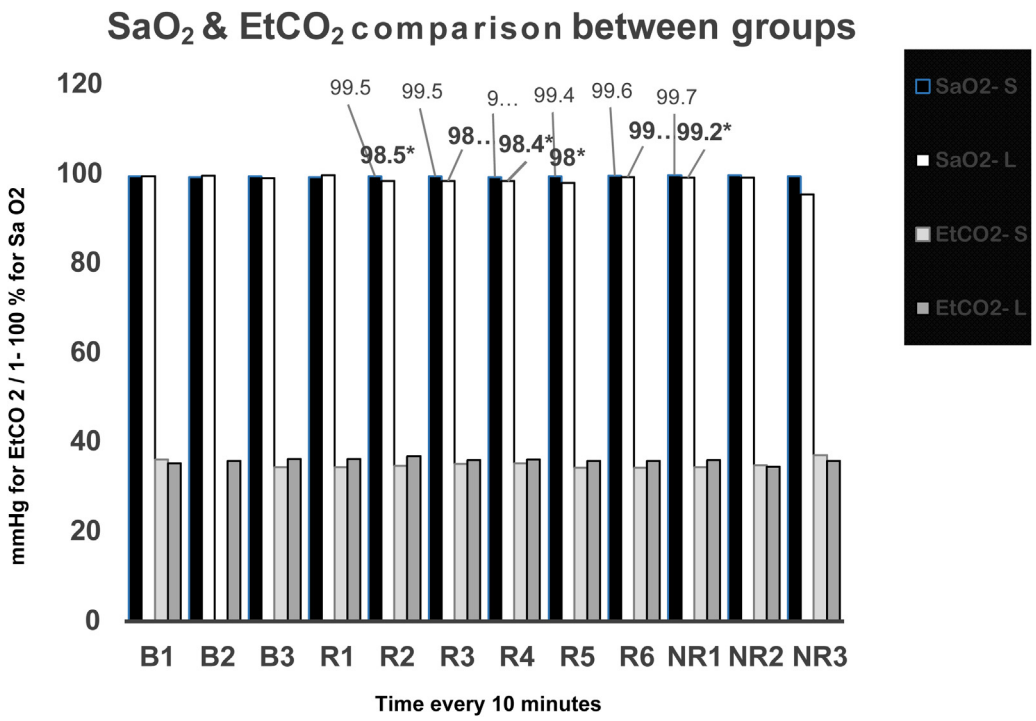

Figure 4 Arterial Oxygen saturation, End tidal carbon dioxide comparison in between groups.
This figure shows statistical not clinical * Significant decrease in SaO_2 during lateral versus supine positions from R2 till NR1 reading records [R2 (98.5 ± 1.3 Vs 99.5 ± 0.9 *p* value0.037), R3 (98.5 ± 1.3 Vs 99.5 ± 0.9 *p* value 0.005), R4 (98.4 ± 1.8 Vs 99.3 ± 0.9 *p* value 0.005), R5 (98 ± 2 Vs 99.4 ± 1 *p* value 0.005), R6 (99.3 ± 1.5 Vs 99.6 ± 0.6 *p* value 0.001), NR1 (99.2 ± 1.4 Vs 99.7 ± 0.7 *p* value 0.026) respectively], with no significant difference in between both of the study groups as regard $EtCO_2$. T test was used for continuous parametric data statistical analysis represented in mean and slandered deviation, and significant data only when *p* value is ≤ 0.05. B (basal reading), R (during retractor reading), NR (non-retractor = reading after retractor removal), SaO_2 (arterial Oxygen saturation), $EtCO_2$ (end tidal carbon dioxide). B, baseline reading before retractor application recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3)], Group L (Lateral position nephrectomy group), group S (Supine position cystectomy group), B (basal reading), R (during retractor reading), NR (non-retractor = reading after retractor removal), SV (stroke volume), EtCo2 (end tidal carbon dioxide tension), and SaO_2 = (arterial oxygen saturation).

such as significant reductions occurred in the MAP with significant reductions in cardiac index [from 3.04 (0.21) to 2.44 (0.26) liter. min^{-1}. m^{-2}, $p < 0.01$] and stroke volume index [from 40 (5) to 31 (5) mL.$beat^{-1}$. m^{-2}, $p < 0.01$].

Yokoyama et al. (2000)[15] only explained our result that COP was probably reduced by a decrease in venous return and an increase in systemic vascular resistance which is write, but from our present study results; we totally oppose Yokoyama and colleagues, as our COP three baseline values and even during retractor application 1st four successive COP readings, there were no significant difference between supine and lateral kidney position except late after retractor application (R5, R6 $p = 0.024$, $p = 0.018$, respectively), this documented that the significant decrease in COP in lateral position compared to supine position occurred (in both Yokoyama and our present study) was attributed to the self-retaining retractors application effect and not a position induced physiological change, as if it is a physiological change; it would happen from the start of position change not late after retractors application.

As regard the CI also the same explanation it was increase compared to baseline value even more after retractors removal (due to venous return improvement after retractors removal) with transient reduction during B3&NR2 in lateral compared to supine position which could be due to the presence of retractors an explanation not totally convincing as the CI reduction in this present study was transient and restricted only to 2 of 12 readings records and if it was due to position change as Yokoyama et al. (2000)[15] explained in his study it must happen early after attaining lateral kidney position not in a sporadic transient manner happened in this present study.

This present study hemodynamic results showed no significant difference in between both study groups as regard MAP & HR (Fig. 1) and SVV (Fig. 5). In opposition to our present study hemodynamic results; Yokoyama et al (2000)[15] found significant reductions occurred in the mean arterial blood pressure and attributed it to the decrease in venous return, but Nakayama and colleagues (2015)[16] concluded that hypotension could be attributed to the use of abdominal ring wound retractor in lower abdominal surgery.

In conclusion, surgical retraction results in a short-lived significant decrease in lung compliance and cardiac output particularly during the lateral-kidney position than the supine position compliance.

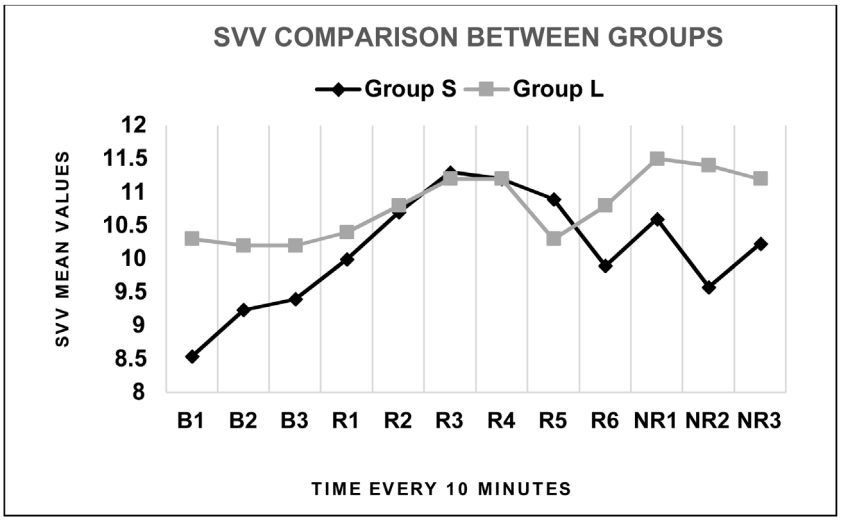

Figure 5 Stroke volume variability comparison in between groups.
This figure shows no significant difference in between ring self-retaining multiple blade retractor application during supine versus lateral positions as regard SVV. T test was used for continuous parametric data statistical analysis represented in mean and slandered deviation, and significant data only when *p* value is < 0.05.
B, baseline reading before retractor application recorded just after endotracheal intubation (B1) and then every 10 minutes (B2 & B3)], R (during retractor readings), NR (non-retractor = readings after retractor removal), SVV (stroke volume variability), Group L (Lateral position group) group S (Supine position group).

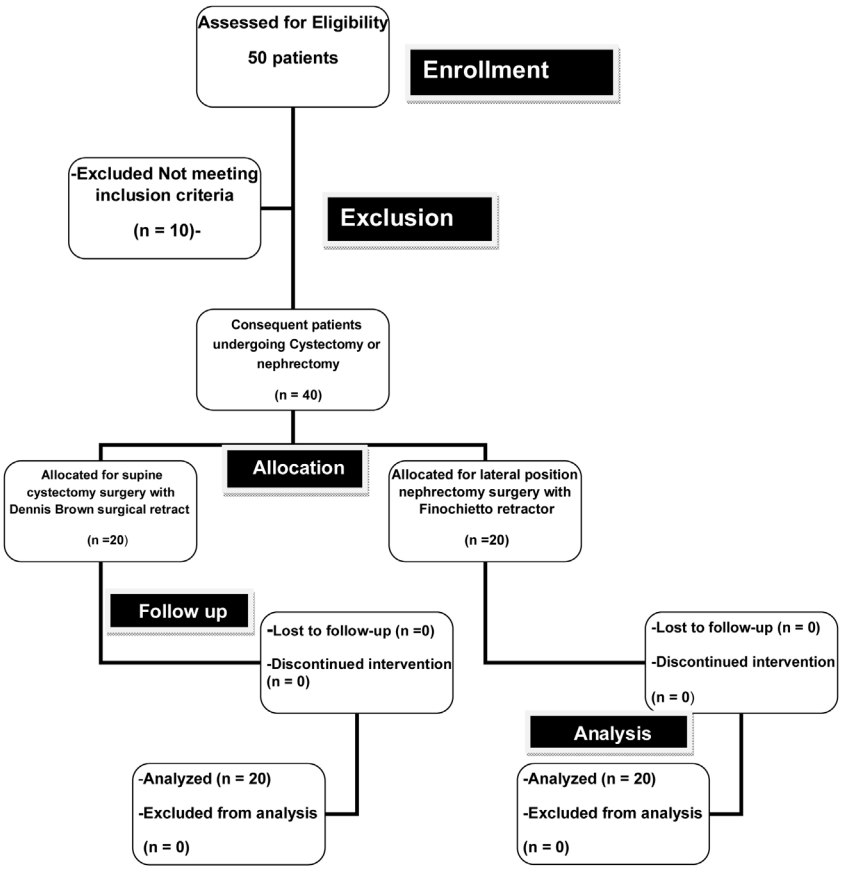

Figure 6 Study flowchart.
This figure represent the study flowchart 50 patient enrolled, 10 patients were excluded 10 not meeting inclusion criteria, remaining total number of 40 patients were selected Consequently patients undergoing Cystectomy or nephrectomy, 20 patients were allocated and analyzed in each group.

Limitations

Our study has several limitations. First of note, we studied two different surgical procedures (cystectomy and nephrectomy) which might have non-comparable conditions like the different type and extent of the surgical incision and duration of surgical procedures. Future cross-sectional study including more patients relaying on more similar surgical procedures are needed. Second, the European and North American recommendations for routine perioperative monitoring including objective monitoring of the neuromuscular block. Unfortunately, these monitors were not available at our hospital during the time of the study. The non-use of neuromuscular blocking monitoring to guide administering atracurium might raise concerns regarding the reliability of changes in lung compliance reported in case of inadequate depth of neuro-monitoring blockade. However, in the present study, atracurium was administered as much as needed with a maximum duration of 30 minutes based on the discretion of the experienced anesthesiologists) >15 years' experience). Third, the use of invasive monitoring for blood pressure and central venous pressures would be more reliable than using the noninvasive blood pressure monitoring. However, our local hospital policy does not allow using invasive pressure monitoring except in patients with multiple comorbidities, who were excluded from this study.

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Conflicts of interest

The authors declare no conflicts of interest.

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NARRATIVE REVIEW

A way forward in pulmonary aspiration incidence reduction: ultrasound, mathematics, and worldwide data collection

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Abstract Aspiration of gastric contents during induction of general anesthesia remains a significant cause of mortality and morbidity in anesthesia. Recent data show that pulmonary aspiration still accounts for many cases with implications on mortality despite technical and technological evolution. Practical, ethical, and methodological issues prevent high-quality research in the setting of aspiration and rapid sequence induction/intubation, and significant controversy is ongoing. Patients' position, drugs choice, dosing and timing, use of cricoid force, and a reliable risk assessment are widely debated with significant questions still unanswered. We focus our discussion on three approaches to promote a better understanding of rapid sequence induction/intubation and airway management decision-making. Firstly, we review how we can use qualitative and quantitative assessment of fasting status and gastric content with the point-of-care ultrasound as an integral part of preoperative evaluation and planning. Secondly, we propose using imaging-based mathematical models to study different patient positions and aspiration mechanisms, including identifying aspiration triggers. Thirdly, we promote the development of a global data collection system aiming to obtain precise epidemiological data. Therefore, we fill the gap between evidence-based medicine and experts' opinion through easily accessible and diffused computer-based databases. A better understanding of aspiration epidemiology obtained through focused global data gathering systems, the widespread use of ultrasound-based prandial status evaluation, and development of advanced mathematical models might potentially guide safer airway management decision making in the 21st century.

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Introduction

Soon after Mendelson described aspiration pneumonia, a study of 1,000 anesthesia-related deaths revealed regurgitation and vomiting as the leading cause of death due to anaesthesia.[1] In the 1960s, anesthesiologists developed improved airway management techniques, including cricoid force and rapid sequence induction/intubation (RSI) for high-risk patients. Since then, there has been a decline in pulmonary aspiration incidence.[2,3] More recently, data from the UK National Audit Project 4 showed that aspiration remains the single most common cause of death related to airway management, where for 34 reported cases, 11 resulted in death or brain damage.[4]

With its reported incidence of 2–7 per 20,000 anesthetic cases, each anesthetist should experience 4–14 pulmonary aspiration events in their career, depending on the area of work and number of emergency cases.[4,5] In emergency surgery, this complication's incidence increases to 0.5%, provided that anesthetic induction occurs in the operating room's controlled environment.[2] There is a further increase to 2.7% for in-hospital emergency cases outside the operating room.[6] We believe that the following three approaches should lead to a further decrease in pulmonary aspiration incidence in the 21st century: ultrasound, mathematics, and global data collection.

Pulmonary aspiration risk assessment: is ultrasound the answer to our prayers?

For each anesthesia case, examination includes an aspiration risk assessment. If compliant with the official fasting times,[7,8] the elective and ''healthy'' surgery patients usually have an uneventful anesthesia, but what about those with concomitant risk factors for pulmonary aspiration? Moreover, what about the significant proportion (up to 35%) of fasted patients, who have a full stomach on gastric ultrasound, despite fasting for a minimum of 6 hours (median of 16 h)?[9] How many of risk factors are needed, and what is their relative weight in a particular patient?

New antidiabetics can add another coefficient to the pulmonary risk assessment equation: GLP-1 receptor agonists like exenatide or liraglutide increase glucose-stimulated insulin secretion, suppress glucagon, and slow gastric emptying.[10] While gastroparesis is already a feature of advanced Diabetes Mellitus, these agents may slow gastric emptying further.[11] Therefore, it seems reasonable to expect an increased risk of aspiration with the use of these agents, particularly in diabetic patients with known peripheral neuropathy and gastroparesis.

Point-of-care ultrasound might be a potential solution to this conundrum. With gastric ultrasound (GUS), we can determine the patients' gastric content in at least 85% of obstetric, 90% pediatric, and 95% of other patients.[12,13] Despite some limitations of GUS, the first being operator dependency,[12] it represents one of the most objective tools for routine aspiration risk assessment for many semi-emergency patients. With GUS we can assess the aspiration risk better than ever before, not underestimating the opportunity to expand our airway examination and assessment[14] to tailor the anesthetic plan and provide safer and more optimal anesthesia care.

If the stomach is empty, we should be able to proceed safely with any airway management approach. However, one should use the correct patient position for scanning: 45° head up right lateral position. In obstetric patients, this position was superior to supine 45° head-up position, as 60% of images that indicated an empty antrum turned out to be incorrect in the right lateral position.[12] If adequate positioning is not possible, the ultrasound interpretation is no longer reliable. We should be aware of such potential false-negative examinations. Thus, appropriate patient positioning is imperative.

If there is food in the stomach, then surgery should be postponed, if feasible. Currently, interpretation of the presence of liquid in the stomach is the most difficult. The proposed cut-off was set at 1.5 mg kg^{-1}, although it is also hard to ascertain which volume poses an increased risk.[15] All in all, gastric ultrasound might also lead to safer pediatric anesthesia, as its use increases the 50:50 chance of correct clinical decision-making to an 85% correct choice of the appropriate induction technique.[13]

However, the major limitation remains that the gastric content's ultrasound findings do not directly correlate with pulmonary aspiration,[12] and studies addressing this issue would be ethically questionable to perform. Additionally, only circa 10% of anesthesiologists globally are currently trained in GUS.[16]

Patient positioning for the RSI: the Holy Grail of controversies?

Secondly, we would like to emphasize an area of RSI controversy that needs to be addressed by advanced mathematical modelling: patient positioning during RSI. Three leading patient positions are generally considered: head up (reverse Trendelenburg); horizontal-supine, and head down (Trendelenburg). The first position advocates many benefits, including better preoxygenation conditions, better intubation conditions, and less chance of regurgitation. However, if/when regurgitation occurs, then material empties into the lungs by gravity. One of the treatments, in this case, is to turn the patient head down,[3,17] which in a controlled setting would require at least 20 seconds (depending on the technical characteristics of the operating table and human factors). Those who prefer the head down position need to acknowledge the worse intubation conditions, worse preoxygenation (unless the patient is first preoxygenated in head-up position and then turned head down anesthetic induction), and a higher chance of regurgitation. But if regurgitation occurs, the material empties of the mouth and the nose. Studies show that the head-down position does not alter the pressure in the lower esophageal sphincter tone, hence questioning whether this position would increase the likelihood of regurgitation.[18]

At present, there is no good evidence in support of either position, except for expert opinion or in specific populations – such as obese patients – where advantages of the head-up position seem to overweight the risks and benefits of alternative positions.[19] We need to ascertain whether these assumptions are correct, as well as investigating the

conditions under which the gastric contents would enter the lungs in the head-down position. Some steps in this direction have been taken, when a group used the simulation manikin to establish the times to intubation and the volume of aspiration in different patient positions.[20] It would also be clinically interesting to determine how much time passes from when the gastric contents' entrance into the esophagus until aspiration, for different patient positions. We suggest building a clinically relevant computer-tomography derived anatomical model and developing numerical mathematical modelling of aspiration. By being based on anatomical data from a variety of patients, such a model could also test the boundary/trigger conditions needed for pulmonary aspiration to occur, i.e., the volume and nature of gastric contents, the pressure gradients, etc. A similar model could also be used to assess the still largely debated application of cricoid force during RSI with consistent cost-benefit analysis, ideally with cadaveric and live animal validation experiments.

Global database reporting system: evidence gathering solution?

The third action to further decrease pulmonary aspiration incidence is the establishment of a global data reporting system. Through a webpage and a mobile device application, an anonymous collection of aspiration events can guide reports and focus on ongoing controversies. This way, we might obtain the relevant data in a few years, as the annual worldwide incidence of pulmonary aspiration is in the order of thousands. By examining the data from 2012, when the annual number of surgeries delivered worldwide was estimated as 313 million, we can calculate the annual global incidence of pulmonary aspiration at least 110,000 cases.[21] The number is probably even higher now, as the frequency of surgical procedures and anesthesia care has again increased over the last 8 years. The ability to gather and analyze hundreds or possibly thousands of pulmonary aspiration cases globally could lead to better-informed practice and evidence-based data, instead of mainly relying on expert opinion. This approach may be a potential strategy to prevent and minimize airway management complications.[22]

The results of a recent worldwide survey on RSI with more than 10,000 respondents[16] showed a huge variability in RSI practice. For example, cricoid force would be used in 71% during RSI for a hypothetical patient with intestinal obstruction and only 50% for any other patient undergoing RSI. This conflicts with deliberate practice principles which ought to be followed in order to achieve and maintain expert performance in RSI. A strong association of cricoid force use with decreasing national income could also be ascertained. Important variability was also found for patient positioning and nasogastric tube use. Such databases allow comparison with previously published data and can balance the discussion to the best available evidence, while determining what happens at the bedside.

As the volume of data continues to grow, its potential for elucidating this decade-long discussion seems to be growing. In critical decisional setting, we have growing evidence that many accidents occur because of human factors, including fixation errors and lack of effective communication. Therefore, we believe that gathering data assumes the other meaning of becoming a way to discuss our errors and to learn from them (promoting the no-blame culture) and to introduce not only technical but also non-technical aids to improve practice and patient safety.[23,24]

Conclusions

For decades, many different techniques have been investigated to decrease the incidence of pulmonary aspiration. Despite much research, many controversies regarding RSI exist. The three measures discussed (gastric ultrasound for pulmonary aspiration risk assessment, mathematical modelling, and global data collection through the exploitation of available social networking platforms) may aid us in improving the safety of airway management decision-making in the near future.

Conflict of interest

The authors declare no conflicts of interest.

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SYSTEMATIC REVIEW

Identification and economic burden of main adverse events of nerve injuries caused by regional anesthesia: a systematic review

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Complications;
Costs;
Nerve injury;
Regional anesthesia;
Complaints

Abstract
Background and objectives: Anesthesiologists and hospitals are increasingly confronted with costs associated with the complications of Peripheral Nerve Blocks (PNB) procedures. The objective of our study was to identify the incidence of the main adverse events associated with regional anesthesia, particularly during anesthetic PNB, and to evaluate the associated healthcare and social costs.
Methods: According to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, we conducted a systematic search on EMBASE and PubMed with the following search strategy: (''regional anesthesia'' OR ''nerve block'') AND (''complications'' OR ''nerve lesion'' OR ''nerve damage'' OR ''nerve injury''). Studies on patients undergoing a regional anesthesia procedure other than spinal or epidural were included. Targeted data of the selected studies were extracted and further analyzed.

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Results: Literature search revealed 487 articles, 21 of which met the criteria to be included in our analysis. Ten of them were included in the qualitative and 11 articles in the quantitative synthesis. The analysis of costs included data from four studies and 2,034 claims over 51,242 cases. The median claim consisted in 39,524 dollars in the United States and 22,750 pounds in the United Kingdom. The analysis of incidence included data from seven studies involving 424,169 patients with an overall estimated incidence of 137/10,000.
Conclusions: Despite limitations, we proposed a simple model of cost calculation. We found that, despite the relatively low incidence of adverse events following PNB, their associated costs were relevant and should be carefully considered by healthcare managers and decision makers.

