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# GENERAL DISCUSSION





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This thesis aims to understand important issues on perioperative safety in middle-income countries and provide potential ways to improve quality and safety. This discussion chapter starts with an overview of the findings and considerations of the previous chapters. Then, it presents some perspectives on the ongoing scientific discussions with special emphasis on “evidence” in patient safety, and, finally, it addresses some future developments and areas of interest for further study.

In the last 10 years the author -as anesthesiologist and pain practitioner- has provided perioperative care for many patients. He became conscious of the need to improve quality and safety there and started his research in the field of perioperative safety. Findings presented have contributed mainly to create awareness about potential scenarios to improve quality and safety in the perioperative period in Colombia.

Three major questions were considered as the basic framework of this thesis and this section is directly related to each one: 1) What is the current state of Randomized Controlled Trials and Systematic Reviews on Patient Safety worldwide?, 2) Is there any validated approach to assess safety at perioperative care in middle-income countries like Colombia? and 3) Which perioperative interventions on quality and safety potentially affect patients in low- and middle-income countries?

### This thesis

Chapter 1 illustrates that, despite the increased alertness for patient safety, there is still a paucity of evidence about interventions in patient safety -at any level of health care-. Even considering well-ranked journals which address specifically topics related to patient safety and the health-care quality, the number of randomized controlled trials and systematic reviews on patient safety is scarce the limited evidence is mainly from developed high-income countries. In the 37-year period analyzed, there were 83 randomized trials and 64 systematic reviews published (11 with meta-analysis).

Scientific output and evidence in the field of patient safety has increased dramatically in recent years. Much of this consists of basic research in related disciplines such as psychology, sociology or organizational studies (1,2). However, none of the top 10 highest-cited patient safety papers comes from a low- or middle-income country (2).

Research on the efficacy of the interventions to decrease unnecessary risks related with patient safety has some particularities, clarified by Brown et al.: First, patient safety interventions are often “complex interventions” which require a carefully planned evaluation and development. Sometimes interventions as well as outcome evaluations are difficult to blind. Second, patient safety interventions are often delivered and implemented at “groups of subjects” (or clusters, i.e. people at operating room, hospitals, certain population area) rather than at an individual level, in an equally complex environment, such as

health organizations. Third, patient safety interventions are often expected to do more good than harm, implying that professional equipoise may be absent. Therefore, traditional study designs such as a parallel randomized controlled trial may not be ethically acceptable. Finally, if patient safety research refers to interventions to prevent harm, countable outcomes are rare events and in many times difficult to assess. They entail for large multicenter studies and collaboration with increase in cost and logistics (1,3–6).

Prospective randomized controlled trial is considered the research design of choice to evaluate the efficacy of health interventions providing the most robust evidence (7). Nevertheless, interventions in patient safety are not suitable to be studied using only this approach. Clearly, studies on interventions (using randomization) are less common than large observational population studies into the incidence and causes of medical errors (2). At a first glance, this could be interpreted as a lack of strong evidence, but as Leape et al. suggest this lack of evidence means that “the traditional evidence-based approach cannot be the sole source of information for advancing patient safety” (5,8).

In quality and patient safety, improvement initiatives could be practical (aimed at producing change) and scientific (aimed at producing new knowledge). These initiatives include more methodological and study designs approaches like variants of trial designs, stepped wedge trial designs, quasi-experimental designs, before-after studies, program evaluations, process evaluations, qualitative studies and economic evaluations (9).

A limitation of chapter 1 is that it does not provide an overall overview of all those approaches. Nevertheless, randomized studies included in this chapter addressed important patient safety topics, like clinical process or procedures, resources or organizational management, medical devices and equipment and finally, safety during the administration of medication or intravenous fluids. Many of them have direct relationship with the perioperative period. In 2004, the World Alliance for Patient Safety of the World Health Organization launched a consensus-based list of global priorities for patient safety, including a research agenda (10,11). After its first edition, this list has not (yet) been updated. The work presented in chapter 1 showed the very limited number of randomized trials and systematic reviews published on the effect of interventions to improve hot listed topics by the World Health Organization. This may reflect an undetermined number of randomized trials and systematic reviews that are published in journals of general practice or other medical specialties due to their special scope (2).

Finally, chapter 1 shows how it is still necessary to hand-search in deep to discover interventions related to patient safety published in the literature. This finding is in agreement with those of other authors who state that hand-search in combination with an electronic search is still the most comprehensive approach to overcome limitations of an electronic process and to reduce retrieval bias (12,13).

