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Essay

Promoting research in pediatric anesthesiology[☆]



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ABSTRACT

Over the past two years there has been increased interest in promoting research in anesthesia as an integral part of academic anesthesia practice in Colombia. The Colombian Symposium on Research in Anesthesia (organized by the Colombian Society of Anesthesiology and the Society of Anesthesiology and Reanimation of Antioquia) formulated and published guidelines to promote this effort. Despite these efforts, pediatric anesthesia is still a subspecialty in which very little research is done. In this opinion article we discuss why and how to promote research in pediatric anesthesia in Colombia.

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Promoción de la investigación en anestesiología pediátrica

RESUMEN

En los últimos 2 años ha habido un interés creciente por promover la investigación como parte integral de la práctica académica en anestesiología en Colombia. El Simposio Colombiano de Investigación en Anestesiología, organizado por la Sociedad Colombiana de Anestesiología y Reanimación y la Sociedad Antioqueña de Anestesiología, formuló y publicó guías para promover este esfuerzo. Infortunadamente y a pesar de estos esfuerzos, la investigación en anestesia pediátrica aún es muy escasa. En este artículo de opinión discutimos por qué y cómo promover la investigación en anestesia pediátrica en Colombia.

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Background

Anesthesiology is a dynamic discipline. New developments in the basic sciences and research in clinical care are improving the safety and quality of our rapidly evolving field. As anesthesiologists, we are responsible for updating our knowledge and clinical practice according to new guidelines generated from research discoveries. Currently, most research in anesthesiology is done in developed countries, where resources are available and where academic centers have embraced the responsibility of generating new knowledge to constantly evolve our field of study.

Research in developing countries is limited due to multiple factors: lack of resources, heavy clinical workload, alternate research as an integral part of academic medicine. Despite these limiting factors, important advances have been made. For example, one can point to the consensus document on research guidelines formulated after the 2011 Colombian Symposium on Research in Anesthesia (organized by the Colombian Society of Anesthesiology and the Society of Anesthesiology and Reanimation of Antioquia). These guidelines were published in August 2012 by the *Revista Colombiana de Anestesiología*.¹ From this publication it is clear that there is a growing interest in promoting research as an integral part of the practice of academic anesthesia in Colombia, and that the Colombian Society of Anesthesia (as well as the regional societies) are invested in developing this effort. Within that context and taking advantage of the growing interest in research from anesthesiologists in Colombia; we propose that the field of pediatric anesthesia be considered as one of the priorities to develop by answering the following four questions.

1. Why is it important to do research in pediatric anesthesia?

While various motivations to pursue research in pediatric anesthesia exist, we elected to focus on three primary motives – discussing each of them within the context of pediatric anesthesia as a discipline and within the context of Colombia in particular.

Findings from research in adults cannot be extrapolated to children

This is clearly exemplified by the history of drug trials. Since the vast majority of drugs have never been tested in children, pediatric health care providers are often forced to apply off-label use and to guess appropriate drug doses for children. In particular, safety and efficacy information for drugs are the most difficult to find for the youngest pediatric patients. These patients are also at greatest risk. To avoid off label use of medications that can result in increased morbidity, the FDA (Federal Drug Administration) and the EMA (European Medicines Agency) passed regulations and incentives such as the FDA's Pediatric Exclusivity Program. Introduced in 1997, this program provides six months of patent protection

exclusivity to drug companies that conduct approved pediatric trials. Over the past 15 years numerous discoveries regarding drug safety and efficacy have resulted from these efforts.²

The same type of incentive may be needed to increase research in pediatric anesthesiology in Latin American countries and to limit the need for interpretation of data from both adult and pediatric studies conducted in other parts of the world. Most of the studies in developed countries include Caucasian children of European origin and are therefore not directly applicable to populations with different genetic and cultural characteristics. Polymorphisms in genes that code for metabolic enzymes vary amongst various racial and ethnic groups and are responsible for differences in the clinical response to medications and side effect profiles.³⁻⁶ Furthermore, some pathology is specific to certain geographical areas and can be studied only in the areas where it occurs.

Research in safety and quality improvement in pediatric anesthesia is necessary for improvement in pediatric care

Quality improvement and safety research has recently acquired more relevance in industrialized countries, where registries designed to capture complications related to the provision of anesthesia in children have been implemented. Some examples of such registries in the United States are: Pediatric Perioperative Cardiac Arrest (POCA),⁷ Wake Up Safe, and the Pediatric Regional Anesthesia Network (PRAN).⁸ The Colombian Society of Anesthesia has a current interest in safety and quality; however, these efforts have only focused on adults. It is time to redirect some of these efforts to the pediatric population.

There is clearly a need for Colombia and other Latin American countries to initiate their own anesthesia registries. Each national healthcare system has unique characteristics that limit direct extrapolation of data from other national registries. Simply put, each country learns the most from their own experience and thus a separate national registry is in their own best interest.