Introduction

In the last decades, developed countries witnessed a significant increase in healthcare costs. At present, because of resources constraints, the financial sustainability of the health system has become of paramount importance. Such an increase in the relevance of economic criteria in decision-making processes, fosters the diffusion of economic assessments in the healthcare setting.[1–3] Cost analyses provide decision-makers with relevant information about resource consumption and trade-off between costs and outcomes associated with different health technologies.[4] The results of such analyses aim to reach rational approaches to introduce novel health technologies, particularly in rapidly evolving medical fields such as anesthesiology.[4] In fact, anesthesiology is a medical field that has been characterized by relevant technologic advances, thus allowing safe pain management[5,6] and enabling the implementation of innovative cost-effective treatment approaches.[7–9]

Therefore, even relatively small risks related to the anesthetic technique might result in substantial negative consequences both for healthcare providers and for universal healthcare systems that are striving to contain costs. Care providers are always more often confronted with the challenge of fostering their reputation in contexts of regulated competition where care quality and patient satisfaction are paramount factors.

In the field of regional anesthesia, and specifically in the context Peripheral Nerve Blocks (PNB), the local anesthetic is injected in close proximity to a nerve or a nerve plexus to achieve an anesthetic or analgesic block. This approach reduces the adverse effects related to general anesthesia but it is not exempt from severe complications[10,11] as a consequence of the injection in the wrong tissue, organ, or cavity.[12,13] For instance, inadvertent intravascular injection of local anesthetics can cause acute neuro- and cardiac toxicity, eventually leading to cardiac arrest.[14] Other complications might result from inadvertent intraneural injection and range from temporary to sustained or even permanent nerve damage. Minor nerve lesions may interfere with the patients' professional life and are associated with medicolegal controversies that raise concerns for both healthcare professionals and hospital administrations. On the other hand, major lesions are associated with loss of limb function, dysesthesia, paresthesia, and chronic pain syndromes, significantly influencing the patients' quality of life.[14–22]

The objective of our study was twofold. Firstly, we aimed at identifying and evaluating the incidence of the main adverse events associated with regional anesthesia, particularly during anesthetic PNB. Secondly, we evaluated the healthcare- and social associated costs of the aforementioned adverse events in order to assess their impact.

Methods

The present study was based on previously published studies and no ethical approval or informed consent were required.

Study identification and eligibility criteria

According to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA),[23] we conducted a systematic search on the electronic databases EMBASE and PubMed. We specifically implemented the following search strategy: (''regional anesthesia'' OR ''nerve block'') AND (''complications'' OR ''nerve lesion'' OR ''nerve damage'' OR ''nerve injury''). We limited the search to the time lapse between January 1st, 2007 and June 1st, 2020 (included). Language restrictions were set to English, Italian, and Spanish. We also included gray literature (i.e., material such as reports and newsletters published by reputable anesthesiologists' associations, fact sheets, etc.).

Two researchers independently filtered the retrieved results by reading titles and abstracts in order to identify publications on the topics of interest and apply specific eligibility and exclusion criteria. Eligibility criteria included randomized controlled trials, observational studies and reviews reporting on adult patients undergoing an operation intervention requiring regional anesthesia. We excluded studies that did not match the topic of interest, operations requiring neuraxial anesthesia (spinal or epidural anesthesia), sparse data regarding the outcomes of interest (incidence, costs, risk). Additional relevant studies were identified by snowballing the reference sections of the selected contributions and conducting manual search to include also pertinent, authoritative grey literature. Any disagreement between reviewers was resolved by discussion.

Data collection, validation, and analysis

Following PRISMA guidelines and Population, Intervention, Comparison and Outcome (PICO)[24] framework, the researchers independently extracted targeted data from the full-text versions of the selected studies. Relevant study characteristics including study type/design, sample size, primary anesthesia technique, incidence of injury, incidence of complications and adverse events were collected and further analyzed. Disagreements in data collection were discussed until consensus was reached. Ultimately, a third independent researcher verified the data extracted to solve discrepancies and check consistency. Data such as median reimbursement resulting from claims were extracted from each study and further analyzed.

Quantitative synthesis of the extracted data was performed through a pooled analysis in order to estimate the weighted average of nerve injury incidence according to the study sample size. In the occurrence of a lack of an explicit report of nerve injury incidence, it was calculated from percentage of the given total reported in the study.

Cost values comparability and measurement

When costs were expressed in different currencies and referred to different time periods, we adopted two standard approaches to make them comparable. We applied the trend of the Consumer Price Index to adjust monetary values (expressed in the preferred currency) coherently with the targeted period, while we applied the Purchasing Power Parities (PPPs, https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm) for the monetary values (expressed in the preferred time period) coherently with the target currency. Specific details were mentioned when applied to the actual values.

Since we adopted a societal perspective, we also considered the productivity losses associated with the PNB-related complications. In this respect, we applied the human capital approach and considered any initiative aimed to reduce PNB-related complications as an investment in a person's human capital placing per-capita income (based on OECD data – see Table 1) as monetary weights on healthy years of life.[25] Based on this monetary measure, we considered lifetime with disability as a productivity loss (up to 65-years age), regardless of the employment status, thus adopting a broad perspective of productivity as a measure of well-being (rather than strict economic welfare).[26–28] We reported productivity changes separately so that one can easily decide on whether or not include them for specific evaluation purposes.

Results

Literature search: included studies

Literature search from EMBASE and PubMed revealed 487 articles. Seventy-five duplicates were identified, and 386 further articles were excluded since they did not match the main topic. Fifteen articles were evaluated in full-text and the manual references screening resulted in the retrieval of 10 additional articles. Five articles were excluded since they did not match the topic and a total of 21 was included (Fig. 1). Ten of them[12–21] only served the purpose of shaping the introduction and discussion of our work, and therefore were included in the qualitative synthesis. Eleven articles[22,29–38] regarding incidence of PNB complications and claim costs were included in the quantitative synthesis.

The analysis of incidence was based on data derived from seven studies. The majority of such studies were multicentric and prospective, with a sample size ranging from 143 to 158,083 cases. As far as costs were concerned, the analysis was based on data from four studies concerning legal claims. In fact, the sole economic analyses in the literature on this topic were based on secondary data from litigation databases of Authorities or Corporative associations. Therefore, all the analyses were retrospective and regarded Anglo-Saxon geographic contexts, with sample sizes ranging from 4,183 to 40,165 cases (Table 2).

Main adverse events associated with regional anesthesia

Among studies focusing on or including PNB, complications were not uniformly classified. In general, we noticed that the studies used a combination of clinical (e.g., seizure, nerve lesion) and overall health effects (e.g., peripheral neuropathy, abscess); sometimes the terms employed were rather generic (e.g., severe neurologic complications) or not strictly related to nerve injury (e.g., infection, pneumonia). This undermined our attempts of assessing the impact of complications in economic terms based on incidence data.

Incidence of the main adverse events associated with PNB

Overall, the incidence of peripheral nerve injury related to PNB performed in the perioperative setting ranged from 3.5 to 5.0/10,000 (Table 3); the mean value resulting from the pooled data was 4.0/10,000 cases. Whiting PS et al.[38] and Capdevila X et al.[35] reported significantly higher incidence values but these two studies, which focused on orthopedic surgery, included a wider range of complications than the other studies, thus not always allowing to identify complications specifically related to nerve injuries. In their systematic review, Kessler J et al.,[15] with their analysis that included large studies such as Rohrbaugh M et al.[39] and Sviggum HP et al.,[21] reported a comparable incidence of complications after interscalene blockade in shoulder surgery.

There were significant differences in terms of surgical interventions and the anesthetic technique applied. In addition, it is important to consider that the incidence varies according to: the proximity of the investigator's look (the closer, the higher the rate of complications), the study design (retrospective vs. prospective) and the timing of the follow-up, as symptoms of nerve injury may not become clinically apparent before several weeks postoperatively.[14,17] These aspects were not evident, except for the distinction between retrospective and prospective studies.

Table 1 Estimates of variables involved in productivity losses estimation (2017).

Context	Life expectancy at birth (years)	Annual income per capita (USD)	
	- a -	- b -	- c -
Euro area	82	na	na
United Kingdom	81	40,530	43,732
United States of America	79	58,270	60,558

Sources: (a) The World Bank (https://data.worldbank.org), (b) WorldData.info (www.worlddata.info), (c) OECD (https://data.oecd.org). USD, United States Dollars.

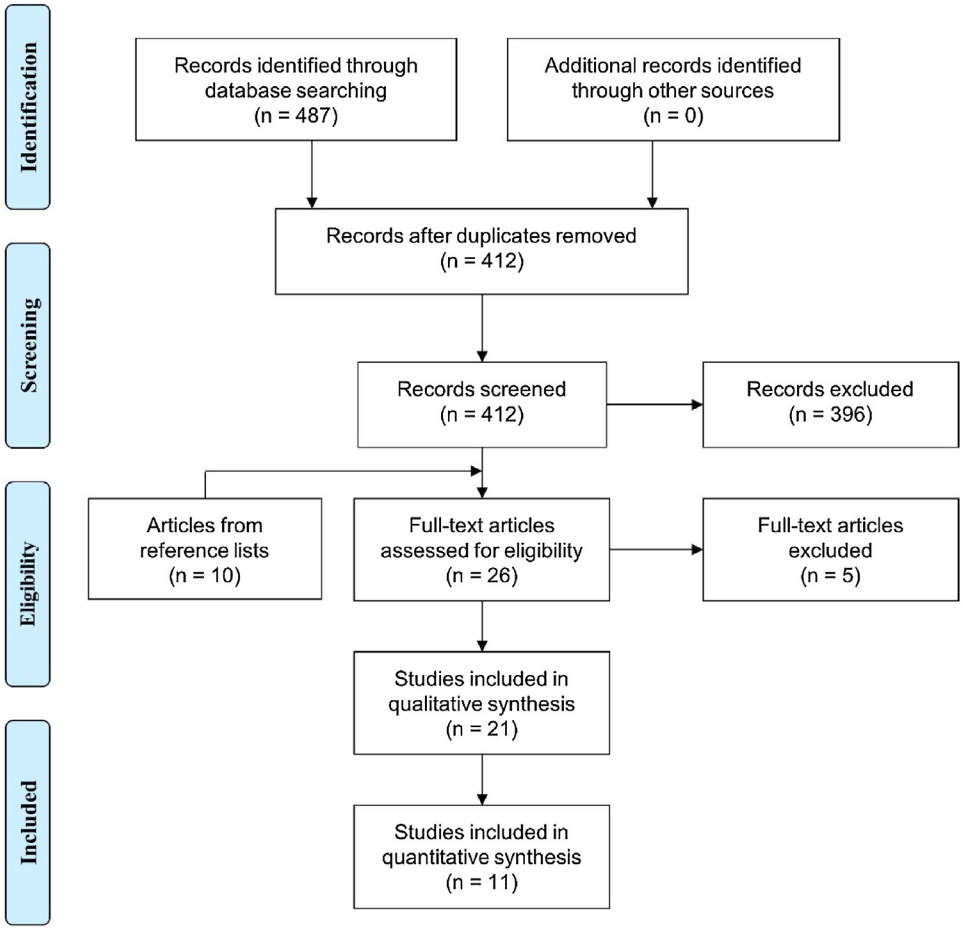

Figure 1 Flow chart of the literature search according to PRISMA Guidelines.

Costs of adverse events associated with PNB

There were a few studies that quantified the economic impact of the complications associated with regional anesthesia and more specifically with PNB. The source of economic information regarding such topic were analyses of medico-legal claims related to anesthesia. These studies focused on two Anglo-Saxon geographic contexts: The United Kingdom and the United States of America (Table 2). According to the data extracted from these studies, the median reimbursement resulting from closed claims was rather different according to the Country involved. Lee et al.[30] and Szypula et al.[22] were the most similar in terms of the anesthetic technique applied. However, while Lee et al.[30] referred specifically to payments associated with claims related to PNB, Szypula et al.[22] referred to regional anesthesia.

Based on the data of the aforementioned two studies, the median cost of a claim associated with PNB ranged between 58,800 USD and 75,000 £ (95,045 USD) with the former value based on prices of 1999 and the latter based on prices of 2006. Using the trend of the Consumer Price Index in the time period between 1999 and 2006 (www.bls.gov/data/), the adjusted value of the US-based median was 85,350 USD; while using the Purchasing Power Parities, the UK-based value was 107,585 USD. We preferred to maintain the value adjusted to the year 2006 in order to avoid excessive correction errors and maintain a conservative approach in our

Table 2 Costs associated with Regional Anesthesia/Nerve injury.

Author/s (year)	Context	Source	Data collection type	Period	Object of study	Sample size	Cost information
Cheney FW et al.[29] (1999)	United States	ASA Closed Claim Project	Retrospective	1990–1998	Nerve damage by surgical or anesthesia instrument (perioperative nerve injury)	670 (over 4,183) claims	All nerve injury median claim: USD 35,000
Lee LA et al.[30] (2008)	United States	ASA Closed Claim Project	Retrospective	1980–2000	Eye blocks and Peripheral nerve blocks (PNB) for surgical anesthesia claims	218 (over 6,894) claims	PNB median claim: USD 58,800 Eye block median claim: USD 126,900
Cook TM et al.[31] (2009)	United Kingdom	National Health Service Litigation Authority (NHSLA) claims dataset	Retrospective	1995–2007	Financial impact of anesthesia-related claims	841 (over 40,165) claims	Regional anesthesia median claim: £ 4,000 Positioning median claim: £ 8,000
Szypula K et al.[22] (2010)	United Kingdom	National Health Service Litigation Authority (NHSLA) claims dataset	Retrospective	1995–2007	Financial impact of regional anesthesia-related claims	366 (over 40,165) claims	CSE median claim: £ 82,000 Eye median claim: £ 24,000 Upper limb median claim: £ 500 Lower limb median claim: £ 6,000

Costs are expressed in United States Dollar (USD) or United Kingdom Pounds (£).

Table 3 Incidence of complications associated to peripheral nerve blocks.

Author (year)	Period	Context	Multicenter	Study type	Sample size	Interventio/block type	Complications	Incidence
Auroy Y et al.[32] (2002)	1998–1999	France	Yes	Prospective	79,979	Interscalene block (3,459)	Peripheral neuropathy	2.9/10,000
						Supraclavicular block (1,899)	Seizures	5.3/10,000
						Axillary plexus	Seizures	0.9/10,000
						block (11,024)	Peripheral neuropathy	1.8/10,000
						Midhumeral	Seizures	1.4/10,000
						block (7,402)	Peripheral neuropathy	1.4/10,000
					158,083	Overall regional blocks	Severe neurologic complications	0.35/10,000
Barrington MJ et al.[33] (2009)	2006–2008	Australia	Yes	Prospective	6,069	Overall	Block-related nerve injury	4/10,000
							Systemic local anesthetic toxicity	9.8/10,000
Belavic M et al.[34] (2013)	2012	Croatia	No	Prospective	143	Overall	Block-related nerve injury	5/10,000
Capdevila X et al.[35] (2005)	2000	France	Yes (8 university hospitals)	Prospective	1'416	Orthopedic	Nerve lesions	44/10,000
						surgery /Femoral	Abscess	15/10,000
						Orthopedic surgery/Interscalene	Acute respiratory failure	78/10,000
						Orthopedic surgery/Interscalene	Laryngeal and recurrent laryngeal nerve paralysis	78/10,000
						Orthopedic surgery/PCB	Severe hypotension	1,500/10,000
						Orthopedic surgery/Distal	Systemic local anesthetic toxicity	263/10,000
						Orthopedic surgery/Axillary	Seizure	79/10,000
Huo T et al.[36] (2016)	2009–2011	China	Yes (11 teaching hospitals)	Prospective	106,596	Overall	Major regional anesthesia complications	3.47/10,000
						Orthopedics surgery (n = 31,097)	Horner syndrome (n = 5), Seizure (n = 1), Hematoma (n = 1)	2.3/10,000
						Urology surgery (n = 16,769)	Seizure (n = 1), Paraplegia (n = 1)	1.2/10,000

Table 3 (*Continued*)

Author (year)	Period	Context	Multicenter	Study type	Sample size	Interventio/block type	Complications	Incidence
						General surgery (n = 17,907)	Horner syndrome (n = 4), Recurrent laryngeal nerve block (n = 5), Extensive neuraxial block (n = 5), Seizure (n = 3), Cauda equina syndrome (n = 1), Hematoma (n = 1), Cardiac arrest (n = 1)	11.2/10,000
						Vascular surgery (n = 1,246)	Recurrent laryngeal nerve block (n = 1)	8.0/10,000
						Plastic surgery (n = 1,579)	Extensive neuraxial block (n = 3)	19/10,000
Saied NN et al.[37] (2017)	2005–2011	USA	Yes (300 community and academicals centers)	Retrospective	64,119	General surgery, vascular surgery, orthopedic surgery and genitourinary surgery	Peripheral nerve injury	4/10,000
							Intraoperative c-reactive protein or death	4/10,000
Whiting PS et al.[38] (2015)	2005–2011	USA, Saudi Arabia, Canada, Lebanon, United Kingdom, United Arab Emirates	Yes (462 hospitals in USA and 34 in the other countries)	Prospective	7,764	Hip fracture surgery (111 of PNB within the original ample)	Minor complications (wound dehiscence, superficial wound infection, pneumonia, and urinary tract infection)	721/10,000
							Major complication (deep wound infection, organ space infection, myocardial infarction, pulmonary embolism, deep venous thrombosis, cerebrovascular accident, postoperative neurological deficit, sepsis, septic shock, coma, and death within 30 postoperative days)	810/10,000
							Overall complications	126/10,000

PNB, Peripheral Nerve Blocks; USA, United States of America.

evaluation. Despite being an objective type of information, it has two main limitations: (a) it tends to provide an evaluation perspective limited to the hospital; (b) even assuming that a claim closed in favor of a patient is a solid criterion to discriminate between a real complication associated with PNB and an economically irrelevant issue, this information does not include the costs connected to those who suffered a complication but did not issue a claim.

The first limitation could be overcome, for instance, by acquiring information about the health outcomes (or at least prognoses) associated with the reported incidence of complications. On the other hand, in the absence of such data, the pragmatic assumption that a claim payment includes the relevant social costs associated with a case of complications should be made in this way, the median cost of a claim becomes a satisfactory parameter in the single case in study. We could overcome the second limitation by projecting the median cost to the population of subjects that are likely to be affected by the complications taken into account in the study. The information on the incidence could be used to estimate this population, while the proportion of closed claims – that ranged from 51% and 53.5% according to Szypula K et al.[22] and Lee et al.[30] – was a candidate parameter to discriminate between relevant (i.e., block-related and economically significant) and irrelevant adverse events.

Therefore, knowing the volume of interventions adopting PNB (V), one could evaluate the costs of its complications by combining the following information:

$$\text{Evaluation of costs in USD} = V * [0.035\%; 0.05\%] * 53\% * [85,350; 107,585] = V * [15.8; 28.5] \quad (1)$$

$$\text{Evaluation of costs in Euro} = V * [0.035\%; 0.05\%] * 53\% * [70,640; 89,040] = V * [13.1; 23.6] \quad (2)$$

We assumed 53% as the proportion of relevant adverse events and the found range of incidence of adverse events associated with nerve injuries due to PNB (from 0.35% to 0.05%) when considering any type of intervention. As far as ''V'' is concerned, we could not find a reliable estimate. Therefore, we maintained it as a variable. More specifically, the first equation suggests that the ''hidden costs'' (i.e., associated with likely complications) for each PNB performed ranged between 15.8 and 28.5 USD.

If one considers that the strength of the previous pragmatic assumption (i.e., the hypothesis that a claim payment includes the relevant social costs associated with a PNB-related complication), an alternative approach consists of assessing productivity losses. In this respect, Lee et al.[30] analyzed the American Society of Anesthesiologists (ASA) Closed Claims database in the period between 1990 and 2010 (overall 8,954 claims) and identified 189 patients who received PNBs in the setting of urgent surgery and with a mean age to 47 ± 14 years. They reported 31 claims related to nerve injuries (16.4%) resulting in permanent and/or disabling damage, while claims related to death (20) or brain damage (10) were the consequence of multiple damaging events, whose etiologies were sometimes difficult to ascertain or track. We could consider this information as a reliable basis to evaluate the productivity losses deriving from permanent disability associated with nerve lesions plausibly caused by PNBs. As further reported in the methods section, we could assume the Average Annual Income per capita (AAI) as a measure of the productivity loss for each year in which the subject could not work (due to the permanent disability) and the difference between the expected productive life (EPL, assuming that an individual is productive up to 65-years of age) and the average age of the sample of Lee et al.[30] as a measure of the years lived.

$$\text{Evaluation of Productivity losses} = V * [0.035\%; 0.05\%] * 53\% * 16.4\% * (\text{EPL}-\text{AGE}) * \text{AAI} = V * [0.003\%; 0.004\%] * (\text{EPL}-47) * \text{AAI}$$

Based on recent estimates shown in Table 1, EPL could be considered equal to 65 (since life expectancy is above this threshold) and AAI considered the OECD value. For instance, in the USA the evaluation of productivity losses results was achieved through the following equation:

$$\text{Evaluation of Productivity losses (inUSA) in USD} = V * [0.003\%; 0.004\%] * (65-47) * 60,558 = V * [32.70; 43.60] \quad (3)$$

This approach suggested that that the ''hidden costs'' (i.e., associated with likely complications) for each PNB performed ranged between 32.7 and 43.6 USD. If also the variability in terms of AGE (as reported by Lee et al.[30] ±14 years) were included in the evaluation, the range broadened between 7.3 and 65.4 USD.

The two evaluation approaches described above suggested relevant costs associated with the phenomenon in study according to the different perspectives assumed. Although the aforementioned hidden costs may appear relatively low, the overall yearly expenditure could be significant for both the hospital and the community.