Culture assessment tools provide an understanding to develop an action plan to improve patient safety (14). The Hospital Survey on Patient Safety Culture was designed to assess staff views on patient safety culture in a hospital and has been translated and validated into several languages and scenarios (15–21). Chapter 2 shows that methods of assessment of safety climate need to be adjusted to regional and local level to meet minimum psychometric criteria. After translation to Spanish and validation process at the perioperative setting, psychometric analyses provided overall support for 9 of the 12 initial factors of patient safety culture and 36 of the 42 initial questions of the questionnaire. Compared to the original version, small shifts of some questions were noted across factors, two factor's titles were modified, and six questions were excluded. These changes could be explained by underlying differences with the original language, cultural environment, and specific setting of use of the questionnaire. The importance of some items that describe interaction among units and teamwork across units may be less perceived in the perioperative setting.

Safety culture is fundamentally a local problem, in that wide variations in the perception of safety culture can exist even within a single organization: the perception of safety culture might be high in one unit within a hospital and low in another unit, or high among management and low among anesthesiologists (22,23). The results of chapter 2 are consistent with previous studies worldwide supporting that questionnaires to assess safety culture require adaptation (including appropriate translation) and setting adjustments (16,18,19,24). Minor differences in this instrument compared with the original one might be not only due to language differences but also due to the setting of use, but this remains as a hypothesis for further studies. This chapter provides the first validated tool for assessment of safety for Latin America, specifically for perioperative settings. Hereby, it aims to stimulate, its broader introduction to the clinical practice in this part of the world considering that it is important to first measure and analyze culture before we can transform it.

Chapter 3 and 4 describe the perceptions of practitioners about quality and safety in relation with a common procedure in perioperative care: central venous catheterization. Chapter 3 is a nationwide survey of registered anesthesiologist at the Colombian Society of Anesthesiologist and showed that ultrasound guidance is not a common technique used for central venous catheterization by Colombian anesthesiologists despite existing evidence that its use enhances safety (25). Interestingly, proportions of use reported in the literature vary between 15% and 96%, depending on the population, year of the survey, country and other hospital settings (26–28). In general, our findings suggests that current use of ultrasound during central venous catheterization in Colombia is not in line with existing evidence-based recommendations. However, this was also seen in developed high-income countries (26–29).

Major barriers for ultrasound guidance use are the lack of equipment and lack of training. Many hospitals in Colombia have only one single portable ultrasound device available in many services and wards. Therefore, knowing that the equipment is available at the hospital does not guarantee its use all the time. In addition, lack of training remains a limitation. The association between age and use of ultrasound for central venous catheterization disappears after adjustment for potential confounders, including availability of the equipment. The low reported use of ultrasound guidance may even be an optimistic estimate, given that some reporting and response bias likely existed in that respondents at certain age, or those using ultrasound guidance could have been more motivated to complete the questionnaire - in which case the frequency of use would be overestimated. Other potential reasons for not using ultrasound guidance may include time pressure and "individual perceptions" about experience, expertise, effectiveness and patient care.

In agreement with results of chapter 3, Henwood et al. recently conducted a nationwide survey of Colombian emergency medicine residents indicating the lack of instructors, equipment and time as a major restrictions to use ultrasound during central venous catheterization (30). These findings, could probably apply to other specializations in Colombia, as well as for other low- or middle-income countries. Fortunately, most anesthesiology residency programs in Colombia now include ultrasound imaging in their medical education, training and clinical practice.

Chapter 4 shows that the use of a landmark technique for catheterization suffers from evident safety issues due to potentially preventable complications. In this study, estimated incidence of mechanical complications was 17%. Similar figures have been previously described, but almost exclusively from high-income country settings, which implies that the incidence of complications is similar for high and middle-income countries.

The number of (attempted) punctures was strongly associated with mechanical complications. The increase in the odds ratio with each of the following puncture compared with the previous one is 1.9. Mansfield et al. described how the rate of complications increases with more than 2 passes of the needle and Eisen et al. showed an odds ratio for mechanical complications of 3.6 with more than 2 punctures (31,32). Findings of chapter 4 are consistent with previous studies and confirm the importance of the number of punctures and mechanical complications during central venous catheterization. Additionally, chapter 4 demonstrates that the increased odds ratio with more punctures in comparison with one has a slow rise until 3 punctures after which it becomes exponentially. Therefore, we support the recommendation not to perform more than 3 punctures at the same site.

