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Editorial

Past, present and future of sedation in Colombia: What is our contribution?☆

Pasado, presente y futuro de la sedación en Colombia. ¿cuál es nuestro aporte?

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Sedation is a controversial issue nationwide and, in order to gain adequate insight on this issue, it is important to review the background of this controversy in the world, and in Colombia of course.

The history dates back to the 19th century with the discovery in 1798 of the analgesic properties of *nitrous oxide* by chemist Humphry Davy who inhaled this agent to determine its effects after experiencing pain in a partially erupted tooth. Later, in 1800, Davy published a treatise on nitrous oxide suggesting that this gas "*could probably be used advantageously during surgical procedures*".[1] Years later, in 1844, Horace Wells (dentists) went back on those studies and used nitrous oxide for removing one of his own teeth and, after him, William Morton (dentist and father of anaesthesia) administered *ether* in tooth extraction in 1846, an invention he could never patent during his life time, not to mention that he lost his fortune and died before he was able to see his work recognised. During the 1930s, the barbiturate *hexobarbitone* was first used intravenously for patient sedation in dental procedures.[1] These are the historical milestones that shaped the beginnings of our specialty.

In the 1980s, sedation began to gain momentum again and, in 1984, the American Society of Anaesthesiology (ASA) started to offer courses on the use of midazolam for sedation. In 1985, the American Association of Paediatrics (AAP), together with the American Society of Paediatric Dentistry (AAPD), published the first guideline for the elective use in children of conscious sedation, deep sedation and general anaesthesia by non-anaesthetists.[2] Later, in 2002, the ASA published the guidelines for sedation and analgesia for non-anaesthetists,[3] creating even more controversy regarding this issue in the anaesthesia profession around the world. On the other hand, in 2014 the Food and Drug Administration (FDA) received multiple claims regarding the Diprivan® (Propofol) insert that stated that it should be used only by personnel trained in the administration of general anaesthesia and who are not involved in the performance of the surgical or diagnostic procedure. All of the lawsuits were dismissed and the FDA has maintained that statement in the label of this medication. In the same year, the ASA made a statement regarding the safe use of propofol, stressing that "*the Society believes that the involvement of an anaesthetist in the care of every patient undergoing anaesthesia is optimal. However, when this is not possible, any non-anaesthetist administering propofol must be trained in the rescue of patients who are more deeply sedated than initially foreseen and who enter briefly into a state of general anaesthesia*".[4]

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In 2007, Current Opinion in Anaesthesiology devoted a supplement to sedation outside the operating room in various settings, and proposed interesting conclusions:

- "*Continuing accredited education under the leadership of anaesthesiology departments*".[5]
- "*Multidisciplinary teams for collaboration among anaesthetists and non-anaesthetists*".[5]
- "*Supervision, support and leadership from anaesthetists based on their greater ability to recover the patient from unforeseen adverse events*".[5]
- "*Development of organisational structures, plans of action, sedation protocols, selection of procedures and patients, and emergent rescue loops*".[5]

In 2010, the European Board of Anaesthesiology (EBA), the European Society of Anaesthesiology (ESA) and representatives from the European scientific societies of anaesthesiology signed the Declaration of Helsinki on patient safety, which was endorsed by other organisations, including the World Health Organization (WHO), the European Patients' Forum (EPF) and the World Federation of Societies of Anaesthesiology (WFSA).[6,7]

In the Declaration, the fundamental role of anaesthesiology in safe peri-operative care is clearly stated, and institutions providing sedation are invited to comply with sedation models recognised in anaesthesiology as safe practice standards.[6,7]

In the world, the most recent development is the expert consensus of the Spanish Society of Anaesthesiology (SENSAR) of 2016.[6] Using the Delphi methodology, the experts made their recommendations based on the proposed topics: statement of the specific and differentiating circumstances that compromise patient safety in settings outside the operating room; categorisation of sedation levels; definition of the way to assess these patients before sedation for procedures performed outside the operating rooms; post-procedure recommendations and discharge/admission criteria; definition and dissemination of basic care criteria in sedation for diagnostic and therapeutic procedures outside the operating theatre.[6]

About this highly important work, it is worth highlighting the following statements: "the expert panel agrees that the person responsible for sedation/analgesia must be different from the person performing the diagnostic and/or therapeutic procedure to which the patient is subjected",[6] and "the most controversial issue has to do with who is considered trained and qualified to administer and monitor the effects of sedation". Moreover, in their conclusions, they emphasise that the scope of the consensus did not include this point and leaves it up to the legal entities to define the type of professional and the competencies required, taking into consideration the opinion of the scientific societies.[6]

After a review of some of the most outstanding contributions from the world of sedation, where the different recommendations over the past decade revolve mainly around the concept of patient safety, it is worth looking into the historical process and our contribution in this country.

Over the past 30 years, medical specialists in different areas, as well as dentists, have been providers of intravenous sedation using nitrous oxide in different types of patients, supported by nursing staff. However, the vast majority of these practitioners have no formal training in this area, practice on the basis of their experience and what they find in the world literature, and do so without a legislation to endorse or ban the performance of those procedures.

Because of the large number of patients in different medical and dentistry specialties requiring sedation outside the operating room, and given previous experiences in the world, the idea of creating teams of sedation by anaesthetists came about in 1996. Since that time, different specialists adopted the idea and, at the present time, there is a large number of anaesthetists with expertise in sedation for adult and paediatric patients outside the operating room during a wide variety of procedures in areas such as gastroenterology, maxillofacial surgery, dentistry, urology, gynaecology, plastic surgery, dermatology, alternative medicine, radiology, cardiac catheterisation, among others.