Discussion

In our systematic review, 21 articles were included in the qualitative synthesis and eleven of them were considered eligible to perform the quantitative synthesis. The pooled analysis of costs included data from 2,034 claims over 51,242 cases with a median claim of 39,524 USD. The overall estimated incidence of complications was 137 in 10,000 patients.

Nerve injury after regional anesthesia is regarded as a major complication and, when the damage is severe, may take weeks or even months to recover completely.[12] One causative factor involves direct intraneural injection of local anesthetics. However, Bigeleisen P et al.[13] challenged such concept by showing that intraneural injection is not invariably damaging. Nevertheless, if intraneural injection is not sufficient factor in the development of nerve injury, it is hard to challenge the idea that it is a serious risk factor, especially when the injection needle reaches the perineurium.

Although several studies have been performed that analyze the etiology and physiology of this issue (together with techniques aiming at reducing its risk), the extant literature showed a paucity of contributions assessing the incidence of complications associated with regional anesthesia, particularly PNB.

It should be noted that the scientific literature on this topic seems to have thrived in recent years. This may be interpreted as an indicator of the growing interest in analyzing this topic from a quantitative perspective. The reported estimates showed a variability that is mainly linked to the type of intervention performed and study design, though there is a convergence toward a representative general value and, in general, reported data indicate a low rate of occurrence.

The fact that regional anesthesia has become routine practice for surgical procedures[22] calls for more thorough analyses of the real costs. Basically, neurologic adverse events caused by PNB may affect patient satisfaction – and the hospital reputation – regardless of quality of the surgical procedure for which PNB was performed. Moreover, the more frequently PNB is performed, the higher the incidence also of infrequent events that may become relevant for both anesthesiologists and hospital managers.

We found that health outcomes associated with complications are reported in a heterogeneous way. Sometimes the authors report their clinical effects, while other authors refer to health outcomes; in fact, the terms used are frequently rather generic. This jeopardizes an effective comparison of the results among different studies and hampers a straightforward interpretation of the reported results, whose aim is to match economic and clinical information. In this respect, the economic assessment would greatly benefit from standardized reporting strategies based on health outcomes that can reliably be linked to complications with definite economic values. For instance, Sawyer RJ et al.[19] proposed an interesting prognosis-based classification to assess the health outcomes of peripheral nerve injuries. However, data from the available incidence studies do not allow a correlation to such classification. The current scientific literature concerning the economic impact of complications associated with regional anesthesia (particularly PNB) is even poorer; in fact, the very few studies available are based on secondary data regarding legal claims in two Anglo-Saxon countries. Based on the available evidence, we tried to demonstrate that this phenomenon is not economically negligible, despite its relatively low rate of occurrence.

Limitations

Several authors have previously stressed the difficulty in estimating the incidence of adverse events associated with anesthesia because of the heterogeneity and quality of the literature on this topic.[16,18] Therefore, we are aware that – despite our focus on rigorous studies and the conservative hypotheses adopted – results must be interpreted with caution.

It is important to emphasize two major aspects regarding peripheral nerve complications caused by PNB. Firstly, they represent an infrequent phenomenon and therefore, its sampling is prone to error due to either the clustering phenomenon or its opposite (i.e., sampling interval without events).[10] Secondly, the etiology of Perioperative Peripheral Nerve Injuries (PPNI) is complicated by several factors beyond the mere anesthetic injection (e.g., diseases affecting the microvasculature of nerves, poor perioperative positioning). Moreover, the clinical manifestations of PPNI may only become apparent before 48-h post-operatively and this may cast doubt on the cause of the injury.[16]

The four studies included reporting on claims did not explicit specify who was charged for the claims. However, one can assume that hospitals were primarily involved, but a characteristic of such costs is that they spread indirectly on healthcare systems and society in general. Therefore, we tried to address this limitation by assessing the socioeconomic burden of PNB-related complications resulting in permanent and/or disabling injuries including productivity loss. We could not discern the level of disability, but the approach considers only one type of reported complication and results are likely to be conservative.

It is important to acknowledge that out of 11 studies, only 4 reported on costs and the remaining seven studies addressed nerve injury incidence. Thus, the present analysis used data from two sub-samples of studies for two different objectives. A further study limitation is the unfeasibility to generate an accurate risk of bias assessment and a plotted analysis; therefore, results should be considered merely descriptive. Moreover, an analysis of the risk of bias among studies and the publication bias would only play a marginal role, as evidence were not assessable.

Summary

Anesthesiologists and hospitals have nowadays to be confronted with the costs associated with complications belonging to misplaced injection of local anesthetics during PNB. We analyzed the extant literature in order to identify the main adverse events associated with PNB, in order to establish a reasonable estimate of their incidence and a model of the costs due to such complications.

Our results support the thesis that, although the rate of adverse events appeared to be relatively low, their associated costs were unneglectable, especially considering the large volume of PNBs performed and the growing role of anesthesiology in supporting innovative surgical techniques. Provided some limitations inherent to the data and based on some necessary hypotheses, we proposed a model of the costs associated with adverse events due to PNBs. From a strict hospital perspective, each PNB performed is associated with hidden costs ranging from approximately 18 to 23 USD (or 15 to 18 Euro). In terms of productivity losses, each PNB performed is associated with about 68 USD. Though the two evaluation approaches may overlap, they are also based on rather conservative hypotheses. Therefore, preliminary results show that such costs are relevant and should be carefully considered by healthcare managers and decision makers.

Despite the limitations of our study, we believe that our results help shed light on a matter that could prove profoundly relevant for healthcare systems which are striving

to contain expenditures while at the same time trying to ensure universal access to healthcare.

Ethics approval and consent to participate

This study consider data already published, therefore, no institutional review board approval or consent to participate were required.

Availability of data and materials

The dataset analysed during the current study is available from the corresponding author on request.

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Conflicts of interest

The authors declare no conflicts of interest.

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SYSTEMATIC REVIEW

Perioperative costs of local or regional anesthesia *versus* general anesthesia in the outpatient setting: a systematic review of recent literature

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Abstract
Background and objectives: In this systematic review, we carried out an assessment of perioperative costs of local or regional anesthesia *versus* general anesthesia in the ambulatory setting.
Methods: A systematic literature search was conducted to find relevant data on costs and cost-effectiveness analyses of anesthesia regimens in outpatients, regardless of the medical procedure they underwent. The hypothesis was that local or regional anesthesia has a lower economic impact on hospital costs in the outpatient setting. The primary outcome was the average total cost of anesthesia calculated on perioperative costs (drugs, staff, resources used).
Results: One-thousand-six-hundred-ninety-eight records were retrieved, and 28 articles including 27,581 patients were selected after reviewing the articles. Data on the average total costs of anesthesia and other secondary outcomes (anesthesia time, recovery time, time to home readiness, hospital stay time, complications) were retrieved. Taken together, these findings indicated that local or regional anesthesia is associated with lower average total hospital costs than general anesthesia when performed in the ambulatory setting. Reductions in operating room time and postanesthesia recovery time and a lower hospital stay time may account for this result.

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Conclusions: Despite the limitations of this systematic review, mainly the heterogeneity of the studies and the lack of cost-effectiveness analysis, the economic impact of the anesthesia regimes on healthcare costs appears to be relevant and should be further evaluated.

Introduction

In recent decades, industrialized countries have witnessed a significant increase in medical care costs.[1] In the current times of resource constraints, the financial sustainability of healthcare systems has become of paramount importance. This increased the relevance of economic criteria in decision-making processes, thus fostering the diffusion of economic evaluations in healthcare.

With regard to surgery, the majority of overall costs are represented by fixed costs and are highly dependent on hospitalization and the length of stay.[2] Incentives toward a leaner and cheaper perioperative process have led to a continuous increase in ambulatory surgery over recent years.[3] However, the assumption that ambulatory surgery is always cheaper than inpatient surgery is not always true: the outpatient perioperative process should be well conceived and optimized to minimize its own fixed costs, as inefficiencies are multiplied by a high turnover.[4]

The main factors affecting ambulatory surgery process fixed costs are the operating room time, the occupancy of the postoperative care unit and the time to discharge. Indeed, the cost-effectiveness of the outpatient perioperative process depends on its ability to optimize these most labor-intensive and resource-consuming phases.[5]

Regional anesthesia has been increasingly employed in the outpatient setting, given its unique characteristics of selectivity and efficacy in the control of acute postoperative pain. Outpatient regional anesthesia economic externalities have been investigated by some studies, which have associated its systematic adoption with a decrease in anesthesia-controlled operating room time and thus in the operating room fixed costs, potentially translating into a significant increase in patient turnover and ultimately hospital revenues.[5,6] Moreover, regional anesthesia is associated with a very high postoperative care unit bypass rate and with a lower incidence of postoperative anesthesia-related side effects, such as nausea and vomiting, excessive sedation and dizziness, which, in the ambulatory setting, may significantly prolong the day-hospital length of stay, jeopardize the meeting of discharge criteria or even cause unscheduled hospital readmissions.[5,6]

On the other hand, the recent evolution of general anesthesia techniques has led some to challenge a supposed superiority of regional anesthesia techniques in the outpatient setting with regard to their safety and side-effect profile. The extensive use of laryngeal masks and anesthetic drugs with a more favorable pharmacokinetic profile has actually led to a reduction in the incidence of postoperative complications, an increase in the postanesthesia care unit (PACU) bypass rate and a potential reduction in the average anesthesia-controlled operating room time.[7] If, following these recent developments, a difference in cost-effectiveness between the two anesthesia regimens still persists, it is not clear.

Despite the importance of the topic for the future development of our profession, in a context where ambulatory surgery is continuously growing and has been estimated to account for the vast majority of all surgical procedures in the near future,[1] a systematic review of all the contrasting evidence on this theme is still lacking.

The aim of this work is to provide a systematic review of the recent literature to test the hypothesis that the use of local or regional anesthesia is associated with significantly lower average total hospital costs than general anesthesia when applied in the ambulatory setting.

Methods

Search strategy

A literature search of the electronic PubMed/MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, and Google Scholar databases was carried out to find relevant data on the costs or cost-effectiveness of general and local or regional anesthesia performed in an ambulatory setting. The primary outcome was the average total cost of anesthesia. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were applied in carrying out this systematic review.[8]

The search algorithm was based on the clinicoeconomic question coded into the PICO framework and constructed combining a set of terms referring to outpatient setting (Patient), regional anesthesia (Intervention), general anesthesia (Comparator), cost or cost-effectiveness analysis (Outcome). To formulate the best query for the literature search, many attempts were made to be sure to include all terms relevant for our clinico-economic question. The final search query was ((outpatient*) OR (out-patient*) OR (ambulatory) OR (day-surgery) OR (day surgery) OR (day-case) OR (day case)) AND ((anaesthesia) OR (anesthesia) OR (anaesthetic*) OR (anesthetic*)) AND (general) AND ((block*) OR (local) OR (regional) OR (loco-regional) OR (locoregional) OR (nerve) OR (spinal) OR (epidural)) AND ((cost-effective) OR (cost*) OR (cost-efficacy) OR (cost-effectiveness) OR (cost-utility) OR (economic*)).

The last literature search was performed on 10th May 2021 in all databases. No specific study design was defined. Search was without language restriction. Reference lists of the retrieved articles were also screened for additional data.

Eligibility criteria

Studies were included in the systematic review when they met each of the following inclusion criteria: a) original article published in peer-reviewed journal; b) the study includes adults only; c) the study compares regional and general anesthesia in outpatient setting; d) the study reports data on cost or cost-effectiveness analysis. Anesthesia was considered general anesthesia whenever loss of consciousness was achieved, and arousal was not achievable at verbal command. With regional anesthesia was meant any technique aimed at achieving a reversible loss of sensation of a limb or a body area through the administration of a local anesthetic in close proximity of a peripheral nerve, a plexus or the spinal nerve roots or the spinal cord. Local anesthesia was considered a reversible loss of sensation of a body wall area achieved through the infiltration of a local anesthetic directly into tissues. An outpatient setting was defined as a surgery or medical treatment for which the patient was discharged the same day (less than 24 hours) regardless of whether it required or not to occupy a hospital bed. The average total cost of anesthesia per case encompassed the perioperative costs of drugs, staff labor and resources used. Readmissions and complications were excluded from the cost calculation.

The exclusion criteria were a) articles not within the field of interest of this review (for example, medical procedures not in ambulatory setting); b) review articles, letters, or editorials; c) case reports or case series (less than 10 patients included); and d) articles published prior to 2000 to restrict the search to the recent literature to retrieve updated costs.

Study selection

Titles and abstracts of the retrieved records were independently reviewed by three researchers (MP, GT, FM) applying the inclusion and exclusion criteria mentioned above. Full texts of the selected articles were retrieved and read to determine their eligibility for inclusion. Any disagreement between authors was resolved by discussion.

Quality assessment

The quality of the studies included in the systematic review was critically assessed using the Consensus on Health Economic Criteria (CHEC) list.[9] The assessment tool had 19 indicators, and each indicator was assessed for every study using yes or no depending on whether the required information was reported. The quality assessment was performed by two independent authors; any disagreement between the authors was resolved in a consensus meeting.

Data extraction and analysis

For each included study, two authors (MP, FM) extracted information concerning basic data (authors, year of publication, country of origin, type of study, medical procedure, number of patients, mean age, gender), methods (type of anesthesia, anesthetic drug), and outcomes (average total costs and main findings regarding the cost analysis). Another author checked all extracted data independently (GT). During data extraction from the selected studies, the following secondary outcomes were judged interesting for the topic and were also included: anesthesia time, recovery time, time to home readiness, hospital stay time, and complications.

All currencies of the included studies were converted to United States dollars (USD) according to CCEMG – EPPI-Centre Cost Converter v.1.6 (last update: 29th March 2021, http://eppi.ioe.ac.uk/costconversion/default.aspx).

Results

Literature search

The literature search from the PubMed/MEDLINE, Cochrane CENTRAL, Web of Science, and Google Scholar databases yielded a total of 1,698 records. After reviewing titles and abstracts and excluding those published prior to 2000 and not related to the clinicoeconomic question, 91 articles were selected. The full text was retrieved for all. Following the eligibility assessment, 63 articles did not meet the inclusion criteria and were excluded from the systematic review. Of these, 23 were excluded because not in the outpatient setting, 17 were reviews, surveys, or abstracts, 16 did not include data on costs, 6 reported sparse data on different anesthesia types and medica procedures and 1 article was a case report. Manual searches of the reference lists of the selected articles did not yield any additional records. Finally, 28 studies including 27,581 patients were identified as potentially relevant and were selected for the systematic review.[10–37] All of the included studies were published in English. These studies covered the period from January 2000 to May 2021. Search results and article selection are displayed in a PRISMA flow chart (Fig. 1).

Selected studies

The characteristics of the selected studies are reported in Table 1. They were conducted in various countries across the world (Europe, North America, Oceania, Africa). The sample size of the included studies ranged from 20 to 14,713 adults who underwent various medical procedures under general and local or regional anesthesia in an outpatient setting. General anesthesia was compared to local anesthesia in 15 studies,[10,13,14,16–24,27,30,33] to spinal anesthesia in 7 studies,[12,15,25,31,32,34,35] and to both in 5 studies.[26,28,29,36,37] Medical procedures were different and included laryngoplasty, knee arthroscopy, biopsy, hernia repair, hysteroscopy, and others. Studies were included irrespective of the induction method of anesthesia (inhalation, infusion, topical). Regional anesthetic techniques encompassed axillary brachial plexus block,[33] ilioinguinal-hypogratric[37] or paracervical[18] or peripheral[24] or sciatic-femoral[23,28,30] nerve block, and epidural[26] or spinal[15,25,28,29,31,32,34–37] or intravenous regional[33] anesthesia. Thirteen studies were randomized controlled trials,[12,22,23,25,26,28–32,34,36,37] 2 of which were double-blinded,[23,25] and 15 were observational with a prospective[16,27,33] or a retrospective[10,11,13–15,17–21,24,35] design. The overall quality of the included studies was assessed with the CHEC list (Appendix A). None of the stud-

Table 1 Included studies comparing costs of general and local or regional anesthesia regimen for different outpatient medical procedures in an outpatient setting.

Authors	Year	Country	Study design	Medical procedure	Number of patients evaluated	Mean age (years)	% Male
Li et al.[10]	2020	USA	Retrospective, observational	Anterior shoulder stabilization surgery	7,103	NR	69.4
Bokshan et al.[11]	2019	USA	Retrospective analysis	Anterior Cruciate Ligament Reconstruction	14,713	<20 years: 30.4% 20—29 years: 27.6% 30—39 years: 19.1% >40 years: 22.9%	59.3
Gebhardt et al.[12]	2018	Germany	Prospective, RCT	Knee arthroscopy	50	48.5	64
Hamilton et al.[13]	2018	Canada	Retrospective cohort study	Shoulder surgery	1,623	50.5	66.7
Chandran et al.[14],[a]	2018	Australia	Retrospective, observational	Injection laryngoplasty	20	63.08	70
Camponovo et al.[15]	2014	Switzerland	Retrospective, observational	Knee arthroscopy	56	50	55.3
Penketh et al.[16],[b]	2014	Canada	Prospective,[c] comparative, observational	Hysteroscopy	118[d]	56.7[d]	–
Sivalingam et al.[17]	2013	USA	Retrospective, observational	Ureteral stent placement for obstructing stones	119	53.11	44.54
Ahonkallio et al.[18],[e]	2012	Finland	Retrospective, observational	Endometrial thermal ablation with Novasure	36	NR	–
Covarelli et al.[19],[a]	2012	Italy	Retrospective, observational	Sentinel lymphnodes biopsy	153	50	52
Stoffels, et al.[20]	2011	Germany	Retrospective, observational	Sentinel lymphnodes excision	300	57.7	60.7
Mitchell et al.[21],[a]	2011	UK	Retrospective, observational	Sacral nerve stimulation	111	56.68	3.33
Kushawaha et al.[22]	2008	United Kingdom	Prospective, RCT	Open hemorrhoidectomy	41	52.68	60.97
Mostafa et al.[23]	2008	Egypt	Prospective, Double, blind, RCT	Knee arthroscopy	60	48.33	41.67
Horn et al.[24],[a]	2007	USA	Retrospective, observational	Upper extremity surgical procedures	213	41.59	55.39

Table 1 (*Continued*)

Authors	Year	Country	Study design	Medical procedure	Number of patients evaluated	Mean age (years)	% Male
Nishikawa et al.[25]	2007	Japan	Prospective, Double, blind, RCT	Prostate biopsy	80	72	–
Nordin et al.[26],[a]	2007	Sweden	Prospective, multicenter RCT	Inguinal hernia repair	616	56	98
Spanknebel et al.[27]	2006	USA	Prospective, observational	Thyroidectomy	1,194	49.57	41.09
Casati et al.[28]	2004	Italy	Prospective, RCT	Knee arthroscopy	120	43.5	54.2
Forssblad et al.[29]	2004	Sweden	Prospective, RCT	Knee arthroscopy	343	NR	NR
Casati et al.[30]	2002	Italy	Prospective, RCT	Knee arthroscopy	40	48.5	60
Danelli et al.[31]	2002	Italy	Prospective, RCT	Hysteroscopic ablation of endometrial neoplasm	40	52.50	–
Lennox et al.[32]	2002	Canada	Prospective, RCT	Gynecologycal laparoscopy	20	34.5	–
Chan et al.[33]	2001	Canada	Prospective, observational	Hand surgery	126	39.67	62.7
Martikainen et al.[34]	2001	Finland	Prospective, RCT	Knee arthroscopy	60	40.3	55
Chilvers et al.[35]	2000	Canada	Retrospective, comparative	Gynecologycal laparoscopic sterilisation	52	34.46	–
Li et al.[36]	2000	USA	Prospective, RCT	Anorectal surgery	93	41.33	72.04
Song et al.[37]	2000	USA	Prospective, RCT	Unilateral inguinal herniorrhaphy	81	39	86.42

NR, not reported; RCT, randomized controlled trial.
[a] Day-case setting.
[b] Day-case setting in the operating room for general and local anesthesia, outpatient setting for local anesthesia.
[c] Cost analysis is retrospective.
[d] Refers only to group of patients underwent local anesthesia in outpatient setting.
[e] Day-case setting for general anesthesia and outpatient setting for paracervical block.

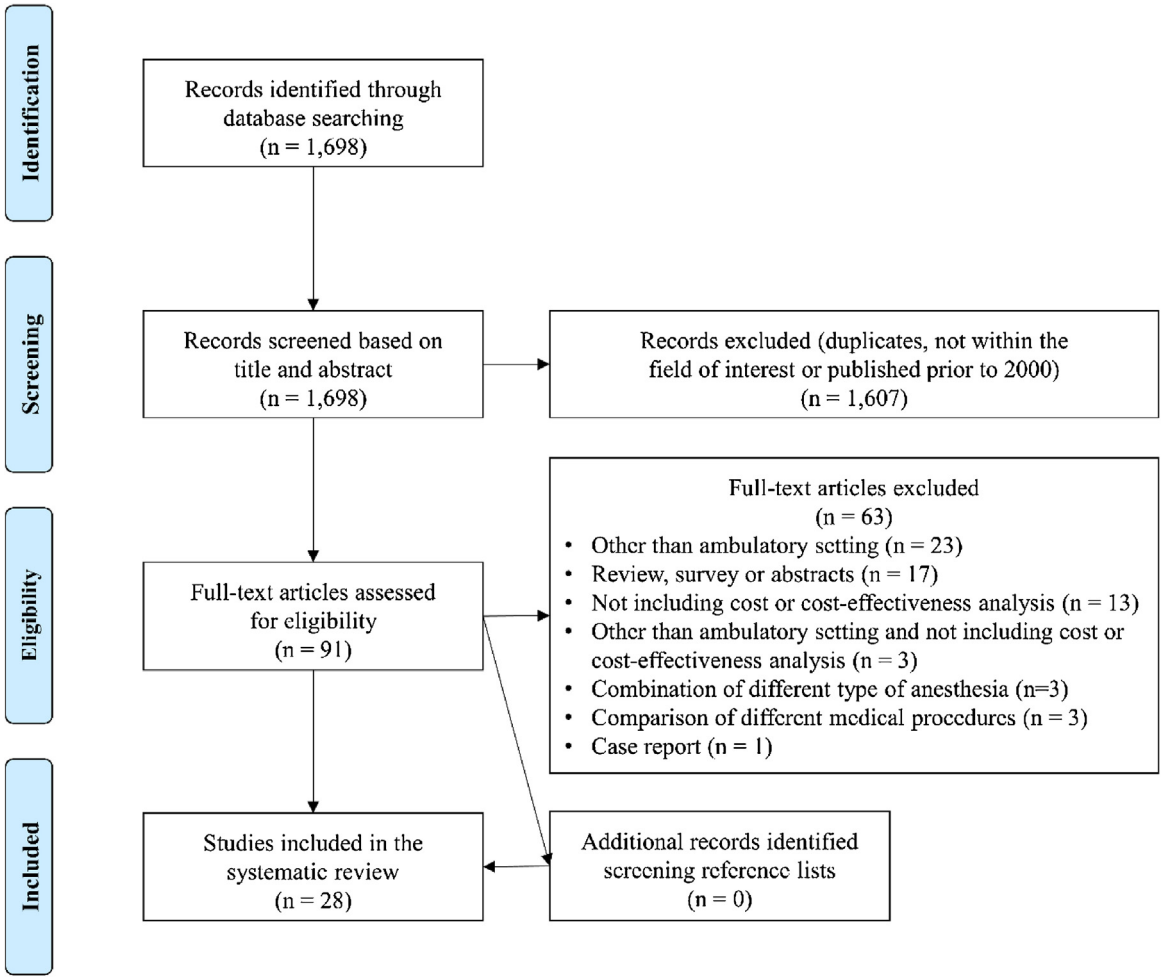

Figure 1 PRISMA flow chart of the retrieved, excluded and analyzed studies.

ies satisfied at least 80% of the CHEC list criteria, and 11 studies met less than 50% of the criteria. Thus, overall, the methodological quality was judged to be moderate.