Chapters 5 and 6 are related to anesthesiological care of obstetric patients. First, after a Cochrane systematic review it was interesting to discover that in patients with

an incomplete miscarriage undergoing evacuation, there is not one unique anesthetic technique to choose. Particular considerations that influence the choice of anesthesia technique for this procedure such as availability, effectiveness, safety, side effects, practitioner's choice, costs and woman's preferences of each technique should be applied when making clinical choices.

Chapter 5 systematically reviewed seven randomized controlled trials involving a total of 800 women comparing effects of any anesthetic technique (general anesthesia, sedation/analgesia, regional or paracervical block) for evacuations of incomplete miscarriages. The available literature remains scarce and suffers from moderate to high risks of bias. In addition, high heterogeneity of interventions and reported outcomes prevents statistical pooling and meta-analysis. In terms of postoperative pain, paracervical block does not improve the control of postoperative pain when compared to sedation/analgesia or versus no anesthesia/no analgesia. The addition of lidocaine to paracervical block versus saline provides better control of postoperative pain. When opioids were used, postoperative nausea and vomiting were more frequent in two trials compared with those using paracervical block. Since 2012, new studies were published considering paracervical block and/or sedation for patients undergoing evacuation of an incomplete miscarriage (33,34) and these findings should be included in an update of the systematic review presented in the chapter 5 of this thesis.

Lack of high-quality evidence is a relative common scenario in anesthesia and evidence based medicine. Clinicians should combine the use of the best-available evidence with their pathophysiological knowledge taking into account mainly, the preferences of patients after a detailed discussion in order to provide the best and safest care (35).

Finally, chapter 6 evaluated the effectiveness of a mechanical low-cost intervention using a right lumbar-pelvic wedge in preventing hypotension after spinal anesthesia for cesarean delivery, a common scenario in low- and middle-income countries. It is ubiquitous obstetric anesthesia practice to implement left lateral uterine displacement in all women during cesarean delivery following the recommendations of several clinical practice guidelines (36,37). In this randomized trial, the use of this intervention was not effective in reducing the incidence of hypotension during spinal anesthesia for cesarean section.

The real value of patient positioning during cesarean section has been under scrutiny, as well as, the existence or clinical relevance of the aortocaval compression syndrome (38). Recent evidence using magnetic resonance images in term singleton pregnant women, confirms that the aorta at the mid- to upper lumbar disk levels was not compressed by using left-lateral tilt and the inferior vena cava is relieved only at a tilt of 30° but not at 15° (39). A Cochrane systematic review assessed maternal positions during cesarean section under spinal anesthesia for preventing maternal and neonatal complications and concluded that there is limited evidence to support or disprove the value of

tilting, wedges or the use of mechanical displacers (40). During the last updating of this review, the paper (contents of chapter 6) was included in order to reduce uncertainty about this intervention without changing the main conclusions.

The incidence of hypotension varies according to its definition and limits comparability of different preventive measures (41,42). Chapter 6 used a commonly accepted definition, and the incidence was high but in agreement with other studies (43). Single blinding and no collection of neonatal data, both clinical or biochemical, were important limitations of this randomized controlled trial. Recent studies suggest that when maternal systolic blood pressure was maintained with fluid and phenylephrine, there was no apparent benefit to left lateral uterine displacement on hemodynamics as well as on neonatal acid-base status during cesarean delivery (38,44,45). Therefore, positioning strategies and recommendations from current guidelines for women undergoing (elective) cesarean section could be refined.

### **Ongoing scientific discussions**

Perioperative safety needs to be contextualized and this thesis provides a validated tool for assessment, specifically for perioperative settings in Colombia. Researchers should try to explore more operating rooms at national level and in other Latin American countries, in order to discover trends, differences and major concerns about safety. In addition, such studies would add more evidence regarding the psychometric properties of the Hospital Survey on Patient Safety Culture questionnaire in the perioperative setting. Similarities between countries (and cultures) would suggest that the questionnaire could be used interchangeably or with minor adjustments (15,18,19,21,46). Its more widespread use could answer questions like: Is the current Colombian (at Popayán city) validation appropriate for other cities in Colombia or even other Latin American countries? Are there differences in cultural environment affecting the validity of the questionnaire in Latin-America?.