Research is an integral part of anesthesia education

The consensus document published after the Colombian Symposium on Research in Anesthesia eloquently supports this point – that research is one of the cornerstones of anesthesiology residency training. The practice of anesthesiology requires anesthesiologists to develop skills in both lifelong learning and critical thinking. Academic programs that teach these competences through active research are more likely to develop excellent clinicians with the long-term commitment to learn. Given that efforts are being made to implement new programs for training of pediatric anesthesiologists in Colombia and other parts of Latin America, it is of particular importance now to include research as an integral part of their academic curriculum.

2. How do I implement new research projects in pediatric anesthesia?

Children are a vulnerable patient population because their intellectual and emotional capabilities are immature. One

must consider the risks and discomfort associated with the proposed research before proceeding. These risks must then be justified against the expected benefits to the child or to society as a whole. The same rights and ethical standards that are granted to adults should be applied when conducting research on children.

Ethical justification and moral issues

Obtaining consent and/or assent respects a patient's basic right to autonomy and is based on the principle that individuals are most capable of determining what is in their own best interest. While in the past children were largely left out of medical decisions, this is no longer the case. Increasingly children are becoming more actively involved. It must also be stated that children have inherent rights even when unable to express them. The researcher becomes the child's advocate to protect these rights. The decision to enroll a child in a research study should never be decided by the researcher alone. Rather, this must occur in accordance with standards of an Institutional Review Board or local ethics committee.⁹

Pediatric protocol considerations

Minimizing risk

No matter how noble the goal of the research study, injury as a direct result of being involved in the study is always possible. The management of potential adverse events must be considered and prepared for ahead of time, with the option to terminate the study should unexpected dangers be discovered. With this in mind, the number of participants and procedures should be limited whenever possible while still meeting the requirements for good study design. Compared to adult studies, the safety and efficacy endpoints may need to be adjusted such that safety follow-up is adequate in terms of length and specificity to detect adverse effects after completion of the study and as children develop and grow.

Minimizing distress

Repetitive invasive procedures may invoke pain, discomfort and fear in the pediatric study patient and must be minimized whenever possible. Some practical considerations to minimize distress include: conducting research in child appropriate settings, having research staff skilled in working with children, limiting venipuncture attempts, considering alternative routes of drug administration and taking into account the schedules of both the child and parent when arranging times for research participation.

Regulations for research in Colombia

Colombia has advanced enormously in terms of regulating research practices in medical settings. In 1993, the Colombian government established legislation that regulates medical research in Colombia. This legislation is based on the 1964 Declaration of Helsinki which outlined the Ethical Principles for Medical Research Involving Human Subjects.¹⁰

After this legislation was adopted, numerous "Comites de Etica en Investigacion" were created in several academic institutions and hospitals in Colombia. This resulted in new

regulations and policies specific to each institution. While these efforts have increased the number of on-going research studies, it is also true that miscommunication between clinical services and review committees continues to hamper progress.¹

3. What is being done in research in pediatric anesthesia in Colombia?

It is difficult to provide a comprehensive review of the current research done in pediatric anesthesia in Colombia because there is no centralized database or institution that can provide this information. Nonetheless, it seems that the number of pediatric research studies in anesthesia and pain is scarce. In general, very few anesthesia studies conducted in Colombian academic institutions are published in international journals. Of these, only a handful involves children. Moreover, papers published in the "Revista Colombiana de Anestesiologia" involving children are extremely rare (less than 1% in the past 12 years).

While discouraging, the current situation is somewhat expected. In general, there is less research done in children than in adults. This is not surprising given the unique characteristics of children. Also, Colombia does not have established programs for formal training in pediatric anesthesia. This makes it extremely difficult for anesthesiologists to embrace research given the lack of a formal educational platform to support it.

4. What is the future for research in pediatric anesthesia in Colombia?

The future is promising for research in pediatric anesthesia in Colombia. Currently, active efforts are being made by the Colombian Society of Anesthesia as well as academic institutions around the country to create formal programs for training of pediatric anesthesiologists. This is a significant step forward in developing an academic environment in which research should have a prominent role. Furthermore, there is a new global health emphasis in integrating efforts from industrialized nations with those of developing countries to improve the anesthetic care of all children. The first International Assembly for Pediatric Anesthesia (hosted by the Society for Pediatric Anesthesia in 2012) was a recent example of a forum for active exchange of ideas between pediatric anesthesiologists from different countries.¹¹

Lastly, new research areas such as quality improvement and safety, are rapidly evolving in pediatric anesthesia. This provides an excellent opportunity for research in countries where emphasis on clinical care is still the norm. The Colombian Society of Anesthesia is uniquely positioned to lead the creation of safety registries to document (and in the future, analyze) the provision of anesthesia for children in Colombia. As these efforts progress, more research involving anesthesia in children will be done and perhaps evolve into an exclusive section for pediatric anesthesia in the Revista Colombiana de Anestesiologia. By generating these avenues, young anesthesiologists interested in pediatrics will embrace

research – staying on the cutting edge of their field and using this knowledge to improve the clinical care of children.

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Conflicts of interest

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