Cost analysis

The main findings of the cost analysis are summarized in Table 2. The average total cost of anesthesia per case encompassed the perioperative costs of drugs, staff labor and resources used, except four studies that also included the cost of room management.[19,22] Readmissions and complications were excluded from the cost calculation. Ten studies[10,11,14,16–18,21,24,26,27] not reporting the average total costs of anesthesia were also included, as they compared the average total costs of the entire medical procedure on the basis of the costs of the anesthetic regimen used. None of the selected studies reported data on cost-effectiveness analysis. Regardless of the medical procedure, the total costs were significantly higher for general anesthesia than local[14,16,17,19–22,27] or regional[11,12,15,18,24,25,28,32–34,37] anesthetic techniques in almost all included studies, other than five studies that reported no statistically significant difference between loco-regional and general anesthesia.[13,23,30,31,35] Only one study reported higher costs in patients who received the loco-regional anesthesia.[10] Furthermore, three studies comparing all three types of anesthesia[26,29,36] confirmed the lowest costs for medical procedures under local anesthesia and similar costs between general and spinal or epidural anesthesia,[26,29] except one showing higher costs under general anesthesia.[36] Major cost savings for medical procedures under local anesthesia were reported for ureteral stent placement (74%),[17] hysteroscopic resection (67% if performed in the office and 50% in the operating room),[16] and anorectal surgery under local anesthesia with sedation (52%)[36]; this last study also included a group undergoing anorectal surgery under spinal anesthesia, for which cost savings of only 18% were reported with respect to general anesthesia. Thus, anorectal surgery under local anesthesia was associated with the lowest costs, mainly due to the ability of patients to bypass phase 1 recovery units.[36] Cost savings of nearly 40% were reported for injection laryngoplasty under local anesthesia,[14] knee arthroscopy under spinal anesthesia[12,15] and endometrial thermal ablation under paracervical nerve block[18] compared to general anesthesia. Significant cost savings in respect to general anesthesia were also reported in anterior cruciate ligament reconstruction[11] under loco-regional anesthesia and in sentinel lymphnodes biopsy/excision under

Table 2 Main findings of the selected studies about cost analysis and secondary outcomes.

	General anesthesia			Local/Regional anesthesia				Outcomes		
Authors	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Li et al.[10]	NR	3,903	15,670	Loco-regional anesthesia	NR	1,576	19,929	Average total costs were significantly higher in patients undergoing regional anesthesia.	Several other contributors to higher costs are described.	Medical procedure costs
Bokshan et al.[11]	NR	3,737	19,249	Loco-regional anesthesia	NR	10,976	17,469	Average total costs were significantly lower in patients undergoing regional anesthesia.	General anesthesia, Hispanic ethnicity, Chronic medical condition, male gender, operative time and age are predictors of increased costs.	Medical procedure costs
Gebhardt et al.[12]	Sulfentanil and Propofol	25	71.92	SA	Chloroprocaine 1%	25	41.02	Anesthesia costs are inferior in case of regional anesthesia.	Spinal had faster recovery with patients reaching discharge earlier (117 *vs.* 142 min)*. Pain occurred earlier in the general anesthesia group. Patients felt significantly more uncomfortable after general anesthesia.	Anesthesia costs

Table 2 (*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Hamilton et al.[13]	Volatile anesthetics or intravenous with propofol	241	60	Interscalene brachial plexus single shot block, or catheter	20–40 mL of 0.5% ropivacaine with 1:400,000 epinephrine	1,382	82	No statistically significant difference between groups.	Increased risk of an emergency department visit within 30 days for patients who received a regional anesthesia.	Costs incurred after surgery
Chandran et al.[14],[a]	NR	6	2071	LA	NR	14	1251	Average total costs of injection laryngoplasty under LA are significantly lower than under GA with cost savings of 40%. Major contributors are direct and indirect operating theater costs.	Length of stay (h): 8.8 GA *vs* 6.4 LA*	Medical procedure costs

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Camponovo et al.[15]	Intravenous propofol and fentanyl	28	104	SA	Chloroprocaine 1%	28	63	SA for knee arthroscopy is associated with cost reductions per patient compared with GA. Cost reductions in the SA group are due to: the ability to systematically bypass the PACU, faster discharge time, the lower incidence of pain and postoperative nausea and vomiting.	Anesthesia time: 64 *vs.* 62 min. Discharge time: 326 (GA) *vs* 203 min (SA)*	Anesthesia supplies, drugs, staff
Penketh et al.[16]	NR	NR	1,485	LA in operatory room LA in office	NR	NR	LA in operatory room: 716 LA in office: 482	Operative hysteroscopic resection under LA is less expensive than under GA, especially if performed in the office compared to the OR. Reduced staff costs are the primary reason for saving.	NR	Medical procedure costs

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Sivalingam et al.[17]	NR	73	30,060	LA	Lidocaine 1%[b]	46	7,770	Average total cost is nearly 4 times greater for the GA group compared to LA. Ureteral stent placement can be safely and effectively performed under LA in the office.	No difference in complications between GA and LA.	Medical procedure costs
Ahonkallio et al.[18],[c]	NR	20	2,333	Peripheral block	20 mL ropivacaine 2 mg mL^{-1},[d]	16	1,333	Endometrial thermal ablation under PB is cheaper than GA and results in significantly reduced health service costs. The difference is due to lower costs of the hospital ward and anesthesia, and partly to overhead costs.	NR	Medical procedure costs
Covarelli et al.[19],[a]	NR	41	373	LA	10–25 mL 1% mepivacaine and 0.5% L-bupicavaine in equal parts	112	258	Average total costs for groin and axillary sentinel lymph node biopsy under GA are significantly higher than those under LA.	No differences in the number of complications.	Operating room management, personnel, drugs, instruments

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Stoffels et al.[20]	NR	89	500	LA	450 mL physiological solution, 50 mL Lidocain 1%, 0.5 mg Epinephrin	211	47	The costs were significantly less in a procedures room performed under local anesthesia compared to general anesthesia in an operating room.	No differences in the number of postoperative complications nor in oncological outcomes.	Anesthesia costs
Mitchell et al.[21],[a]	NR	64	1,244	LA	NR	47	1,026	Sacral nerve stimulation under LA is associated with reduced costs compared to GA.	LA is associated with shorter hospital stay[e] and quicker recovery. Similar symptom score and success rate for both anesthesia.	Medical procedure costs
Kushwaha et al.[22]	Propofol 1.5–2 mg kg^{-1} and fentanyl 10 $\mu g\,kg^{-1}$ with sevoflurane[f]	22	714	LA	20 mL 1% lidocaine with 1:10,000 epinephrine	19	503	Excluding the cost of post-operative follow-up, LA was 1.5 times cheaper than GA. This difference is due to the saving in GA and recovery room costs.	LA is associated with similar tolerance and clinical outcome compared to GA.	Suture materials, drugs, day surgery bed, staff costs, recovery room, post-operative medication.

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Mostafa et al.[23]	Intravenous remifentanil 0.5 μg kg^{-1} min^{-1} or alfentanil 2 μg kg^{-1} min^{-1} and propofol 9 mg kg^{-1} h^{-1}	40	492 for remifentanil 541 for alfentanil	Sciatic-femoral nerve block	25 mL ropivacaine	20	393	Costs of disposals, pre-operative and post-operative times are higher for the sciatic-femoral block group, however average total costs (including also drugs) are insignificant between GA and sciatic-femoral nerve block.	Length of stay in PACU: 28 min for remifentanil GA *vs* 25 min for alfentanil GA *vs* 28 for sciatic-femoral nerve block	Disposal, drugs, staff
Horn et al.[24],[a]	Propofol with sevoflurane or desflurane, fentanyl or sufentanyl	121	4,780	Peripheral nerve block	Mepivacaine 1.5% with 10% sodium bicarbonate	92	3,656	Perioperative costs in the peripheral nerve block group are significantly lower than in the GA group.	PACU time: 49 min (GA) *vs* 15 min (PNB)*	Medical procedure costs

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
								The use of peripheral nerve block in upper extremity surgery is feasible and associated to significant cost savings.	Postoperative complications: 11.7% (GA) *vs* 3.3% (PNB)*	
Nishikawa et al.[25]	Intravenous fentanyl 1 $\mu g\,kg^{-1}$ and propofol 6 $mg\,kg^{-1}\,h^{-1}$	40	74	SA	Lidocaine 1% 1 m L	40	49	Average total costs are significantly lower in the SA group. Costs of drugs and supplies used in the operatory room are reduced for the SA, whereas the labor costs are higher in both operatory room and recovery unit.	Time to home-readiness: 30 min (GA) *vs* 38 min (SA)* No pain in the recovery unit for 75% patients in GA *vs* 80% patients SA groups. *	Drugs, equipment, staff
								SA may be a suitable cost-effective alternative to GA for elderly ambulatory prostate biopsy.	No adverse events at home.	

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Nordin et al.[26],[a]	NR	199	2,964	SA/epidural anesthesia LA	SA/epidural anesthesia: NR LA: 50:50 mixture of 1% mepivacaine and 0.5% bupicavaine	SA/epidural anesthesia: 164/35 = 199 LA: 205	SA/epidural anesthesia: 3,010 LA: 2,508	Average total costs of LA are significantly lower than the other two groups. Intra-operative (anesthetic equipment, duration of surgery and anesthesia) and post-operative (time in recovery room, unplanned overnight admission) costs are reduced for LA compared to SA/epidural anesthesia and GA. No difference between SA/epidural anesthesia and GA.	NR	Medical procedure costs
Spanknebel et al.[27]	NR	85	3,153	LA	Lidocaine and bupicavaine	217	2,760	Average total costs are significantly higher for GA than LA. Extensive procedures and increased operating room times impact significantly on costs.	Thyroidectomy under LA results in similar outcome and morbidity rate to GA with reduced costs.	Medical procedure costs

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Casati et al.[28]	Intravenous remifentanil 0.1—0.3 μg kg^{-1} min^{-1} and propofol 2—4 μg mL^{-1}	40	317	sciatic-femoral nerve block SA	sciatic-femoral nerve block: 25 mL 2% mepivacaine	sciatic-femoral nerve block: 40	sciatic-femoral nerve block: 220	The use of sciatic-femoral nerve block results in the lowest total costs. Costs of drugs and disposable material required for anesthesia are lower in the SA group than the others.	Regional anesthesia techniques reduce the rate of admission and the duration of stay in the PACU as compared with GA. The time readiness for home discharge are shorter in the GA group than regional anesthesia.	Drugs, devices, staff
					SA: 8 mg 0.5% bupicavaine	SA: 40	SA: 308			
Forssblad et al.[29]	Propofol and alfentanil	88	236	LA	LA: 30 mL 0.5% prilocaine with 4 μg mL^{-1} adrenaline	LA: 181	LA: 76	The knee arthroscopy in LA is associated with lower cost than knee arthroscopy in SA and GA, because of the shorter recovery time of LA that reduces the need for recovery beds and postoperative care.	Recovery time: 139.1 min (GA) *vs* 33.6 min (LA) *vs* 230.1 min (SA).	Drugs, devices, staff

(*Continued*)

	General anesthesia			Local/Regional anesthesia				Outcomes		
Authors	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
				SA	SA: 60–90 mg 5% lidocaine with 5–10 mg ephedrine	SA: 74	SA: 219		Time in hospital: 280.4 min (GA) *vs* 130.4 min (LA) *vs* 350.3 min (SA)	
Casati et al.[30]	Intravenous remifentanil 0.1–0.3 μg kg^{-1} min^{-1} and propofol 2–4 μg mL^{-1}	20	291	Sciatic-femoral nerve block	25 mL 2% mepivacaine	20	288	Average total costs between GA group and sciatic-femoral block group in patients undergoing knee arthroscopy are not statistically significant. Costs related to the time spent in the PACU are statistically significant lower for the sciatic-femoral block group (USD 2.0) compared with the GA group (USD 55.7).	Time in the hospital: 170 min (GA) *vs* 277 min (Sciatic-femoral block)* Length of stay in PACU: 23 min (GA) *vs* 5 min* VAS pain: 7 (GA) *vs* 0*	Disposable materials, drugs, staff
Danelli et al.[31]	Intravenous remifentanil 0.25 μg kg^{-1} min^{-1} and propofol 4 μg mL^{-1}	20	260	SA	10 mg 0.5% bupivacaine	20	282	No differences in average total costs between the two groups.	Hospital discharge time: 156 min (GA) *vs* 296 min (SA)*	Disposable materials, drugs, staff

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
									Pain control is similar.	
Lennox et al.[32]	Fentanyl 2 μg kg^{-1} and propofol 2 mg kg^{-1}, 65% nitrous oxide	10	127	SA	3 mL 10 mg lidocaine and 10 μg sufentanil	10	94	Average total cost of anesthesia and recovery is significantly less for patients in the SA group than the GA group. Recovery costs are similar, whereas mean costs of anesthesia is significantly less in the SA group. Cost savings are due to lower cost of anesthetic supplies, sterilization, drugs.	Anesthesia time: 6.6 min (GA) *vs* 6.6 min (SA) PACU time: 112 min (GA) *vs* 101 min (SA) Postoperative pain: 50% (GA) *vs* 0% (SA)* Nausea/vomiting: 0% (GA) *vs* 30% (SA)	Supplies, drugs, staff

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Chan et al.[33]	Propofol, fentanyl, with isoflurane (up to 1.5%), 60% nitrous oxide	39	718	Intravenous regional anesthesia	Intravenous regional anesthesia: 35–45 mL 0.5% lidocaine	Intravenous regional anesthesia: 45	Intravenous regional anesthesia: 513	The intra- and post-operative costs are the least in the intravenous regional anesthesia group than GA and axillary block, reflecting cost savings of approximately 30% in both cases. intravenous regional anesthesia is associated with short induction time, lower anesthetic drug and equipment costs in the operatory room, and with less demand on nursing time and lower drug and supply costs in the PACU.	Total hospital stay time: 240 min (GA) *vs* 180 min (intravenous regional anesthesia)* *vs* 244 min (axillary block) Anesthesia time: 83 min (GA) *vs* 72 min (intravenous regional anesthesia)* *vs* 106 min (axillary block) PACU recovery time: 70 min (GA) *vs* 45 min (intravenous regional anesthesia)* *vs* 63 min (axillary block)	Disposable materials, drugs, staff
				Axillary block	Axillary block: 40–50 mL 3% chloropro-caine and 2% or 1.5% lidocaine with 1:200,000 epinephrine	Axillary block: 42	Axillary block: 755			

(*Continued*)

	General anesthesia			Local/Regional anesthesia				Outcomes		
Authors	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Martikainen et al.[34]	Intravenous propofol 2 mg kg^{-1} and alfentanil 1 mg with sevoflurane (up to 8%)	30	333	SA	3 mL 2% lidocaine	30	293	Average total costs are significantly reduced for SA. However, GA is more cost-effective than SA in ambulatory knee surgery, if a short recovery unit time is required.	Recovery unit time: 218 min (GA) *vs* 224 min (SA) Time to home-readiness: 96.4 min (GA) *vs* 140.8 min (SA)* Post-operative pain low (VAS < 4 in 100% patients in SA *vs* in 86.7% in GA groups).	Disposable materials, drugs, staff
Chilvers et al.[35]	Propofol, fentanyl or sufentanil, and mivacurium or succinyl-choline, with isoflurane nitrous oxide	28	99	SA	2–2.5 mL 1% lidocaine and 10–25 μg fentanyl	24	107	Average total costs for anesthesia and recovery are similar between the two groups. Use of SA in alternative to GA does not reduce costs or improve efficacy of anesthesia and recovery for outpatient laparoscopy.	Anesthesia time: 10 min (GA) *vs* 18 min (SA)* PACU recovery time: 94 min (GA) *vs* 123 min (SA)* Time to discharge: 124 min (GA) *vs* 150 min (SA)	Disposable materials, drugs, staff

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
Li et al.[36]	Intravenous propofol 2.5 mg kg^{-1}, fentanyl 1—2 μg kg^{-1} with 0.5—2% sevoflurane, 65% nitrous oxide	31	289	SA	SA: 30 mg lidocaine and 20 μg fentanyl[g]	SA: 31	SA: 208	Average total costs are significantly decreased for LA than SA and GA because both intraoperative and recovery costs are the lowest. Patients in the LA group are able to by-pass phase 1 recovery unit requiring less nursing labor (thus less costs). GA is associated to the highest costs.	Anesthesia time: 40 min (LA) *vs* 72 min (SA)* vs 75 min (GA)*	Drugs, supplies, staff
				LA with sedation	LA: topical 2% lidocaine gel and sedation-analgesia with propofol 75 μg kg^{-1} min^{-1} and 0.5 μg kg^{-1} fentanyl. 15 mL 2% lidocaine, 15 mL 0.5% bupicavaine, 0.5% epinephrine (1:200,000)	LA: 31	LA: 138		Phase 1 stay: 0 (LA) *vs* 52 min (SA)* *vs* 44 min (GA)* Time to home-readiness: 76 min (LA) *vs* 193 min (SA)* *vs* 171 min (GA)* Hospital stay: 116 min (LA) *vs* 266 min (SA)* *vs* 247 min (GA)* No differences in post-operative side effects or unanticipated hospitalizations.	
Song et al.[37]	Propofol 2.5 mg kg^{-1} min^{-1} 1% sevoflurane, 65% nitrous oxide	28	369	SA	SA: 1.2—1.5 mL 0.75% bupicavaine and 25 μg fentanyl	SA: 25	SA: 330	Average total costs are the lowest for the ilioinguinal-hypogastric nerve block group (reduced supplies during the intraoperative period, reduced labor during post-operative period). No difference between GA and SA.	Anesthesia time: 109 min (ilioinguinal block) *vs* 119 (GA) *vs* 116 (SA)	Drugs, staff, resources

(*Continued*)

Authors	General anesthesia			Local/Regional anesthesia				Outcomes		
	Anesthetic	No. of patients	Average total costs (USD)	Type	Anesthetic	No. of patients	Average total costs (USD)	Main findings about cost analysis (primary outcome))	Other study findings (secondary outcomes)	Resources included for the calculation of costs
				Ilioinguinal-hypogastric nerve block	Ilioinguinal-hypogastric nerve block: 30 mL of 0.25% bupivacaine, 1% lidocaine and propofol 25–150 $\mu g\,kg^{-1}\,min^{-1}$	Ilioinguinal-hypogastric nerve block: 28	Ilioinguinal-hypogastric nerve block: 288	Ilioinguinal-hypogastric nerve block is the most cost-effective techniques for outpatients undergoing unilateral herniorrhaphy with respect to recovery, patient comfort, and associated incremental costs.	Phase 1 PACU: 5 min (ilioinguinal block) *vs* 40 (GA)* *vs* 35 (SA)* Phase 2 unit: 153 min (ilioinguinal block) *vs* 168 (GA) *vs* 276 (SA)* Time to home-readiness: 133 min (ilioinguinal block) *vs* 171 (GA)* *vs* 280 (SA)* Time to actual discharge: 158 min (ilioinguinal block) *vs* 208 (GA)* *vs* 309 (SA)* Maximum pain VAS: 15 (ilioinguinal block) *vs* 39 (GA)* *vs* (34) SA* Maximum nausea VAS: 1 (ilioinguinal block) *vs* 27 (GA)* *vs* 4 (SA)*	

NR, not reported; PACU, post-operative anesthesia care unit. Currency is expressed with United States dollars (USD). **Type of anesthesia**: GA, general anesthesia; LA, local anesthesia; SA, spinal anesthesia.

[a] Day-case setting.
[b] Four patients received also i.v. midazolam.
[c] Day-case setting (8 h) for general anesthesia and outpatient setting (4 h) for paracervical block.
[d] When necessary also Alfentanil 0.5 mg.
[e] Overnight stay for 38% of patients of the GA group due to adverse effects of the anesthesia.
[f] This group received also a perianal block as for the LA group.
[g] Patients received also 1–2 mg midazolam i.v. for sedation.
[*] Statistically significant.

local anesthesia.[19,20] Reduced staff costs[16,33,36] and drugs or supplies,[18,20,25,26,32,33,37] ability to bypass the postoperative PACU or phase 1 recovery unit,[15,24,36] and shorter recovery time[12,22,26,28,29,37] are the main anesthetic procedure factors associated with health care cost reductions.