At the moment, there are no clear strategies to expand the use of ultrasound guidance during central venous catheterization in Colombia. Due to the restricted availability, which is mostly due to financial shortages, its use is low and the perception about quality and safety does not seem to affect the current practice. With the estimated costs of a basic ultrasound equipment being around 50.000 USD, this remains as a problem of potential improvement.

Increase in the amount of studies available in the scientific medical literature is very fast and expanding exponentially. The information provided in Chapters 1 and 5 should be updated to add more recent evidence to their questions. How much of these new data is coming from low- or middle-income countries, any from Latin America? Is patient safety in the perioperative setting receiving more attention in recent years? In this re-



gard, low- and middle-income countries need to produce more high-standard evidence in quality and safety in the perioperative setting.

Some issues suggest strong similarities between countries but there is scarcity of information to contrast. Therefore, there is a patient-safety paradox in scientific literature: developed high-income countries with a high safety level produce the most available literature, whilst evidence from low- and middle-income countries which would have a much bigger benefit is lacking. While research agenda in patient safety may prioritize some concerns to certain countries or areas, there are many common issues that could be addressed globally with collaboration.

### **“Evidence” and patient safety**

From its origins in 1990s, evidence based medicine was a movement supporting the use of evidence from high-quality randomized controlled trials and observational studies, in combination with clinical expertise and the needs and wishes of patients (35). Evidence based medicine quickly became a core topic in an intellectual community committed to making clinical practice more scientifically and empirically grounded and thereby achieving safer, more consistent, and more cost effective health care (47,48).

Taking into account that not all situations in health care require nor enable a randomized controlled trial, nobody denies the advantages of this movement and its successes (47,49,50). Sometimes, high-quality evidence could not be available and in addition, evidence could be biased by vested interests to favor some actors of the process, e.g. industry or opinion leaders (47,51,52). Much of the work of evidence based medicine has focused on issues of “evidence”, i.e. the problems of bias and error, the use of composite endpoints, the abuse of surrogate markers and subgroup analyses, selective dissemination of evidence and limited translation and implementation to real clinical scenarios (53).

Clinical practice must survive and improve in this “non-perfect world”. To apply “evidence” in the clinical care of an individual patient, clinical expertise becomes very important. Clinical expertise includes the combination of physiology, pathology, pharmacology, and many other information with clinical experience into practice (54) and balancing them using critical thinking for decision-making. “Critical thinking” focuses on asking appropriate questions allowing to examine existing concepts, beliefs and biases for the purpose of enhancing and improving understanding and problem-solving (55). This mind-set, that dates back to the days of Socrates (470-399 BC), should not be confused with “educated guessing”. Then, by “critical thinking”, clinicians are able to decide if evidence fits with the concrete, individual circumstances and apply it. That way, evidence based medicine does not become a law, but a scientifically well-based recommendation.

Evidence based medicine must be understood as a combination of scientific tools developed to improve patient care. Therefore, evidence based medicine should not be

about “evidence”, but about responding to patient problems -as much as possible- with evidence. In order to judiciously adapt “evidence” to the care of individual patients -in their particular situations- it is necessary to know how patients think and feel about their problems (52). Clinicians cannot discover patient values, preferences, and contexts without interacting meaningfully with them and researchers have been including more and more patient-reported outcomes in order to meet a common road for “evidence” and patient preferences and concerns. This way, evidence based medicine enables both: shared-decision making between care-provider and patient based on evidence based data and value-based health-care taking into account, that the patients can finally experience the potential benefits of their surgical intervention.

Finally, evidence based health care must integrate patient safety, too. As other areas, patient safety can be refined by using high-quality evidence, but considering its particularities and differences. Observational data are highly relevant in patient safety research and sometimes considered enough to implement policies, as well as, common sense interventions. In addition, it is unrealistic to wait for randomized controlled studies for all interventions in patient safety. A great approach to integrate evidence based medicine principles in patient safety was described by Kaveh Shojania et al. and Lucian Leape et al. in 2002: “the best approach for ensuring patient safety will be one in which the general insistence on evidence does not prevent implementation of practical, low-risk, -but understudied- interventions, that rationally seem likely to work” (8,56). Hereby they clearly state, that evidence based medicine includes “critical thinking”.