These groups were behind the idea of regulating the practice of sedation in some way, and after a process that lasted more than 8 years, Resolution 1441 was passed in 2013. In this resolution, the word sedation appears for the first time in the licensure standards. Later, this resolution was modified by means of Resolution 2003 of 2014,[8] which contains important achievements, including the prohibition of simultaneity, which requires that the person in charge of giving sedation must be different from the person performing the procedure; a determination of the required monitoring; and the definition of those cases in which the presence of an anaesthetist is mandatory. Of course, these items are greatly important in terms of patient safety, but there were other things that were not achieved, like the recognition of sedation as something strictly within the realm of the practice of anaesthesia, given that it was not supported by world or national literature. Unclear also were the level of competencies required for administering sedation, and who should bear the cost of the procedure. Given that these considerations were not included in the legislation, the result was the emergence of a host of very short "courses" with no formal syllabus offered by various organisations. Moreover, the practice became such that a certification was enough to comply with regulatory requirements, making it unsafe for the people who received sedation from these non-anaesthetist professionals.

Going back in history, it is important to highlight the publication in the first issue of the Colombian Journal of Anaesthesiology of 2012 the article with the largest number of searches in the history of the Journal: the National Consensus on "Recommendations for sedation and analgesia by non-anaesthetist physicians and dentists in patients over 12 years of age".[9] This controversial article has given rise to many discussions and discrepancies among the authors, but it is the best academic support available to this date, and is the reference on which the Health Ministry and Secretariat have based the resolutions mentioned above.

In 2014, in view of the door left open by the resolution, and in response to the interest of anaesthetists that work almost exclusively in sedation and thinking about patient safety, the decision was made to create the Sedation Committee of the Sociedad Cundinamarquesa de Anestesiología (S.C.A.). The

aim was to strengthen sedation in Colombia, starting with education, and also to lobby with government entities, considering the country's needs and also the importance of putting an end to informal courses nationwide. The Sociedad Colombiana de Anestesiología y Reanimación (S.C.A.R.E.) was then asked to include among its committees a National Sedation Committee with the main objective of updating the consensus and developing guidelines that could provide real clinical evidence, avoiding past mistakes.

Consequently, S.C.A.R.E. undertook to prepare the Clinical Practice Guideline together with the COCHRANE group, highly recognised in the world in relation to academic and research projects, and invited all scientific societies involved with the topic to participate. Seven societies, included ours, replied to the summons: Radiology, Obstetrics and Gynaecology, Gastroenterology, Emergency Medicine, Oral and Maxillofacial Surgery, and the Academy of Paediatric Dentistry. The members of the core development group were highly competent specialists from the different societies; the guideline was peer reviewed from the methodological and scientific perspective and prepared *de novo*, considering that no guidelines were found that met the criteria for the adoption of an existing guideline and considering also that this guideline is not addressed to a special population but rather to people who give sedation (whether they be anaesthetists or not). Entitled "Clinical Practice Guideline for Sedation Administration outside the Operating Room in Patients Over 12 Years of Age",[10] it represents the most important academic contribution in the area of sedation not only in our country but in the rest of the world, because of its characteristics and methodological and epidemiological design. Moreover, unlike consensus and existing guidelines, it included a question to determine whether the anaesthetist is the only practitioner who should administer sedation, considering the knowledge and competencies of our profession. Unfortunately, the evidence in the literature did not answer our question favourably, although it did provide an additional tool: a very well organised competencies curriculum for sedation providers,[11] which requires training in high-fidelity simulation, operating room and clinical settings. It also limits training in sedation only to physicians and dentists, excluding the possibility of nursing or any other staff receiving that training. The training is led only by anaesthetists and may be offered by universities or scientific societies who meet the criteria mentioned above.

Despite this academic achievement, there has been a continued interest in regulatory intervention, hence the work by the S.C.A. and S.C.A.R.E. committees together with the Ministry of Health for the creation of the technical annex which mentions Resolution 2003 of 2014. As mentioned previously, this resolution had been unclear about training, but the Annex was prepared on the basis of the guideline and is under verification for the Colombian Ministry of Health and Social Protection at the present time.

This year, the XXXII Colombian Congress of Anaesthesiology and Resuscitation will devote a block of sessions to sedation during which the work of disseminating the guidelines will continue, with presentations from national and international speakers on topics of interest for anaesthetists. The First Congress on Sedation ever organised in Colombia will take place in September, under the leadership and sponsorship of S.C.A. The congress has a roster of national and international experts in the subject who will provide a stronger academic and practical foundation for our work as specialists in this area.

The future is in our hands and we need always remember that, ideally, we as anaesthetists should be the only ones allowed to provide sedation. However, as already stated, clinical evidence does not support this statement, and the only way to demonstrate that we are the most competent is by continuing to be the bulwark of safety. We need to be the ones to publish research papers and review articles, train our residents with a formal course on sedation, leave our comfort zone in the operating room and practice in other settings (either inside or outside the hospital). We need to know that we offer an advantage even though the law allows sedation by non-anaesthetists, and we should be providing guidance regarding what non-anaesthetists need to know and how far they can go. The Resolution and the Guideline are clear in stating that only anaesthetist can provide sedation to patients with comorbidities and this is where we need to prove that we are the best. This way, we will be the species best suited to respond to change since, in Darwin's words, it will not be the strongest or the most intelligent species that will survive, but only the one that can better adapt to change.

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