Among studies comparing different types of regional anesthesia, two randomized trials found spinal anesthesia to be more expensive than both sciatic-femoral nerve blocks in patients undergoing knee arthroscopy,[28] even if the costs of drugs and disposables were lower, and ilioinguinal-hypogastric nerve block for unilateral inguinal herniorrhaphy[37] and reduced PACU costs were the primary reasons for this difference for both surgeries. Chan et al.[33] found that intravenous regional anesthesia decreased costs of 30% compared to axillary brachial plexus block due to shorter induction time and lower drug and supply requirements. Two studies which used treatment codes for patient selection did not specify the type of peripheral block performed.[10,11]

Contrasting results were achieved by analyzing the costs of a subgroup of studies focusing on knee arthroscopy, which was investigated in 6 randomized clinical trials[12,23,28–30,34] and in one retrospective observational study.[15] Cost advantages were demonstrated for regional anesthesia[12,15,28,34] in half of the studies, but similar costs were found in the other two trials.[23,30] The remaining study[29] confirmed that there was no statistically significant difference between spinal and general anesthesia but found reduced costs only for knee arthroscopy under local anesthesia. Reduced drugs and/or disposable materials and recovery time were associated with cost savings, further supporting the overall results of this systematic review.

Secondary outcomes

Twelve trials[12,14,15,21,28–31,33,35–37] reported data on the duration of hospital stay; all studies found a shorter length of stay for local[14,21,29,36] or regional[12,15,30,31,33,37] anesthesia, except one that did not reveal any difference.[35]

Postanesthesia recovery time was investigated in 12 studies.[12,21,23,24,28–30,32–35,37] Local or regional anesthesia techniques significantly decreased the PACU time.[12,21,24,28–30,33,35,37] In particular, Song et al.[37] showed that patients undergoing ilioinguinal-hypogastric nerve block spent less time in the phase 1 PACU (5 minutes) compared to patients operated on under general anesthesia (40 minutes) but also than patients undergoing spinal (35 minutes) anesthesia; moreover, these latter techniques required more time to recover in the phase 2 unit than the other two techniques. Thus, ilioinguinal-hypogastric nerve block was associated with lower costs than the spinal technique as regional anesthesia for unilateral herniorrhaphy. No difference in the duration of recovery stay was found in three studies.[23,32,34] Time readiness for home discharge was significantly shorter for general anesthesia in 3[25,28,34] out 5 studies reporting this datum.[25,28,34,36,37]

Data on anesthesia time conflicted with three studies reporting lower times for local and regional techniques[33,35,36] and three[15,32,37] finding no statistically significant difference.

The overall rates of complications or side effects and clinical outcomes were similar[12,13,17,19–22,25,36] or more favorable[15,24,30,32,37] for medical procedures under local or regional anesthesia.

Discussion

The vast majority of the studies included in this systematic review were concordant in showing an association between local or regional anesthesia and lower perioperative costs, regardless of the surgical procedure.[11,12,14–30,32–34,36,37] This is consistent with data identifying in the operating room time the major fixed cost incurred during the perioperative process.[2] The anesthesia-controlled operating room time was defined as the portion of this time required by the anesthesiologist to perform the anesthesia technique of choice. When this time is reduced, overall hospital costs decrease. We know that regional anesthesia is associated with a reduction in anesthesia-controlled operating room time, fastening both the induction and postoperative phases.[5] Our main finding is that local anesthesia is associated with a greater reduction in total costs further confirms the hypothesis of a reduction in anesthesia-controlled operating room time as the main factor affecting the overall total cost reduction observed, as local infiltrative anesthesia requires, on average, less time to be performed.

Only two studies[23,30] found the cost profile of peripheral nerve block-based anesthesia to be similar to that of general anesthesia regarding sciatic nerve block. A possible explanation can be that sciatic nerve block is a so-called ''deep block'', i.e., an advanced block, requiring more skills and possibly more time to be performed than other peripheral nerve blocks usually applied in the outpatient setting. Marhofer et al.[38] describes well the relative difficulty in the localization of the nerve and the surrounding anatomical structures due to their depth. However, Ehlers et al.[39] and Marhofer[40] have also shown that this block may be associated with a faster onset and higher efficacy when ultrasound-guided compared to nerve stimulation guidance. It remains to be demonstrated that these advantages actually translate into increased cost-effectiveness when compared to general anesthesia or other techniques in the ambulatory setting.

The second factor with a known impact on the perioperative process total costs is the PACU bypass rate or the recovery time when the patient requires postoperative supervision. The PACU is a highly work-intensive environment whose fixed cost is relevant.[2] Total cost reduction may be achieved in case of a consistently high PACU bypass rate by a reduction in nurses equivalent staff required.[23,30] Our results confirm regional and local anesthesia techniques to be associated with a higher PACU bypass rate and a lower recovery time in comparison to general anesthesia.

The third factor that affects average total costs is the time to readiness for discharge, directly affecting the day-hospital length of stay. As discussed above, the overall day-hospital length of stay represents a significant fixed cost in the ambulatory perioperative process.[4] Regional anesthesia has been associated with a lower incidence of postoperative anesthesia-related complications and side effects, translating into a quicker functional recovery and a lower time to discharge.[3]

In general, we can conclude that local and regional anesthesia is associated with lower total hospital costs when performed in the ambulatory setting. It is likely due to three factors: a reduction in total anesthesia-controlled operating room time, a reduction in postanesthesia recovery time and an overall shorter length of stay. These results apply to contexts where regional anesthesia can be performed regularly and systematically and where dedicated pathways are in place to enhance patient turnover in the outpatient setting, which is often the case in ambulatory surgical centers. Indeed, as stated by Philip and colleagues, a higher PACU bypass rate will only generate cost savings if utilization actually increases or staffing actually decreases.[23,30] Moreover, the reduction in anesthesia-controlled operating room time per procedure is a few minutes and thus becomes significant only if many ambulatory procedures are performed in a given program and if an induction room allows for performing the following block while the previous patient is still undergoing surgery.[5] Cost-effectiveness comparisons of different anesthesia techniques are dependent on the surgical duration of the case.[41,42] Schuster et al.,[41] in 2005, performing a regression function, demonstrated that the advantage of spinal anesthesia over general anesthesia in terms of operating room total fix costs reduction can be estimated to be 13% for a 50 minutes case, 9% for a 100 minutes case, and 5% for a 200 minutes case.[23,30] These data highlight the fact that regional anesthesia cost-effectiveness depends on patient turnover and is higher in contexts characterized by high turnover and high case load per operating room, such as ambulatory surgery.

Our systematic review has some limitations. Heterogeneity among studies may represent a potential source of bias in a systematic review. This heterogeneity is likely to arise through baseline differences among the patients in the included studies, diversity in methodological aspects between different studies, and different study quality. We detected significant heterogeneity and poor quality of design among several studies in our systematic review. However, we used the CHEC list to assess the methodological robustness of the studies, and some of the criteria were not properly applicable to all studies since most of them were cost-minimization analyses. The meta-analysis was substantially hampered by the presence of this heterogeneity, which would make it challenging to compare the studies. Heterogeneity was also present in estimates of savings, which vary widely and may be explained by several reasons, such as implementation differences, hospital setting, and patient mix. These analyses are often not comparable among published studies due to variations in the type of cost data and accounting practices used. Such limitations preclude the possibility to estimate an effect size.

Our literature search was carried out on four major medical databases that should provide robust and reliable search results. The inclusion of other sources might refine our search strategy, specifically the inclusion of specialized databases (i.e., NHS Economic Evaluation Database). Moreover, we selected studies published since 2000 to be sure to include only the most recent and updated data about costs. However, problems with the breadth of costs and outcomes considered exist in all the studies. Last, none of the included studies was a cost-effectiveness analysis; thus, comparing the relative costs and outcomes of the two different anesthesia regimens and estimating the possible healthcare gains were not feasible. This means that the robustness of the results and conclusions about the impact of the anesthesia regimen on the average total costs is uncertain. Hence, a cost-effective analysis is necessary to undertake an assessment of both costs and effectiveness and to determine which anesthesia regimen is the most cost-effective procedure for ensuring that resources are being used wisely.

Conclusions

Despite the limitations of this systematic review, mainly the heterogeneity of the studies and the lack of cost-effectiveness analysis, the economic impact of the anesthesia regimes on healthcare costs appears to be relevant and should be further evaluated.

Conflicts of interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:10.1016/j.bjane.2021.09.012.

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CASE REPORT

Ultrasound-guided central venous access for patients in the Intensive Care Unit in prone position: report of three cases

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Prone position;
SARS-CoV-2 pneumonia;
Case report

Abstract
The prone position is extensively used to improve oxygenation in patients with severe acute respiratory distress syndrome caused by SARS-CoV-2 pneumonia. Occasionally, these patients exhibit cardiac and respiratory functions so severely compromised they cannot tolerate lying in the supine position, not even for the time required to insert a central venous catheter. The authors describe three cases of successful ultrasound-guided internal jugular vein cannulation in prone position. The alternative approach here described enables greater safety and well-being for the patient, reduces the number of episodes of decompensation, and risk of tracheal extubation and loss of in-situ vascular lines.

Introduction

The prone position is a widely used measure to improve oxygenation during severe Acute Respiratory Distress Syndrome (ARDS) treatment, enhancing patient survival rates.[1] During the COVID-19 pandemic, we have often observed Intensive Care Units (ICU) overcrowded with patients in prone position.[2] COVID-19 patients often require intravenous administration of several drugs and vasopressors; therefore, they require the placement of a central venous line. In a patient in prone position, the Internal Jugular Vein (IJV) is the only feasible venous access for ultrasound-guided placement of a Central Venous Catheter (CVC). The existing literature dealing with the insertion of a CVC in the patient in prone position is scarce,[3,4] and it reports few cases in the perioperative and ICU settings. In some of these reports, the placement of central venous lines in patients in prone position is even described by the authors as a last resort.

The present report aims to describe the use of ultrasonography for inserting a central venous catheter in the internal jugular vein of patients in prone position, and the feasibility of this approach in ICU and Operating Room (OR) current practice.

Case reports

Patient 1: Female, 51 years old, American Society of Anesthesiologists (ASA) physical status II, past medical history of

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High Blood Pressure (HBP), depressive disorder and dyslipidemia. She was admitted to the ICU for SARS-CoV-2 pneumonia with severe hypoxemic respiratory failure. Shortly after admission, she was submitted to urgent tracheal intubation and mechanical ventilation, but due to hypoxemia severity, she was immediately placed in prone position and ventilated with an inspired oxygen fraction (FiO_2) of 1.0, with subsequent improvement of oxygenation.

Patient 2: Male, 64 years old, physical status ASA III, past medical history of HBP, type 2 Diabetes *Mellitus* (DM2), dyslipidemia, obesity, smoker, severe obstructive sleep apnea syndrome, and cerebrovascular disease. He had been in the ICU for 15 days for SARS-CoV-2 pneumonia, with bacterial superinfection, severe ARDS, and extremely low lung compliance. He had a right subclavian vein CVC in situ for 14 days and showed evident worsening of inflammatory markers (Procalcitonin and C-Reactive Protein).

Patient 3: Male, 71 years old, physical status ASA III, past medical history of HBP, insulin dependent DM2, and chronic kidney disease status III. He had been in the ICU for 21 days due to SARS-CoV-2 pneumonia, with bacterial superinfection and severe ARDS. He had a right IJV CVC in situ for 12 days, with evident inflammatory signs at the catheter insertion site and showed worsening of inflammatory markers.

All three patients were unable to tolerate the supine position. After emergency tracheal intubation of Patient 1, her severe clinical instability did not allow keeping her in supine position for the time requested for the placement of a CVC. Patients with severe ARDS generally are kept in prone position for periods of 16 to 20 hours daily,[1] but Patients 2 and 3 were kept in the prone position continuously for periods of more than 48 hours, because they could not tolerate the supine position. Prior attempts to switch to supine position, precipitated severe hypoxemia (peripheral oxygen saturation less than 50%) and hemodynamic instability (hypotension and dysrhythmias). Patient 3 even presented a peri-arrest period, with extreme bradycardia associated with severe hypotension. Given the worsening clinical status and suspected infection of Patients 2 and 3, requiring antibiotic therapy adjustment, we decided to replace the central venous catheter immediately, and with the patients in prone position.

Inserting CVC in the right IJV in two of the three patients would be feasible, but we decided to place the catheter in the left IJV in all patients. The rationale was the lower theoretical risk of inadvertent entry of the guidewire into the right ventricle, with the risk of cardiac arrhythmias and eventual cardiac arrest in a patient in prone position and already receiving inotropics, that are potentially arrhythmogenic drugs.

For CVC placement in the IJV, we turned the heads of the patients to the left and after verifying orotracheal tube positioning, we firmly secured it. To ensure better neck exposure and capturing of ultrasound images of cervical structures, we applied a slight elevation of the trunk with a pillow, extended the neck, applied traction over the ipsilateral shoulder with adhesive tape (or help from a collaborator), and tilted the bed to 15° Trendelenburg (Fig. 1A).

US machines used were the Logiq™ P9 (GE Healthcare) with a linear probe (6—12 MHz) and the Siemens Acuson™ X600, with a linear probe (5—10 MHz). Maintaining an aseptic technique, the operator was positioned at the patient's head. The US machine screen was placed on the patient's side and facing the operator, ensuring ideal ultrasound ergonomics and optimal hand-eye coordination for performing the technique.

The probe was initially placed on the lateral side of the patient's neck, in a transverse plane, enabling the identification of the Sternocleidomastoid Muscle (SCM), the Carotid Artery (CA) and the IJV. Compared to CA, the IJV image is a hypoechoic, non-pulsatile and more collapsible structure. IJV size varies among patients and is highly dependent on intravascular volume status. Before IJV puncture, we moved the probe caudally, from the base of the mandible to the

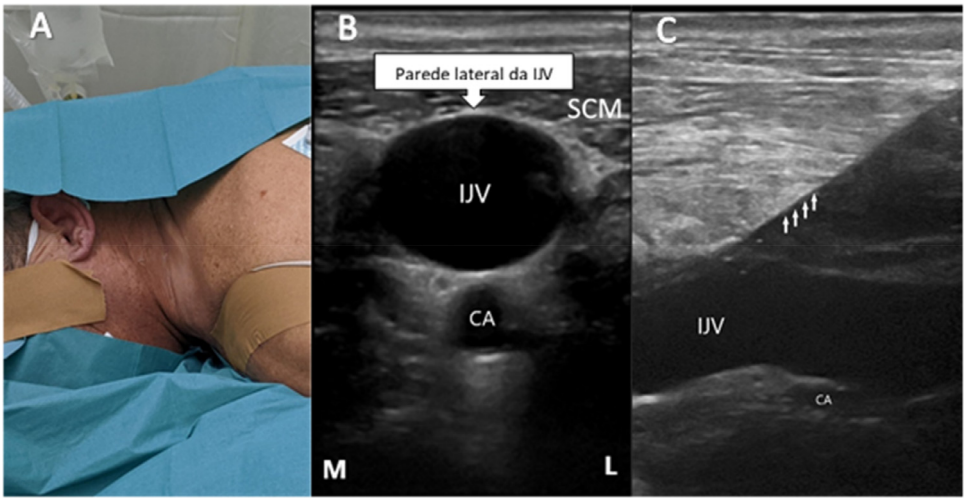

Figure 1 **A**, Positioning of the patient for CVC placement in the prone position; **B**, anatomical US landmarks of the out-of-plane approach; **C**, Direct ultrasound image of needle insertion during in-plane approach. CVC, Central Venous Catheter; SCM, Sternocleidomastoid Muscle; IJV, Internal Jugular Vein; CA, Carotid Artery; ↑↑↑↑, needle; M, Medial; L, Lateral.
Parede lateral da IJV = IJV lateral wall

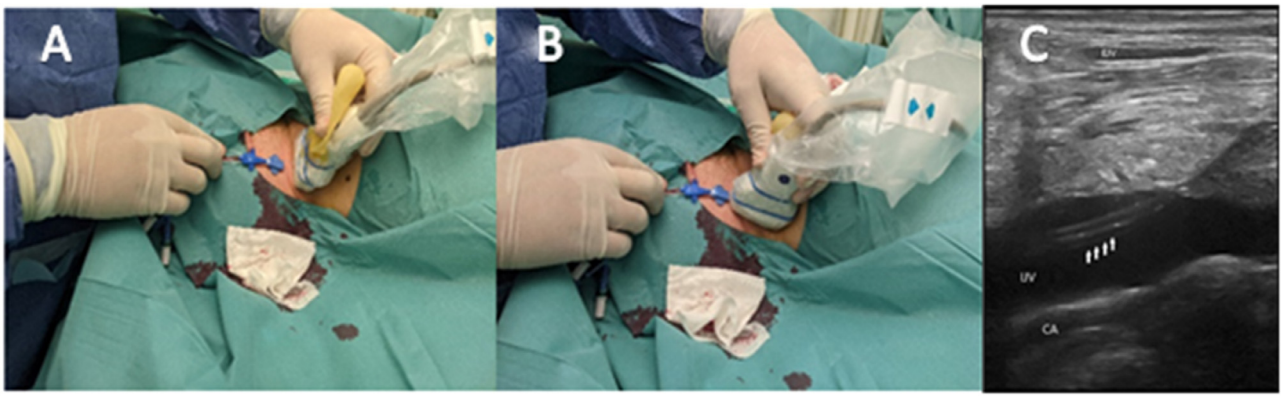

Figure 2 **A**, Probe orientation for the out-of-plane approach to confirm the correct position of the CVC; **B**, Probe orientation for the in-plane approach to confirm the correct position of the CVC; **C**, Direct ultrasound image of the CVC inserted inside the IJV in the in-plane approach. CVC, Central Venous Catheter; EJV, External Jugular Vein; IJV, Internal Jugular Vein; CA, Carotid Artery; ↑↑↑↑, Central Venous Catheter.

base of the neck and performed a careful analysis of the anatomical relationship between the IJV and the Internal Carotid Artery, and confirmed IJV trajectory and patency.

When performing the anterior approach with the patient in supine position, the needle penetrates the anterior wall of the IJV, usually anterior and lateral to the CA. On the other hand, when one performs the modified anterior approach on a patient in prone position and with ipsilateral rotation of the neck, the needle penetrates the IJV lateral wall, usually anterior to the CA (Fig. 1B).

After identifying anatomical ultrasound landmarks using the out-of-plane approach, the needle pierced the skin with an entry angle of about 45° with the operator continuously applying aspiration in the distal third between the mandible angle and clavicle. After the vein was punctured, the CVC was inserted using the Seldinger technique.

Since the CA was located posteriorly to the IJV in this position (Fig. 1B) and, because arterial blood color of critically ill patients with COVID-19 can be misleading and be misperceived as venous blood, it is desirable to verify the correct positioning of the guidewire (or needle) in the IJV before inserting the dilator. Rotating US probe from the transverse to the longitudinal plane enables confirmation of IJV cannulation (Fig. 1C).

The length of insertion of the CVC (7 French, 3 or 4 lumens, 20 centimeters long, Arrow®) was adjusted to the height of each patient. After checking the proper placement of the catheter inside the IJV (Fig. 2 A—C) and confirming the patency of all lumens, the catheter was fixed to the skin by a silk suture.

For all three patients, at the end of the procedure, gas analysis was obtained to confirm venous blood, and a post-ero-anterior chest X-Ray was performed to confirm the correct location of the catheter tip and rule out complications. All procedures were uneventful.

Discussion

In this case report, IJV cannulation was successfully performed through a modified anterior approach, in patients kept in prone position due to severe pneumonia caused by SARS-CoV-2.

Patients with ARDS due to SARS-CoV-2 present reduced physiological reserve and cardiorespiratory instability that may preclude them from tolerating supine position even for the execution of short-time procedures, such as hygiene care or CVC placement. In these circumstances, maintaining the prone position warrants greater patient safety and well-being, reduces the risks of tracheal extubation and loss of in situ vascular lines, and the number of episodes of clinical decompensation, that can increase need for higher FiO_2, leading to worsening of the lung injury.

Like every invasive technique, CVC placement is associated with risks and complications. These are largely associated with operator experience, use of US, and patient-related factors such as coagulation disorders, anatomical anomalies, and obesity.

Among the most frightening complications, severe arrhythmias can be triggered by central venous catheterization and can progress to cardiac arrest requiring advanced life support in the prone position. This will always be a limiting factor for this technique, despite the fact that the effectiveness of resuscitation maneuvers in prone position has been reported.[5]

Ideally, this approach should be performed by two operators, allowing continuous real-time visualization of the CVC insertion on the US screen, with expected improvement in patient safety and procedural efficiency.

Conclusion

The limited number of cases described in the literature dealing with the US-guided placement of vascular lines for patients in prone position, makes this case report more relevant. If performed by trained and experienced personnel, the modified anterior approach may be an effective, feasible and safe alternative for the placement or replacement of CVC in ICU patients who need to be kept for extended periods in the prone position.

More studies are required to validate the benefits and effectiveness of this approach. There is the prospect of the approach being used in other scenarios, such as during surgery performed in prone position and when other types of

catheters need to be inserted (e.g., hemofiltration and extracorporeal oxygenation).

Conflicts of interest

The authors declare no conflicts of interest.

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CASE REPORT

Pudendal nerve block for circumcision of pediatric patient with Pierre Robin Sequence: case report

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KEYWORDS
Child;
Pierre Robin syndrome;
Regional anesthesia;
Case report

Abstract Pierre Robin Sequence (PRS) is a congenital condition characterized by micrognathia, glossoptosis, and cleft palate that presents with airway obstruction and developmental delay with or without other congenital anomalies. These patients' anesthesia management is challenging because of difficult ventilation and intubation. Regional anesthesia methods should be considered for these patients on a case-by-case basis. This report presents primary use of regional anesthesia for circumcision of a 9-year-old boy with PRS.

Introduction

Pierre Robin Sequence (PRS) is a congenital condition characterized by micrognathia, glossoptosis, and cleft palate that presents with airway obstruction. This sequence of defects is often accompanied by impaired nutrition, developmental delay, and airway obstruction that is mostly prevalent in the second month of life causing respiratory failure.[1,2] These features and limited mouth opening complicate each step of airway management, especially mask ventilation and intubation. Difficult airway management and airway obstruction may result in intra- and postoperative respiratory complications. These patients also may be more sensitive to opioid due to chronic airway obstruction and hypoxia.[2] Due to an anticipated difficult airway and possibility of opioid sensitivity, possibility of regional anesthesia should be considered in these patients depending on the surgery.