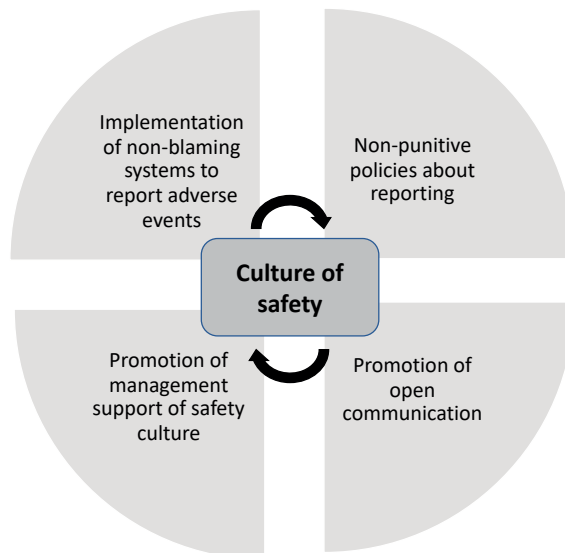
### **Future perspectives**

In the previous years, there had been incredible innovations in anesthesia, such as the introduction of new anesthetics, new devices for airway management and advanced monitoring of vital signs. The developments from recent years reflect the maturity of anesthesia as a specialty with a steadily decline in perioperative mortality (57,58). To enable healthcare professionals to adapt themselves to all these changes, continuous medical education must be prioritized. Training does not stop after medical residency training and we should be very aware about that. Colombian Society of Anesthesiologist (SCARE) is leading the process of re-certification in Colombia for the specialty, but the government should pursue policies towards efficient and effective continuing medical education for all specialties (59,60).

Nowadays, clinical and scientific work is focused on continuous improvement, a better understanding of patient outcomes, and delivery of the highest quality of care through education and training, research, audit, incident reporting, and the setting of safety standards (61). Quality and patient safety are integral part of high-quality patient care and they must be considered as undistinguishable.

Our primary mission in health care is to improve the health and quality of life of patients. This begins with a properly understanding about what do they recognize as quality of life, what do they report and to what do they give more importance. Value-based health care requires patients to provide information regarding their feelings, their symptoms and any short- or long-term effect of health interventions. Patient reported outcomes seem to be more important than any other outcomes like clinical, physiological, biochemical or caregiver-reported (62–64). In perioperative care, patient reported outcomes measures (PROMs) and patient reported experience measures (PREMs) are the missing link in defining a good outcome and much of the current research should consider to implement these type of measures to address real quality of care (65). Potential areas of research include short- and long-term patient important outcomes in perioperative care, effects of perioperative interventions on quality of life afterwards and to look for more appropriate metrics to measure the contribution of anesthesiology -as a part of a perioperative system- in the total quality of care and patient experience (66).

In terms of safety culture, potential areas of improvement for low- and middle-income countries are: 1) implementation of non-blaming systems to report adverse events, 2) enhancement of non-punitive policies with respect to error reporting, 3) promotion of open communication, and 4) promotion of management support of safety culture, including assessment (67) (Figure 1).



**Figure 1.** Strategies to promote improvements in safety at perioperative period focused of the evaluation and response to error.

Anesthesiology has been acknowledged as the leading medical specialty in addressing issues of patient safety at perioperative period, but also, should pursue to impact outside of operating rooms (68). Almost all mechanisms described on this thesis are related mainly with a micro-level framework (Patient centered care by providers) in healthcare, and some of them on the meso-level (Hospital strategies and processes) (57). Colombia, as well as similar countries, has an interesting diversity of healthcare needs. In urban settings, the healthcare offer is among the best in Latin America with top-quality hospitals and educational programs comparable to those in the US or Europe. In contrast, in most rural areas, including some of the most remote locations in the world (like the pacific coast or the Amazon forest), a frail and fragmented healthcare system prevails, similar to those in third world countries (69–71). This diversity, represents a strong challenge for patient safety because measures and interventions would be adapted depending on the level of care pretending to improve. How to deal with such a strong diversity in many aspects at the same time? Additionally it is important to understand how macro-level related major external factors that influence clinical performance such as economic and administrative issues, social conditions, technological changes and health care inequities influence quality of care in general and patient safety in particular (72–74).

Based on the findings presented in this thesis and during its development, some measures have been adopted by practitioners, managers and academics at Universidad del Cauca, Hospital Universitario San José and Clínica La Estancia, all in Popayán, Colombia in benefit of quality and safety of patients during the perioperative period. During the development of this thesis, the author has made a strong and long-standing collaborative relation with the Department of Anesthesiology of Erasmus University Medical Center involving many members of the Departamento de Anestesiología of the Universidad del Cauca. This demonstrates the direct impact of research-based collaborative efforts between countries (75).

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