Case report

The patient was a 9-year-boy with PRS who was scheduled for circumcision. The patient was born full-term and had a six-month-long pediatric care unit stay at 4 months of age due to severe respiratory distress, when he needed an emergence tracheostomy after several attempts at difficult intubation and ultimate failure. When he presented for circumcision, he was a 20 kg boy with adenomegaly, a large nose, glossoptosis, high-arched narrow palate, and significant micrognathia (Fig. 1). On preanesthetic exami-

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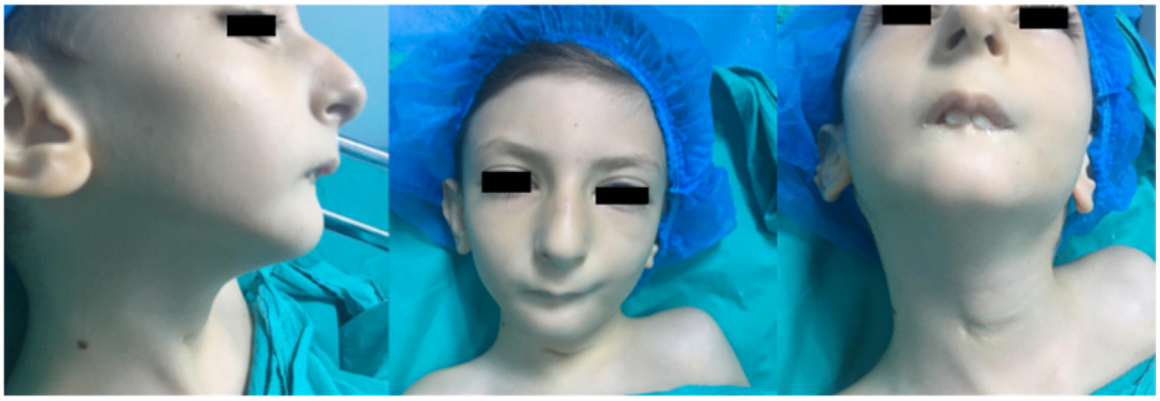

Figure 1 Tracheostomy history of a patient with Pierre Robin Sequence with micrognathia, high palate, mouth opening less than 2 cm.

nation, he had a mouth opening of less than 2 cm, normal neck mobility, and a Mallampati score of 1. The general examination and laboratory tests results were all normal. A high probability of difficult ventilation and intubation commanded an anesthetic plan with regional anesthesia. After discussion with the surgical team, it was planned to perform a pudendal nerve block. The patient, who already had a peripheral intravenous line placed in the ward, was taken to the operating room after premedication with 0.05 $mg.kg^{-1}$ intravenous midazolam. That dose provided adequate anxiolysis whilst minimizing unwanted airway depression. The patient had standard monitoring (SpO_2, ECG, NIBP) and bispectral index (BIS). The first BIS value was measured as 98. Propofol infusion 50 $\mu gr.kg^{-1}.min^{-1}$ was started intravenously, and maintenance was based on BIS value between 60–80. The patient was put in lithotomy position and then bilateral pudendal block was performed with a neurostimulator. A total of 10 ml of 0.25% bupivacaine and 0.1 $\mu gr^{1-5}.kg^{-1}$ dexmedetomidine was injected. First, surgical incision was made 10 minutes after the block and the patient did not need any other analgesic throughout the operation. The patient received 4 $L.min^{-1}$ oxygen via Venturi mask. Spontaneous breathing was preserved, and no intervention for airway control was needed. Hemodynamic and respiratory parameters remained stable perioperatively. At the end of a 1-h surgery, the patient was taken to the recovery unit after he regained consciousness and his BIS value was 90. Pain evaluation was done with the FLACC Score at 5^{th}, 15^{th}, 30^{th}, 60^{th}, and 120^{th} minutes and scores remained 0 for the first 2 hours postoperatively. He was then discharged to the ward for a 24-h postanesthetic follow-up and did not need any additional analgesia.

Discussion

Airway management makes the anesthetic plan for Pierre Robin Sequence patients very challenging. Preanesthetic airway evaluation must be done carefully with close attention to mouth opening, dental structures, Mallampati score, neck circumference, neck extension, tonsils, palate, and previous tracheostomy scars. Difficult airway management should be expected on the day of surgery. When the surgical plan is suitable, choosing regional anesthesia over general anesthesia for patients with likely difficult airways can minimize anesthetic risks. Pediatric Regional Anesthesia Network (PRAN) emphasizes the rise in the use and safety of regional anesthesia in children in recent studies.[3] Circumcision is one of the most frequent penile surgeries and is commonly performed as day surgery. Analgesia options for this painful procedure include intravenous analgesia, caudal block, penile block, and pudendal nerve block.[4] Caudal block is a safe and commonly performed neuraxial anesthesia, however it carries the risk of requiring general anesthesia, though at a small rate. The success rate of penile block can vary and hence its use may require general anesthesia. It is preferred to perform pudendal nerve block due to its higher success rate compared to penile block and better safety profile compared to caudal block. Recent studies show that pudendal nerve block provides better analgesia in hypospadias surgery than caudal block.[5] The pudendal nerve derives from second, third, and fourth roots of sacral plexus. Inside the pudendal canal, the nerve first gives off inferior rectal (anal) nerves, and then divides into perineal nerve and the dorsal nerve of the penis/clitoris. There are different anatomical approaches (transvaginal, transperineal, perirectal), and also different techniques (anatomical landmark, using nerve stimulator, and ultrasound guided) for performing pudendal nerve block. In this report, a perirectal approach with the nerve stimulator in the lithotomy position was chosen. Injection point and direction is more lateral from anus and rectum, therefore structural injury risk is low in this technique.[4,5] Bleeding, hematoma, mucosal laceration, and infection are potential complications, especially with the transvaginal approach. As in the other blocks, there is a risk of intravascular local anesthetic injection and systemic local anesthetic toxicity. Motor block and sphincter functional dysfunction can be rarely observed after caudal block but has not been reported after pudendal block.[5] Supplementary administration of propofol infusion with BIS monitoring allowed us to manage the surgical period without causing anxiety in the pediatric patient. Furthermore, not only did using dexmedetomidine as an additive for the block increased the analgesic time, but it may also have contributed to sedation intraoperatively and postoperatively. There was no need for opioids. Pudendal nerve block for circumcision provided a comfortable intraoperative and postoperative period for the patient with adequate

analgesia and no anxiety. In patients with anticipated difficult airway, such as Pierre Robin Sequence patients, regional anesthesia methods should be considered depending on the surgery.

Conflicts of interest

The authors declare no conflicts of interest.

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CASE REPORT

Ultrasound-guided continuous costoclavicular block through retrograde stimulating catheter technique for postoperative analgesia in shoulder surgery: a case series

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KEYWORDS
Ultrasonography;
Regional anesthesia;
Shoulder;
Costoclavicular

Abstract In five patient undergoing surgery for proximal humerus fracture we investigated into postoperative analgesia provided by continuous costoclavicular block using continuous stimulating catheter. The postoperative pain scores were less than 4 in all patients except in two patients who required intravenous tramadol 50 mg as a rescue analgesic. The radiocontrast dye study executed in two patients revealed contiguous contrast spread through the brachial plexus sheath with the catheter tip in the interscalene space. We propose that a continuous costoclavicular block with a retrograde stimulating catheter is a feasible alternative regional anesthesia technique for postoperative analgesia in shoulder surgery.

Introduction

The costoclavicular block (CCB) was described as an alternative to traditional lateral infraclavicular block for forearm and hand surgery.[1] In the CCB, the brachial plexus cords are approached in the costoclavicular space at the midpoint of the clavicle below the subclavius and the pectoralis muscle under ultrasound (US) guidance. Anatomically, the cords are

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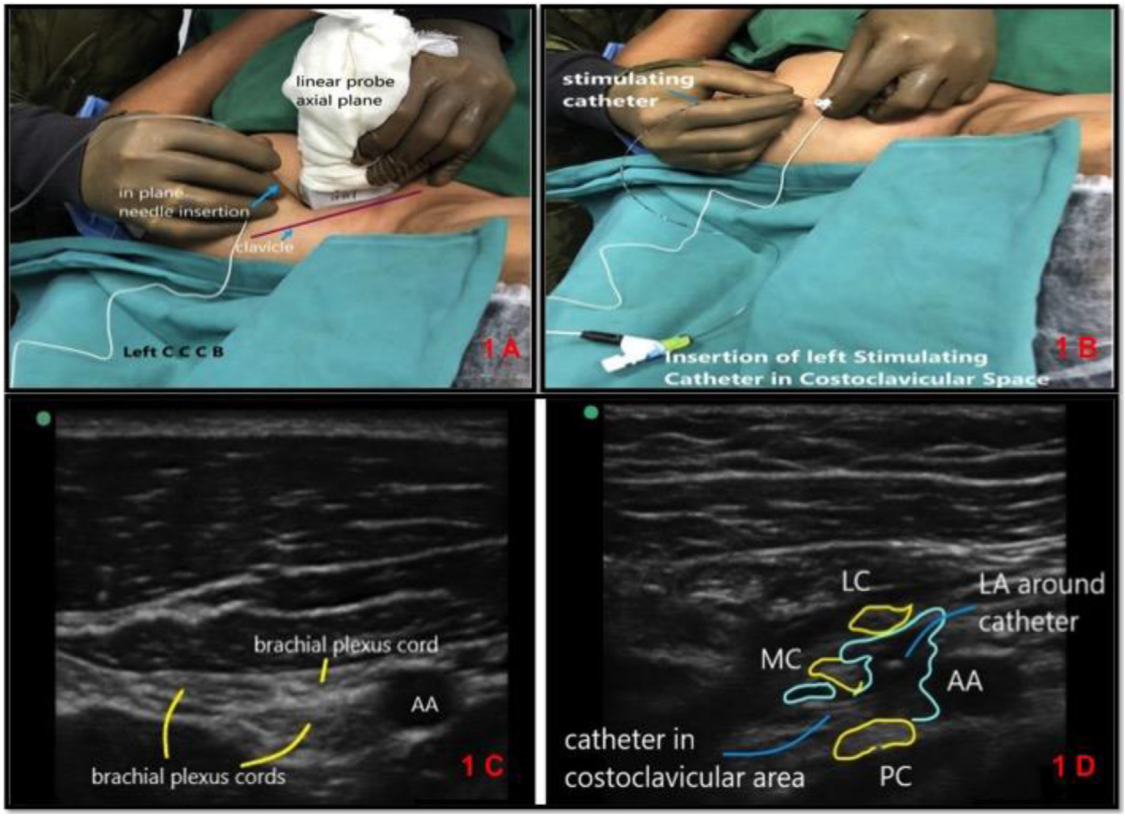

Fig. 1 A, left Costoclavicular block: In Plane approach with a linear transducer; Needle insertion from lateral to medial. B, insertion of stimulating catheter. C, ultrasound image depicting the brachial plexus cords. D, stimulating catheter positioned in the costoclavicular space; Injection of LA displaces the cords; A hyperechoic dot is seen of the catheter.

arranged more superficial and are clustered together lateral to the axillary artery. The costoclavicular space is continuous cranially with the supraclavicular fossa and caudally with the medial infraclavicular fossa, thus it can be used as a conduit for a catheter for continuous CCB. In this case series of five patients with proximal humerus, we implemented continuous stimulating catheter in the costoclavicular area to evaluated postoperative analgesia provided by continuous CCB. All patients received a standard general anaesthesia. We performed a radiocontrast dye study in two patients to evaluate the catheter tip position and spread of drug in the costoclavicular space.

Case report

After approval of the hospital ethics committee (Sancheti Instute of Orthopedics and Rehabiliation, Pune, India), five patients undergoing open surgery for proximal humerus fracture under general anesthesia were enrolled for this case series after their written informed consent during January to July 2019. Patients with American Society Anesthesiologists (ASA) physical status greater than III, pregnancy, neuromuscular disease, renal disorders, skin infection at the needle insertion site, prior surgery on infraclavicular fossa, history of brachial plexus injury, bleeding disorder, or allergy to local anesthetic were excluded.

With the patient in the supine position and under due asepsis, a linear array US probe (5–13 MHz, Sonosite, USA) was placed in a transverse oblique plane in the costoclavicular space (Fig. 1A), and the three cords of the brachial plexus lateral to the axillary artery were visualized (Fig. 1C). A 50-mm, 17G insulated needle with a 19G, 100-mm stimulating catheter (StimuLong Nanoline- Pajunk®, Germany) was used for the block. Under US guidance, the needle was inserted in-plane from lateral to medial direction (Fig. 1B) till its tip was positioned between the posterior and medial cord (Fig. 1D). The posterior cord was identified by the extensor response of the fingers using neurostimulation at 0.4 mA. At this point, the needle was stabilized, and its bevel was rotated by 90 degrees to face cephalad towards the supraclavicular fossa. The stimulating catheter was then inserted to a depth of 7–8 cm from the needle tip under continuous neurostimulation (Fig. 1B). The needle and catheter were visualized in the costoclavicular space in all images (Fig. 1D). The evoked muscle response observed at a current of 0.8–1.2 mA was of the deltoid and biceps in one patient each; and of multiple muscles including the deltoid, biceps, and triceps in three patients. After injecting 12 mL of 0.2% ropivacaine with 30 μg clonidine, the contractions ceased, and the catheter was fixed and subcutaneously tunneled on the medial aspect of the chest wall. The entry point was secured with sterile biofilm (Tegaderm, 3M®). General anesthesia was then induced with intravenous (IV) propofol 2–2.5 $mg.kg^{-1}$, fentanyl 2 $\mu g.kg^{-1}$, and cisatracurium 0.15 $mg.kg^{-1}$; and the airway was secured with an appropriately sized endotracheal tube. The tunnelled catheter was safely tucked below

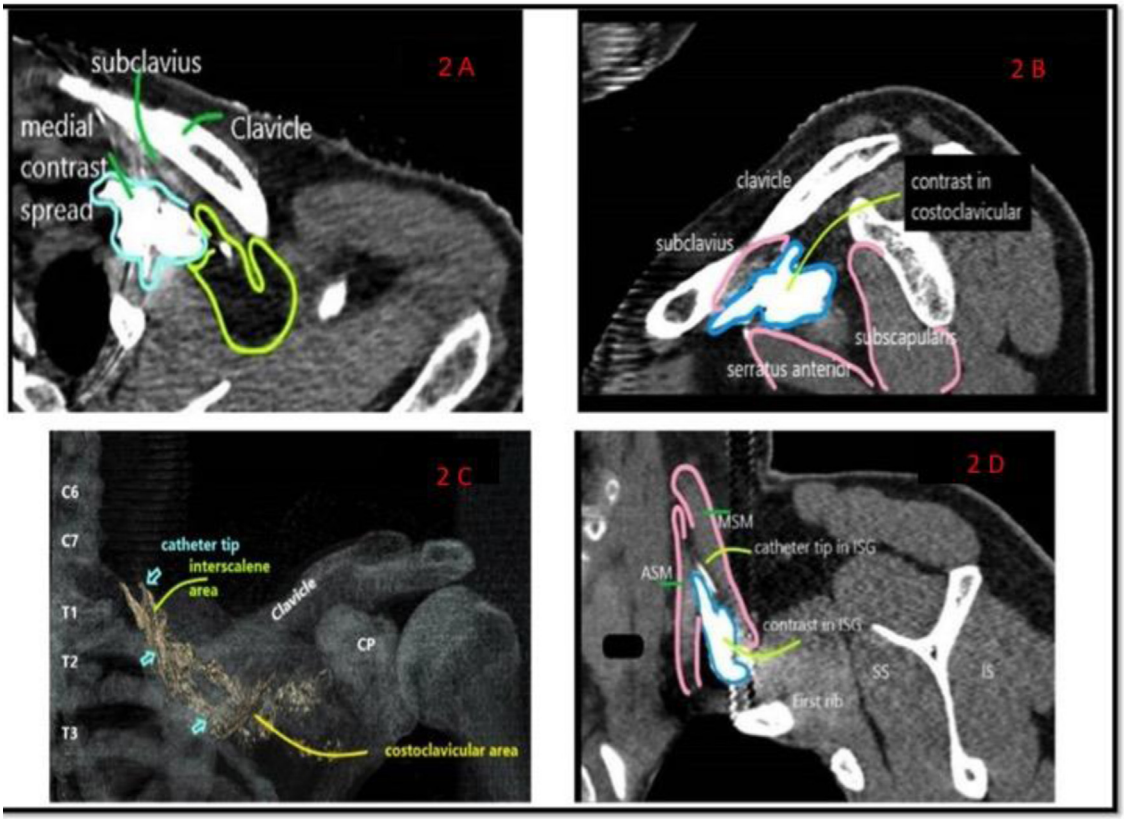

Fig. 2 A, axial view of contrast collection below the subclavius with a more medial contrast spread. B, sagittal view of contrast collection in CCS below the subclavius muscle. C, volume rendering CT technique of radiocontrast injection delineates the spread from CCS to the interscalene area delineating the cervical roots. CP, coracoid process. D, coronal view of contrast translocation in the posterior interscalene area between ASM and MSM. ASM, anterior scalene muscle; MSM, middle scalene muscle; SS, subscapularis; IS, infraspinatus; ESM, erector spinae muscle.

the drapes. During the surgery, 0.1% ropivacaine was infused at 4 $mL.h^{-1}$ through the catheter which was continued post-operatively.

After completion of the surgery, neuromuscular blockade was reversed with appropriate doses of neostigmine and glycopyrrolate, and the patients were transferred to post-operative recovery after tracheal extubation. The VAS at 0, 6, 12, and 24 hours was recorded and tramadol 50 mg IV was administered as rescue analgesia if VAS was more than 4. The first analgesic request time and the requirement of rescue analgesia in 24 hours were recorded. The VAS was less than 4 in the first 24 hours, at all points of time in all patients except in two who required tramadol 50 mg IV at 18 and 19.5 hours, respectively.

All patients were monitored in PACU and there was no drop in oxygen saturation in the immediate postoperative period. As a routine protocol in our institution, US-guided diaphragm excursions were noted before patients were discharged from the recovery room after all brachial blocks above the clavicle. None of the patients revealed hemi-diaphragmatic paresis. On the second postoperative day before the removal of the catheter, a CT (computed tomography) radiocontrast study was performed in two patients after informed consent. Five millilitres of Omnipaque (iohexol 300 mg $I.mL^{-1}$ diluted in 7 mL of normal saline 0.9%) was injected through the catheter and CT images of the dye spread were analysed in consultation with a senior radiologist.

The axial scan depicts the contrast beneath the subclavius muscle and a more medial spread in the infraclavicular area (Fig. 2A). A sagittal image demonstrated the contrast spread was seen localized beneath the subclavius, superficial to the serratus anterior and in front of the subscapularis muscles (Fig. 2B). An image of the CT volume rendering technique revealed a spread above the clavicle in the supraclavicular and interscalene area and below the clavicle, beneath the subclavius muscle in the costoclavicular space (Fig. 2C). The contrast injection leads to more cephalad spread filling the interscalene space between the anterior and the middle scalene muscle (Fig. 2D).

Discussion

In this case series, continuous CCB using retrograde stimulating catheter provided effective postoperative analgesia for open proximal humerus surgeries. The retrograde stimulating catheters could be placed successfully without any technical difficulty using neurostimulation. Further, the radiocontrast studies revealed the contiguous spread of contrast through the brachial plexus sheath in the supraclavicular region with a maximum spread in the costoclavicular space.

The shoulder joint is chiefly innervated by the suprascapular nerve which emerges from the superior trunk and the axillary nerve from the posterior cord at the lateral edge of the pectoralis minor. The other nerves contributing towards innervation are the subscapularis and lateral pectoral nerves arising from the posterior and lateral cords, respectively. Interscalene block is the gold standard regional anesthesia technique for shoulder surgery but it carries a risk of phrenic nerve palsy, with volumes greater than 5 mL. Literature mentions CCB efficiently anesthetizes the axillary, subscapular, and the lateral pectoral nerves which innervate the shoulder joint.[3] However, it is doubtful whether the suprascapular nerve which emerges from the superior trunk and courses below the omohyoid is blocked in CCB.

Our case series is based on the understanding that the costoclavicular space is continuous cranially with the supraclavicular fossa and caudally with the medial infraclavicular fossa above the superior border of the pectoralis minor muscle.[1,2] Previous anatomical study of costoclavicular space confirms the lateral cord is engulfed in a separate connective tissue, and the medial and posterior cords are closely opposed to each other. We, therefore, intended to place the stimulating catheter between the medial and posterior cord and then directed the catheter cephalad towards the supraclavicular fossa. The final tip position was confirmed with continuous neurostimulation by evoked muscle responses of the deltoid, biceps, or mixed contractions of the deltoid, biceps, and triceps. Positioning the catheter as demonstrated by CT contrast studies at the level demonstrated in our study is probably appropriate for shoulder surgeries.

Though there are randomized controlled trials comparing CCB with other regional anesthesia techniques for distal upper limb surgery, retrograde placement for catheter through costoclavicular space for shoulder surgery has not been previously described. Victoria et al discussed retrograde placement of a catheter in the supraclavicular area through the costoclavicular space.[4] However, a limitation of their technique was the need to advance the needle blindly behind the anechoic shadow of the clavicle; the final catheter tip position appeared as a hyperechoic dot at the corner pocket on the US.[4] Aldwinkle retorts that the above-mentioned technique is not simple, efficacious, or safe.[5]

Our technique embarks upon ''the journey behind the dark side of the moon'', as has been categorically and rightfully mentioned by Aldwinckle.[5] The stimulating catheter allows the continuous objective assessment of the catheter tip positioning in close contact with the brachial plexus. Thus, the combined use of the infraclavicular approach and supraclavicular placement of the catheter allows lesser volumes of a local anesthetic to block nerves innervating the shoulder joint. Local anesthetic injection at this point is followed by caudal spread as evident from two CT contrast studies performed in our series. Though we do not report phrenic nerve paresis, this needs to be investigated in a larger sample size. The ease of catheter fixation with lower chances of catheter displacement is the other potential advantage of this technique.

In our case series, there was no procedural complications in the form of vascular penetration, paresthesia related to the needle-nerve contact and during insertion and removal of the stimulating catheter. On the 5th postoperative day, a neurological evaluation of the operated side (block side) did not reveal sensory-motor dysfunction before patients' discharge. Surgeons follow up at 4 and 6 weeks was also normal in all the patients.

The tunneled catheter with biofilm dressing in our series was not a hurdle for the surgeon while performing surgery. Alternatively, catheters can be placed out-of-plane if the surgical team feels the catheter insertion interferes during surgery. In this series, we used 12 mL of local anesthetic for CCB. We need to explore subsequently whether a lesser volume of local anesthetic would be equally efficacious. Thus, we propose that a US-guided CCB with a retrograde stimulating catheter is a feasible alternative regional anesthesia technique for postoperative analgesia for shoulder surgery.

Conflict of interest

The authors declare no conflicts of interest.

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CASE REPORT

Management of airway obstruction following lidocaine nebulization in a case of tracheal stenosis: case report

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KEYWORDS
Airway obstruction;
Lidocaine;
Tracheal stenosis

Abstract Stenting for lower tracheal stenosis is a tricky situation and for the safe conduct of anesthesia, it is imperative to maintain spontaneous respiration. Airway topicalization is routinely recommended for anticipated difficult airway. We report a case of upper airway obstruction following lidocaine nebulization in a patient to be taken for tracheal stenting for lower tracheal stenosis. We would like to highlight that close monitoring of the patient is advisable during airway topicalization to detect any airway obstruction at the earliest and how fiberoptic intubation can play a pivotal role to secure the airway in an emergency scenario.

Introduction

Tracheal stenting for lower tracheal stenosis caused by anterior mediastinal mass poses a challenge to both anesthesiologists and surgeons. Depending upon the location, length, and severity of the stenotic segment, various anesthesia techniques for airway management may be chosen. To allow rigid bronchoscopy for tracheal stenting, spontaneous respiration is preferred to maintain airway patency by preserving transluminal pressure.[1,2] Nebulization with 4% lidocaine avoids cough reflex and aids in better patient cooperation. We hereby report a case of complete upper airway obstruction following nebulization with 4% lidocaine, while preparing the airway for tracheal stenting under sedation in a patient of lower tracheal stenosis, changing our primary plan, and turning a semi-emergent condition into an emergent one. Though fiberoptic intubation is not recommended as the first choice to manage the difficult airway in an emergency situation, it was lifesaving and probably the best choice available to secure the airway at the earliest in our case.

Case report

A 50-year-old female weighing 70 kg was scheduled to undergo tracheal stenting for severe lower tracheal stenosis caused by anterior mediastinal mass. On preanesthetic check-up, the patient was dyspneic in supine position,

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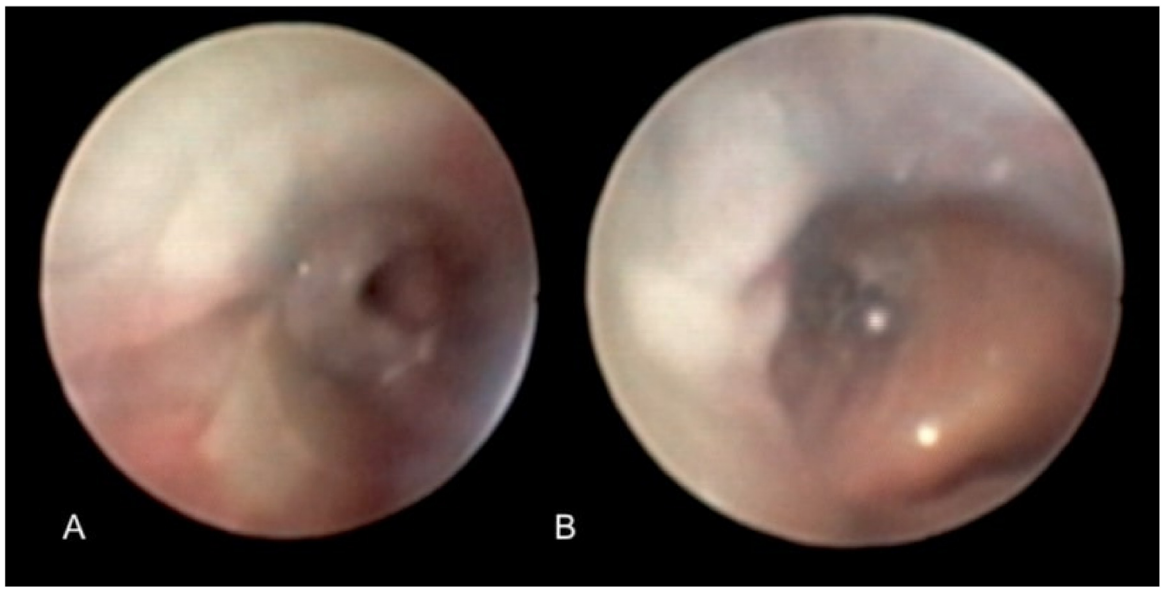

Figure 1 Segment of tracheal stenosis as seen through endotracheal tube (ET) using flexible intubation video endoscope (FIVE).

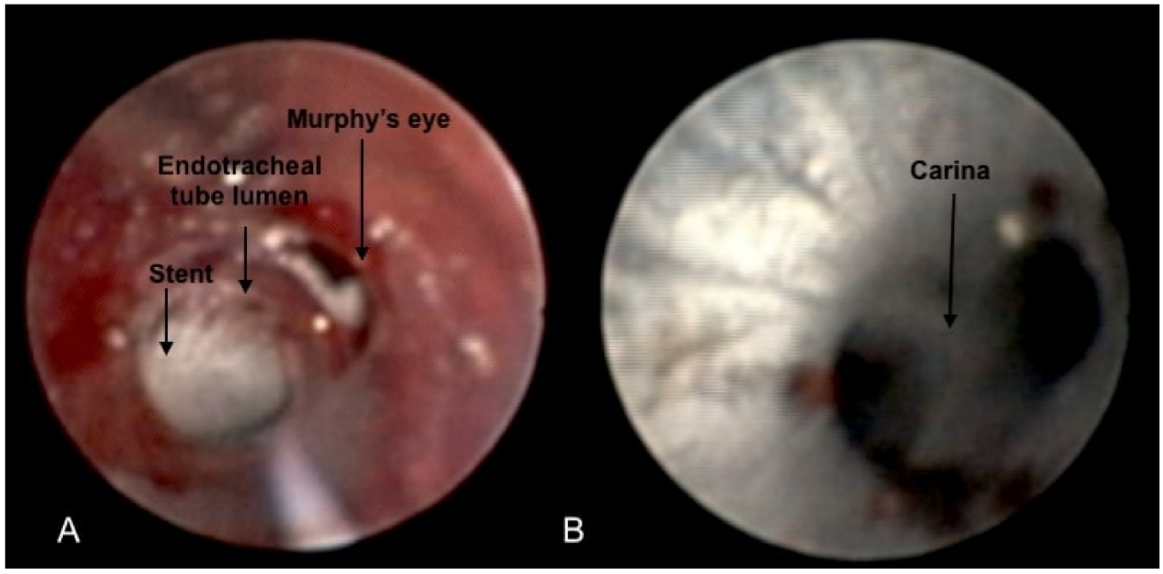

Figure 2 Post-procedure endoscopic views showing Y shaped tracheal stent (2A) just distal to the tip of ET and (2B) at the level of carina.

although comfortable and maintaining an oxygen saturation (SpO_2) of 99% on room air in the sitting position. The patient had no comorbidities and her blood investigations were normal. Modified Mallampati score was 2 and spirometry revealed reduced forced expiratory volume in the first second (FEV 1–1.95 L, 53% predicted), peak inspiratory, and peak expiratory flow rates (PEF–180 $L.min^{-1}$, 30% predicted). Arterial blood gas (ABG) analysis revealed mild impairment of oxygenation in the supine position with a pH of 7.457, PaO_2 of 70.8 mmHg, and $PaCO_2$ of 34.6 mmHg on room air. A thorax CT revealed an anterior mediastinal mass causing severe tracheal narrowing approximately 1.5 cm above the carina. Stenotic segment length was 1 cm with major and minor axis diameter of 4 mm and 3 mm, respectively. A preliminary plan was decided after discussion with the multidisciplinary team. Rigid bronchoscopy (RB) was planned under intravenous (IV) propofol and dexmedetomidine sedation after anesthetizing the airway by 4% lidocaine nebulization. On the day of surgery, the patient was nebulized with 5 mL of 4% lidocaine via a nebulizer mask with an oxygen flow rate of 12 $L.min^{-1}$ in the preoperative area. After 5 minutes of lidocaine nebulization, the patient developed stridor and dyspnea in the sitting position as well. Soon the patient became restless and developed tachycardia (heart rate 135 beats/min) and tachypnea (respiratory rate 28 breaths/min), and her saturation dropped to 92%. She was transferred immediately to the operating room (OR) for emergency tracheal stent-

ing. The patient was agitated and unable to lie down, so the OR table was changed to 90° head-up position, and all routine monitors were attached while oxygenating with 100% oxygen via nasal prongs. She developed hypotension (blood pressure 80/40 mmHg) and SPO_2 dropped to 90%. Nasopharyngeal airway (NPA) size 7.0 mm was inserted and a breathing circuit was attached to it using a 15-mm connector of the endotracheal tube (ET) size 7.0 mm. Sevoflurane with 100% O_2 was administered via breathing circuit to allow for emergency nasal intubation using Karl Storz, flexible intubation video endoscope (FIVE) (Model 11301 BNXK) through the other nostril. End-tidal carbon dioxide ($ETCO_2$) was noted to be as high as 90 mmHg. With the help of FIVE, the airway was secured with 6.5 mm ET and once the tube tip was placed just above the level of stenosis, the patient was hyperventilated to wash off retained CO_2. After changing the patient's position to supine, an invasive arterial catheter was inserted, and IV noradrenaline was started at 0.05 $\mu g.kg^{-1}.min^{-1}$ and titrated to maintain mean arterial pressure between 65–70 mmHg. Anesthesia was maintained with IV propofol infusion titrated to maintain a bispectral index of 40–60, fentanyl 2 $\mu g.kg^{-1}$ and atracurium 0.5 $mg.kg^{-1}$ loading dose followed by 0.1 $mg.kg^{-1}$ intermittent boluses. FIVE-guided examination of the stenosed area was done via ET (Fig. 1). The available deployer for tracheal stenting had an outer diameter of 11 mm which could not be passed through ET of any size, so under FIVE-guidance, ET was withdrawn till it was just beyond the glottis and tracheostomy stoma was made and deployer was inserted through it to place Y-shaped tracheal stent (Fig. 2A and B). Thereafter, the tube was inserted again to lie just above the stent margins and tracheostomy stoma was closed and the patient was electively ventilated to reach normocapnia and IV noradrenaline was gradually tapered off. The patient was extubated and shifted to the postoperative area for observation. Her postoperative vitals were stable, and she was later shifted to the ward.

Discussion

Tracheal stenting for lower tracheal stenosis is a tricky procedure that involves maintaining airway patency while providing optimal time and conditions for the surgeon. Maintenance of spontaneous respiration is essential during the induction of anesthesia to avoid airway obstruction.[1,2] In our case, after lidocaine nebulization, the patient developed stridor due to upper airway collapse, as shown with FIVE. Local anesthetic (LA) can depress laryngeal muscles or interfere with the receptor activity at the laryngeal level causing loss of upper airway muscle tone and precipitate airway collapse.[3] Similar scenario has been reported by Ho et al.[4] Airway obstruction by preexisting upper airway abnormalities can be anticipated by airway ultrasound, spirometry, CT, and MRI. But airway collapse by local anesthetic seems to be difficult to predict by such investigations, as it was not yet reported.

Fiberoptic intubation is not recommended as the first choice in severe acute airway obstruction.[5] However, in a sitting position, it was the most feasible option available to quickly secure an airway and with tracheal stenosis just 1.5 cm above carina, tracheostomy was unlikely to be helpful. NPA can prove to be a useful tool by relieving upper airway obstruction and improving oxygenation and ventilation by connecting it to a breathing circuit until a definitive airway can be secured. Inhalational agent can be administered through this set up to sedate the patient while avoiding loss of spontaneous respiration.

We would like to suggest that nebulization with LA should be dealt with caution and if feasible, should be done in a controlled OR environment and patients should be closely monitored for any signs of obstruction. Fiberoptic intubation by a competent and experienced anesthesiologist could be an important tool in securing emergent airways in such scenarios of acute airway obstruction with tracheal stenosis.

Conflicts of interest

The authors declare no conflicts of interest.

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Brazilian Journal of ANESTHESIOLOGY

CLINICAL IMAGES

Entrapped thrombus in transit

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A thrombus-in-transit, defined as a free-floating clot in the right heart, may be observed in patients experiencing acute pulmonary embolism.[1,2] The accompanying image exhibits a serpentine thrombus-in-transit entrapped within a patent-foramen-ovale (Fig. 1: Panel A). In addition to the pulmonary vasculature, such a thrombus can potentially embolize systemically, precipitating life-threatening conditions such as stroke and myocardial infarction. Consequently, emergent surgical embolectomy is imperative and necessitates institution of cardiopulmonary bypass. In our patient, a 15-cm snake-like thrombus, that was extending into the left atrium from the right atrium (Fig. 1: Panel B) was extracted intact (Fig. 1: Panel C).

Anesthetic management is challenging, especially when increased pulmonary vascular resistance and tachyarrhythmias related to pulmonary embolism precipitate acute right heart failure and systemic hypotension. Anesthesia induction can further worsen systemic hypotension compromising coronary perfusion and ventricular contractility. This may precipitate hemodynamic collapse necessitating emergent institution of cardiopulmonary bypass, during or shortly after anesthesia induction. Consequently, prior to induction, the surgical team should prepare and drape the patient in readiness to make the incision. However, cannulation of femoral vessels for emergent institution of cardiopulmonary bypass is not recommended as additional thrombi in the inferior vena cava can potentially embolize during manipulation.[2,3]

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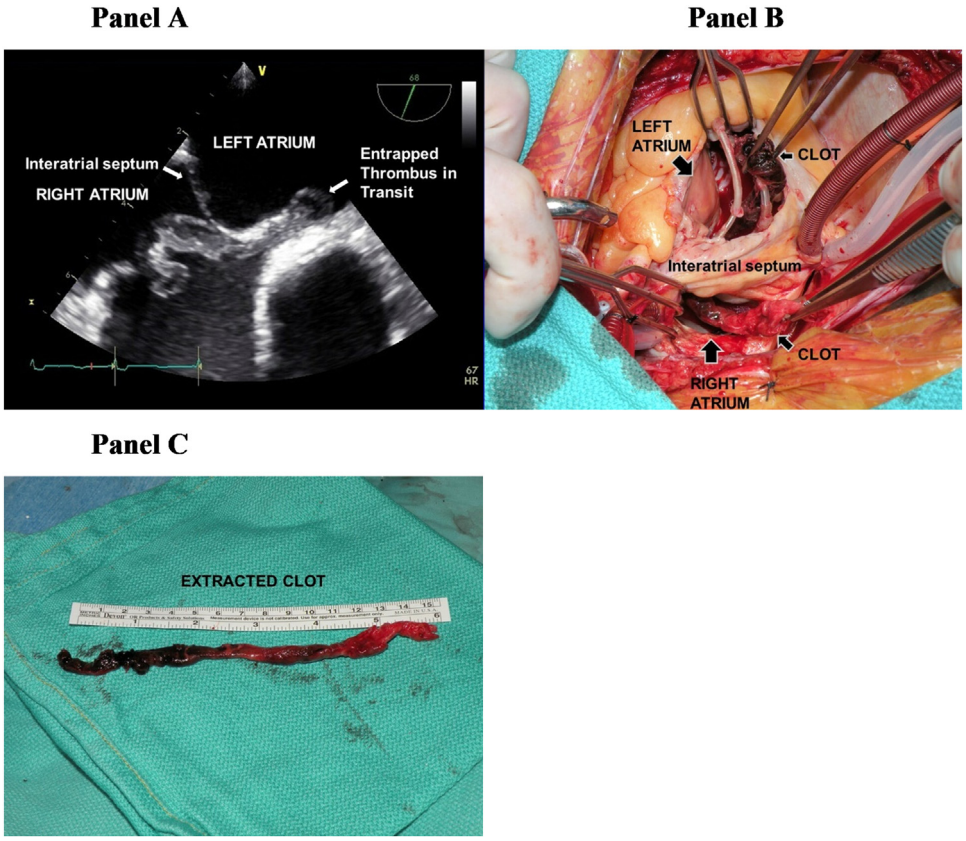

Figure 1 Caption: An entrapped thrombus in transit, visualized with transesophageal echocardiography (Panel A), was found to be extending from the right atrium into the left atrium through a patent-foramen-ovale during surgical exposure (Panel B) and was extracted in its entirety (Panel C).

Conflicts of interest

None.

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CLINICAL IMAGES

Intraoperative point-of-care subcostal Inferior Vena Cava (IVC) imaging to detect embolism during hip arthroplasty: clinical image

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These images and video were obtained using a low-frequency curvilinear probe, at the subcostal Inferior Vena Cava (IVC) view on a patient with poor functional reserve undergoing a Total Hip Arthroplasty under spinal anesthesia. Embolic material in-transit was initially identified after hip luxation with progression of severity culminating in an embolic storm during cementing (Fig. 1). The embolic phenomena preceded hemodynamic instability and an episode of cardiac arrest in pulseless electrical activity. Cardiopulmonary resuscitation was successful. Surgery finalized without further events once the

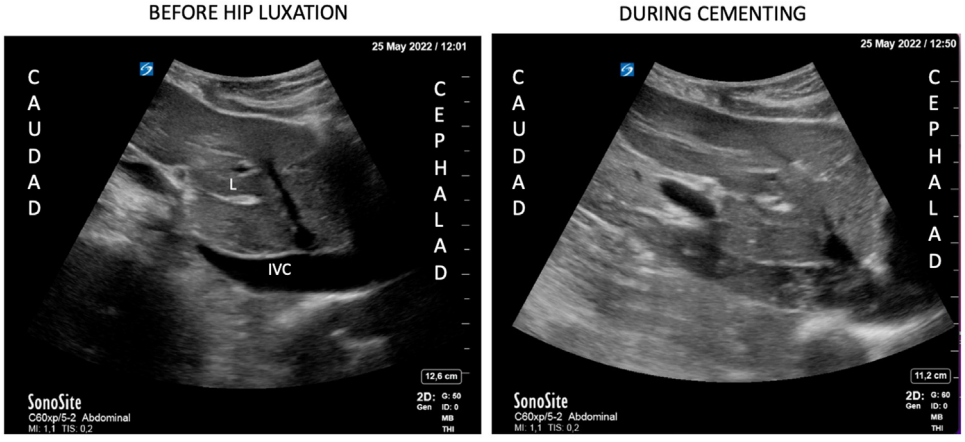

Figure 1 IVC subcostal view before hip luxation and during cementing. L, Liver; IVC, Inferior Vena Cana.

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patient was stabilized. Once fully recovered, the patient was discharged home within 72 hours. She provided written informed consent for publication.

Embolic events are common but mostly undiagnosed phenomena during hip and knee arthroplasties.[1] However, severe embolic episodes may lead to hemodynamic collapse. The etiology of these emboli is believed to be mixed with bone and soft tissue debris, thrombus, and cement.[2] The use of Transesophageal Echocardiography (TEE) is well-described in the literature to diagnose and quantify embolic events during arthroplasty.[3] However, TEE is not readily available in non-cardiac operating rooms and may not be feasible to perform in patients under spinal anesthesia and mild sedation. We here report the use of the subcostal IVC view as less invasive and more widely available alternative to monitor for embolic phenomena in real time during orthopedic surgery. The early identification of severe embolic events can alert the anesthesiologist and assist in early resuscitation and hemodynamic support, as well as potentially guide surgical technique and timing to prevent further embolization.

Conflicts of interest

None.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjane.2023.02.007.

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Brazilian Journal of ANESTHESIOLOGY

LETTER TO THE EDITOR

Cost-minimization analysis of the continuous real-time pressure sensing technology in parturients requesting labor epidural analgesia

Dear Editor,

Epidural analgesia and anesthetic techniques are routinely used in the perioperative setting, including the labor and delivery unit and for chronic pain management. The success of these procedures relies on the correct identification of the epidural space by the operator. Globally, approximately 140 million births occur every year. Epidural labor analgesia is used in most births either alone or as a component of a combined spinal epidural technique.

Surface landmarks, tactile feedback from the needle, and Loss-Of-Resistance (LOR) to saline or air injection are traditionally used to guide the needle into the epidural space. Epidural analgesia, based on successful identification, successfully finding of the epidural space, is an integral part of the practice of anesthesia. This traditional LOR technique has undergone major modifications as a result of improvement in the needle, catheter, and technique following the first demonstration by Dogliotti in 1931.[1] However, reported epidural failure rates using LOR for epidural space identification vary greatly and have been reported to range from 1.5% up to 23%.[2]

In addition, complications such as Accidental Dural Puncture (ADP) are an important and common complication of epidural block with reported rates of 0.5% to 4%.[3] ADP occurs if the dura is perforated by the epidural needle or by the epidural catheter.[4] Following ADP, the incidence of Postdural Puncture Headache (PDPH) has been reported to be more than 25% in young patients. Pregnant women are particularly prone to PDPH,[5] which is frequently severe or incapacitating, markedly postural, and of at least several days duration. It often interferes with maternal-infant interaction. It is a substantial source of higher anesthetic burden, extended hospitalization, and the necessity for further therapy and procedures such as epidural blood patch.[4]

The use of continuous, real-time pressure sensing technology has been recently validated as a tool to identify the epidural space. To date, there is no published data showing cost of the continuous real-time pressure sensing technology technique. Therefore, the aim of this study was to conduct a cost-minimization analysis of real-time pressure sensing technology in parturient requesting labor epidural analgesia.

The study protocol was approved by the Institutional Review Board of the University of Texas Medical Branch at Galveston (UTMB) (IRB # 19-0056, 4 April 2019). In order to estimate the costs on Labor Epidural Analgesia (LEA) and the downstream complications for the cost-minimization analysis, we used data from Electronic Health Records (EHR) (Epic Clarity Database, Epic Systems Corporation, Verona WI) at the UTMB to identify parturient aged between 18 and 50 who had epidural anesthesia for planned vaginal delivery between November 2015 and February 2019.

For the cost-minimization analysis, we estimated the total cost, from the hospital perspective, for the hospital stay for delivery and readmission for EBP, if any. We first categorized patients into two groups by the presence of epidural replacement. Successful epidural placement is defined as baby delivered without epidural replacement or additional analgesia technique or medications. Within each group, we further categorized the patients into three groups: 1) No PDPH or EBP; 2) With PDPH but no EBP; 3) With EBP. Patients who had multiple epidural procedures for epidural anesthesia during hospitalization were considered to have epidural replacement. PDPH after epidural anesthesia was identified using the International Classification of Diseases (ICD), 10th Revision, Clinical Modification (ICD-10-CM) codes O74.5 and O89.4. All costs were adjusted to the same time period (February 2019), using the Consumer Price Index for medical care.

The decision model framework for cost-minimization analysis comparing real-time pressure sensing technology and traditional LOR technique is presented in a supplemental figure. This hospital perspective analysis was performed using TreeAge Pro 2019 (TreeAge Software, Inc., Williamstown, MA). The effectiveness was pain during delivery estimated by patients on a Numerical Rating Scale (NRS), ranging from 1 to 10. We assumed these two methods are equally effective in managing pain during labor, which has a

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Table 1 Cost[#] associated with epidural anesthesia for planned vaginal delivery.

Epidural replacement	PDPH	EBP	n	Mean ± SD	Median[§]
No	No	No	3928	17,414.53 ± 6335.22	16,272.40
	Yes	No	66	19,201.23 ± 13686.01	17,026.01
		Yes	20	23,772.33 ± 6856.11	21,359.12
Yes	No	No	454	22,452.14 ± 13038.52	20,457.53
	Yes	No	8	24,935.07 ± 5093.90	24,212.93
		Yes	7	25,700.02 ± 4157.85	25,279.51

[#] Total cost for the hospital stay for spontaneous vaginal delivery and readmission for EBP, if any.
[§] Median costs were used in the cost-minimization analysis model. SD: Standard Deviation; PDPH: Post-dural-puncture headache; EBP: Epidural blood patch.

Table 2 Incremental cost of the traditional method compared to the real-time pressure sensing technology method.

Method	Cost	Incremental cost	Effect (pain score)	Dominance
Study device	16,363.02	0.00	2.00	
Traditional	16,866.96	503.94	2.00	Dominated

NRS of 2. The parameters used in the model are listed in supplemental Table 1, including the aforementioned cost estimates from the six scenarios. The probabilities of epidural replacement and PDPH for the real-time pressure sensing technology were obtained from our prior publication. The same cost estimates were used on the arm of real-time pressure sensing technology with the additional cost of using this device.

For cost estimation, we included 4483 deliveries among 4353 parturient. We examined parturient characteristics, including age, Body Mass Index (BMI), gravidity, parity, and race at the inpatient visit for delivery. Our population was mean age of 27.4 years, mean BMI of 32.3, mean gravidity of 2.7 and parity of 1.7. Majority race/ ethnicity was Hispanic or Latino (57.8%), followed by White (26.7%) and African American (11.3%). In the 4483 deliveries, 469 (10.5%) had epidural replacement and 101 (2.25%) had postdural puncture headache. Not surprisingly, those who had epidural replacement and epidural blood patch had the highest cost, while those without, had the lowest cost (median cost $25,279.51 vs. $16,272.40) (Table 1). These cost estimates were used in the cost-minimization analysis comparing the real-time pressure sensing technology and the traditional LOR method. Parameters used in the cost-minimization analysis model are presented in the supplemental Table 1. The decision model is presented in the Supplemental Figure 1. Using real-time pressure sensing technology as the comparison reference, the incremental cost of the traditional method is presented in Table 2. Compared to the traditional LOR technique, real-time pressure sensing technology costs about 504 US dollars less per hospital stay on average. Given that we used the same cost estimate for delivery and complication treatment on both arms in each of the six scenarios, the cost savings achieved by the real-time pressure sensing technology was due to the lower likelihood of epidural replacement and PDPH (Table 1).

To our knowledge, this is the first, large-scale study in the literature comparing costs of the traditional LOR technique and real-time pressure sensing technology in parturient requesting Labor Epidural Analgesia (LEA). In this cost-minimization analysis study, we found that compared to the traditional LOR technique, real-time pressure sensing technology saves about 504 US dollars in parturient requesting labor epidural analgesia per hospital stay on average.

Funding

The study was supported by Milestone Scientific, Inc. The sponsor was not involved in data acquisition, analysis, or interpretation of the results. This manuscript was written by the investigators. None of the authors has a personal financial interest in this research.

Conflicts of interest

Rovnat Bababzade, declared that he received one-time honoraria for delivering lectures on use of continuous real-time pressure sensing technology in parturients for Milestone Scientific. Other listed authors declare that they have no conflicts of interest.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjane.2022.06.004.

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LETTER TO THE EDITOR

Comparison of tranexamic acid and stapling line reinforcement in laparoscopic sleeve gastrectomy in postoperative bleeding outcomes

Dear Editor,

Laparoscopic Sleeve Gastrectomy (LSG) is a type of bariatric surgery considered safe and technically simpler to perform than gastric bypass. One risk of this technique is bleeding in the staple line, with an incidence of up to 10%.[1,2]

The option of using Tranexamic Acid (TXA) as an auxiliary method to reduce bleeding is a possibility and has the advantages of low cost and fast execution.[1] A dose of 1g has been suggested to produce a reduction in bleeding that is not improved by giving higher doses and is likely to be sufficient for most adults.[3,4]

Due to the small number of studies on the use of TXA and the controversial results in Staple line Reinforcement (SR) techniques in bariatric surgeries, the authors decided to compare the efficacy of SR and the use of TXA in the reduction of complications of the LSG technique.

The study was a prospective, comparative, double-blind, non-randomized clinical trial, approved by the institutional Research Ethics Committee (CAAE 95198518.9.0000.5085/ Number 4.058.659) and registered in the Brazilian Registry of Clinical Trials (REBEC RBR-4w39gz). Patients aged 18 to 65 years, American Society of Anesthesiologists (ASA) physical status II or III, who underwent LSG from January 2019 to June 2020 were included in the study.

The selected patients either received venous tranexamic acid (1g) at anesthesia induction (TXA Group), no intervention (Control Group — CG), or received Staple line Reinforcement (SR group) without TXA. Perioperative care protocols were the same for all groups.

To help minimize potential bias induced due to non-randomization, the researchers who collected the data and measured the outcomes did not know which group each patient belonged to. The sample size calculation was an estimated n of 90, with a confidence level of 95% and a margin of error of 5%.

Clinical and surgical data were collected. Data from laboratory tests were also collected at the time anesthesia was administered and 24 h postoperatively. Intraoperative bleeding was evaluated by the number of hemostatic interventions performed to control the bleeding points in the staple line. Estimated intraoperative bleeding was assessed by weighing the gauze and the volume of blood found in the suction pump reservoir at the end of the operation. Postoperative bleeding was evaluated in patients who underwent reoperations, and a comparative quantitative evaluation was performed of the hematological data obtained by laboratory tests at the time anesthesia was administered and 24 h postoperatively (Table 1).

The following were used: chi-square test for categorical variables, ANOVA for parametrical numerical variables, and Kruskal-Wallis for nonparametric variables. Post hoc analysis was performed with the Bonferroni test. Statistical significance was set at $p < 0.05$.

A total of 89 patients were included: 31 in the Control Group (CG), 30 in the Tranexamic Acid Group (GTXA), and 28 in the Staple line Reinforcement Group (GSR). The clinical characteristics of the patients were similar among the groups. Moreover, there was no difference in the duration of surgery and anesthesia (Table 1).

Although a significant reduction in the surgical time was observed in another study for patients who used TXA,[1] in this clinical trial, this factor was not statistically relevant. In a retrospective review,[5] a significant increase in the surgical time of patients who received SR intervention was verified, as well as the necessity of having this method performed by trained professionals to avoid complications resulting from this procedure[5] (Table 1).

The hemodynamic variables and hematological data were similar among the groups before surgery. Regarding the parameters for bleeding assessment, bleeding volume was greater in the CG (median 80 mL; 30—300) than in the GTXA (median 50 mL; 20—110) $p = 0.013$, but there was no difference concerning the weight of the gauze and the number of interventions applied to control bleeding (sutures and clips) among the three groups. In the postoperative period, GTXA patients were observed to have a higher hemoglobin value ($p = 0.023$), higher hematocrit ($p < 0.001$), greater prothrombin activity ($p = 0.004$), and lower INR value ($p = 0.013$) than the control group. The GSR also had a higher hematocrit value ($p < 0.001$) and prothrombin activity ($p = 0.004$) than the CG. A similar result was shown in the study performed by Chakravartty et al.,[3] which also applied this approach for bariatric surgeries (Table 1).

In the CG group, one patient developed a large hematoma of the abdominal wall that did not require intervention, and

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Table 1 Comparation between groups.

Variables	Group			*p*-value
	Group Control	Group TXA	Group SR	
Clinical characteristics of patients				
Age				
Med (Min–Max)	37 (24–59)	36 (19–62)	36 (19–64)	0.672[a]
Gender				
Female	26 (83.9%)	19 (63.3%)	22 (78.6%)	0.158[b]
Male	5 (16.1%)	11 (36.7%)	6 (21.4%)	
Diabetes Mellitus				
Yes	7 (22.6%)	7 (23.3%)	7 (25%)	0.976[b]
No	24 (77.4%)	23 (76.7%)	21 (75%)	
Hypertension				
Yes	10 (32.3%)	10 (33.3%)	8 (28.6%)	0.920[b]
No	21 (67.7%)	20 (66.7%)	20 (71.4%)	
Previous Surgeries				
Yes	19 (61.3%)	18 (60%)	12 (42.9%)	0.291[b]
No	12 (38.7%)	12 (40%)	16 (57.1%)	
Weight (kg)	96.5 ± 10.9	103.9 ± 15.1	99.4 ± 9.4	0.062[c]
Height (cm)	160.5 ± 8.6	164.4 ± 7.9	161.7 ± 5.8	0.116[c]
BMI	37.3 (33.6–41.9)	38.1 (32.4-50.3)	38 (33.5-43.4)	0.475[a]
Length of surgery (minutes)	92 ± 18	85 ± 17	86 ± 19	0.329[c]
Length of anesthesia (minutes)	140 ± 22	128 ± 23	133 ± 28	0.197[c]
Comparison of hemodynamic variables and hematological data in the preoperative period between the groups evaluated				
Heart rate (bpm)	76 (52–92)	73 (54–95)	72 (55–114)	0.792[a]
Systolic BP (mmHg)	120 (80–158)	108 (90–160)	113 (84–160)	0.097[a]
Diastolic BP (mmHg)	74 (40–99)	70 (43–100)	80 (50–94)	0.577[a]
Mean BP (mmHg)	88 ± 16	85 ± 13	87 ± 11	0.550[c]
Hemoglobin ($g.dL^{-1}$)	12.3 ± 1.3	12.65 ± 1.2	12.20 ± 1.0	0.076[c]
Hematocrit (V/V) %	36.7 ± 3.7	38.1 ± 3.5	37.3 ± 2.8	0.263[c]
Platelets	252 ± 43	251 ± 55	236 ± 37	0.327[c]
Prothrombin Time (s)	14.4 (13.3–15.4)	14.3 (13.4–16.5)	14.2 (13–15.2)	0.134[a]
Prothrombin Activity (%)	84 ± 5	84 ± 8	85 ± 5	0.690[c]
TTPa (s)	31.1 (21.3–39.2)	31.6 (21.5–39.9)	31.4 (24.5–39.1)	0.567[a]
RTTPa	1.05 (0.72–1.33)	1.06 (0–1.22)	1.05 (0.83–1.33)	0.088[a]
INR	1.12 (1–1.21)	1.11 (1–1.32)	1.11 (1.04–1.22)	0.615[a]
Fibrinogen ($mg.dL^{-1}$)	289 ± 59	298 ± 41	310 ± 46	0.244[c]
Comparison of interventions to control bleeding and intraoperative bleeding between the groups evaluated				
N° of interventions for bleeding control (Suture or Clips)	8 (4–24)	11 (6–18)	9 (6–16)	0.469[a]
N° Clips for hemostasis	2 (0–18)	5 (0–12)	3 (0–10)	0.483[a]
Gauze Weight (g)	15 (10–50)	20 (10–50)	20 (10–65)	0.580[a]
N° Staples	6 (5–8)[a]	6 (6–7)[a]	6 (5–7)	0.005[a]
Vol. of blood on pump (mL)	80 (30–300)[a,b]	50 (20–110)[a]	100 (50–120)[b]	0.013[a]
Comparison of hematological data in the postoperative period between the groups evaluated				
Hemoglobin ($g.dL^{-1}$)	12.3 ± 1.4[a]	13.2 ± 1.4[a]	12.8 ± 0.9	0.023[c]
Hematocrit (V/V) %	36.4 ± 4.2[a,b]	38.7 ± 3.6[a]	38.8 ± 2.8[b]	0.000[c]
Platelets	266 (196–408)	251 (116–382)	274 (173–378)	0.463[a]
Prothrombin Time (s)	14.6 (11.9–15.7)	14.6 (13.4–29.2)	14.6 (13.5–15.7)	0.905[a]
Prothrombin Activity (%)	80 (71–96)[a,b]	82.5 (62–99)[a]	85 (69–93)[b]	0.004[a]
TTPa(s)	29.1 ± 1.8[a]	30.3 ± 2.7	30.7 ± 2.3[a]	0.032[c]
RTTPa	1.02 ± 0.11	1.04 ± 0.07	1.04 ± 0.08	0.547[c]
INR	1.16 (1.06–1.9) [a]	1.11 (1–1.35) [a]	1.13 (1.05–1.27)	0.013[a]
Fibrinogen ($mg.dL^{-1}$)	309 (205–481)	329 (234–477)	341 (252–492)	0.208[a]

BMI, Body Mass Index; TXA, Tranexamic Acid; SR, Staple Line Reinforcement; BP, Blood Pressure; TTPa, Activated partial thromboplastin time; RTTPa, Activated partial thromboplastin time ratio; INR, International normalized ratio.

[a] Kruskal-Wallis;

[b] Chi-Square;

[c] ANOVA; For statistical significance the value of $p < 0.05$ was considered; Equal over-written letters indicate statistical difference in the inter-group post hoc analysis.

another patient required surgical intervention for intra-abdominal bleeding on the first postoperative day, with 300 mL of blood being aspirated.

Four patients in the CG group had to remain hospitalized for 3 days. Thus, the time of hospitalization was longer in the CG (median 2; 2—3) than in the GTXA (median 2; 2—2), and in the GSR (median 2; 2—2) ($p = 0.019$).

The length of hospital stay of patients undergoing bariatric surgeries may vary among institutions using different discharge protocols. Although there already are strategies and protocols to reduce the length of hospital stay, such as ERAS, additional methods for avoiding complications that increase the length of hospital stay are continuously being investigated. Considering that bleeding is a complication commonly reported by studies that investigated the surgical complications of bariatric surgery and had the largest impact on hospital stay, the possibility of improving patient outcomes by intervening in this problem becomes even greater.

Despite the risk of thromboembolic events, the safety of this approach was demonstrated by the absence of thromboembolic events and adverse events in this study, and the patients were monitored for at least 6 months after surgery. This result was similar to the few studies that used TXA in the context of bariatric surgeries, including Chakravartty et al.,[1] who used tranexamic acid in the preoperative period of LSG.

Despite the limitations, the use of tranexamic acid was statistically relevant in reducing intraoperative bleeding volume, presenting less postoperative complications, which led to a reduction in the length of hospital stay. Thus, tranexamic acid can be an important alternative for preventing bleeding in the stapling line of patients undergoing LSG.

Ethical approval statement

Institutional Research Ethics Committee (CAAE 95198518. 9.0000.5085/Number 4.058.659) and registered in the Brazilian Registry of Clinical Trials (REBEC RBR-4w39gz).

All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent statement

Informed consent was obtained from all individual participants included in the study.

Conflicts of interest

The authors declare no conflicts of interest.

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LETTER TO THE EDITOR

Letter to the Editor regarding "Comparison of the intubation success rate between the intubating catheter and videolaryngoscope in difficult airways: a prospective randomized trial." Braz J Anesthesiol. 2022;72 (1):55-62

Dear Editor,

Airway management is fundamental to the practice of anesthesiology and recent guidelines have summarized best practices in securing the airway in surgical patients.[1,2] The definition of a difficult airway has been debated but it is generally accepted that if a trained clinician cannot view the vocal cords and/or cannot place the endotracheal tube into the trachea, this airway could/should be documented as "difficult".[3] Despite these recent publications, it is still unclear how best to manage the unexpected or unanticipated difficult airway. Without quality publications to rely on, the management of the unanticipated difficult airway is often guided by personal preference, anecdotes, and tunnel vision among practicing clinicians. Indeed, laryngoscopy and intubation are two separate procedures and require different troubleshooting techniques when difficulty is encountered. The recent prospective trial published by Ozdemirkan and colleagues[4] randomized patients with difficult airways (i.e., failed direct laryngoscopy on the first attempt) to either a laryngoscopy enhancement (i.e., the McGrath video laryngoscope) or an intubation enhancement (i.e. the Frova intubating catheter with a coude tip in conjunction with direct laryngoscopy) for the second attempt. Specifically, the participating clinicians in this study were expert anesthetists with > 50 intubations with both devices. This study is highly novel and impactful for the field of anesthesiology. I have a few questions and comments for the authors.

The authors performed a thorough airway preoperative assessment, pre-oxygenated their patients sufficiently prior to induction of anesthesia, and chose dosages of propofol and rocuronium to optimize intubating conditions. Nevertheless, they found 50 patients who were difficult to intubate by direct laryngoscopy in the 32 months of their study (January 2015 to August 2017). I have several questions about the Methods. How many patients during this time period were easy to intubate by these experienced clinicians? Did all of these patients consent to possible enrollment in this study? The unconscious patients deemed difficult to intubate were randomized into the study. How were randomization and allocation concealment performed? Did the clinician performing intubation always have a helper to decide what the treatment would be (McGrath vs. Frova)? Were both devices available in all operating rooms or did these come from a central location? Did mask ventilation occur as the randomization process was being performed? The patients in this study were mostly young and health people undergoing elective surgery. What surgeries were the patients undergoing? Why did the authors use such large endotracheal tubes? Size 7.5—8.5 mm in women and 8.5—9.5 mm in men are difficult to place in the trachea even under the best of circumstances. Were these cuffed or uncuffed tubes? Did the authors perform cricoid pressure or the backwards-upwards-rightward pressure maneuever to optimize the view of the vocal cords? Also, a glaring concern about this study is that it was registered on the Australia New Zealand Clinical Trials registry retrospectively (i.e., in 2018 after data collection had already occurred).

Regarding the Results, in the Cormack and Lehane view between the two devices is markedly different. With the McGrath, 17/24 patients were a grade 2 view whereas only one person was a grade 2 view with the Frova intubating catheter and direct laryngoscopy (22/25 patients were grade 3 views with Frova intubating catheter). This finding clearly delineates that laryngoscopy and intubation are two separate procedures and require different troubleshooting techniques when difficulty is encountered. Specifically, the Frova intubating catheter is indicated when the laryngoscopy view is suboptimal. The key findings that 22/25 people could be intubated with the Frova catheter compared to 16/24 with the McGrath did not reach statistical significance but is clinically impactful. It is also worth noting that combined use of the McGrath and Frova was successful when the initial attempt was unsuccessful.

The implications of this study are potentially vast. In limited-resource environments, what tool(s) should anesthesia providers have on hand when direct laryngoscopy is not adequate? The data in this publication can also be helpful for the education of resident physicians and student anesthetists. Prior studies have shown that trainees need 30–50 successful attempts in order to be proficient in different

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procedural tasks.[5] However, these numbers have wide variability and do not necessarily reflect performance in unique or stressful situations such as the unanticipated difficult airway. Are there opportunities to practice with the McGrath and the Frova intubating catheter in "easy" airways in order to be prepared for the rare unanticipated difficult airway? Once the authors comment on my questions above, the readers of this journal will be able to determine if the strong experimental methods of this published study (internal validity) apply to other patients undergoing surgery and anesthesia around the world (external validity).

Conflicts of interest

The authors declare no conflicts of interest.

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LETTER TO THE EDITOR

Comment on: Effect of magnesium sulfate with ketamine infusions on intraoperative and postoperative analgesia in cancer breast surgeries: a randomized double-blind trial

Dear Editor

To begin, we would like to congratulate Hassan and Mahran for their well-conducted research featured recently in the *Brazilian Journal of Anesthesiology*. While the meticulously double-blinded randomized trial outlines a reduced intraoperative and postoperative opioid consumption with the addition of magnesium sulfate to ketamine infusion in patients undergoing breast cancer surgeries,[1] certain points mandate elucidation to extend a clinical perspective to the authors' findings. Firstly, the index study relies on the hemodynamic parameters as surrogates for intraoperative nociception and hence, fentanyl administration. Alongside the debatable sensitivity and specificity of the former in nociception monitoring,[2,3] the matter is compounded by the lack of comparative account of hypertensives in the two study groups (albeit, the authors describe uncontrolled hypertension as an exclusion criterion). Secondly, the authors fail to present any details on whether or not any form of depth of anesthesia monitoring was employed. Thirdly, the comparable postoperative pain and sedation scores between the two groups are difficult to explain, in background of a substantially lower postoperative morphine requirement and/or consumption in the magnesium sulfate + ketamine group as opposed to the ketamine alone group.[1] Lastly, while the ability of the study to detect any statistically meaningful differences in chronic pain could have been precluded by a small sample size, the incorporation of patient satisfaction and/or postoperative recovery would have added incremental value.

Conflicts of interest

The authors declare no conflicts of interest.

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