# TITLE PAGE

**Title**

Effectiveness of procedural sedation and analgesia in pediatric emergencies. A cross-sectional study.

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## Abstract

**Introduction.** Pain is defined as an unpleasant emotional and sensory experience associated with bodily harm or with situations that cause fear and anxiety. However, it is often undertreated in pediatric emergency departments. This study aims to assess the effectiveness of sedation-analgesia techniques, level of satisfaction among healthcare professionals and relatives, and agreement between the satisfaction of healthcare professionals and relatives. **Method**. A cross-sectional design was conducted. Sociodemographic and clinical variables were recorded, together with those for effectiveness using the Face, Legs, Arms, Cry, Consolability scale (FLACC) and the Wong-Baker FACES scale, and the satisfaction using the 10-point Likert scale. STATA 16 was used for data analysis. **Results**. A total of 94 procedures were registered. Our results suggested that these techniques were effective or mildly effective in only half of the cases. Satisfaction was considered good across the board, and the agreement between healthcare professionals (i.e., pediatric nurses and pediatricians) was considered substantial. However, the agreement between healthcare professionals and relatives was moderate. **Conclusions**. Our results suggested that the adequate management of pain in pediatric emergency departments is still a challenge, although the availability of international guides. Future research lines should be focused on analyzing possible causes of the inefficacy of some sedation-analgesia techniques, and the causes of the differences between the perspectives of healthcare professionals and relatives. These research lines may be useful to improve our quality of care and pediatric patient comfort.


*Keywords:* Pediatrics, emergency, sedation, effectiveness, satisfaction

## Introduction

Pain is defined as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" according to the International Association for the Study of Pain (IASP) Subcommittee on Taxonomy. This definition has become globally accepted by professionals, including the World Health Organization (WHO)[1]. This definition may be not sufficient when dealing with pediatric patients or individuals incapable to verbalize their pain. Thus, one of the definitions that may be better adapted to this population is that "pain is a multifactorial personal experience with physiological, behavioral, emotional, developmental, and sociocultural components that can all lead to a different perception of pain" [2]. According to the American Academy of Pediatrics [3,4], proper pain management under sedation is crucial to promote patient welfare, control patient behavior and ensure a positive psychological response to treatment.

Children in emergency departments (ED) usually undergo uncomfortable or stressful procedures, such as the establishment of venous access, wound suturing or fracture reduction. Thus, the administration of sedation-analgesia and local anesthesia techniques to diminish pain, fear, and discomfort in infants is a frequent practice. Using sedation-analgesia in other settings different from the surgical is usually referred to as PSA (Procedural Sedation and Analgesia) [5–8]. However, despite the availability of international guidelines, pain experienced by pediatric patients in ED is often inadequately managed [7,9,10].

The Research in European Pediatric Emergency Medicine (REPEM) group carried out a multicenter study and recorded the most commonly used pharmacological techniques, professionals administering sedation-analgesia techniques, protocols used, facilitators and barriers, and degree of satisfaction of professionals [7]. The results evidenced that the most used drugs were midazolam and ketamine, followed by others such as intranasal fentanyl and

inhaled nitrous oxide. Pediatricians were the main professionals administering sedation-analgesia in an emergency setting, and described certain issues that might limit proper pain management, including lack of training and an adequate place in the emergency department (ED) [7]. Along similar lines, Whitley et al. (2021) found different barriers to the management of pediatric pain in ED, such as lack of experience, insufficient support from colleagues, difficulty assessing pain in children, and fear of adverse effects. In a pediatric ED context, Rybojad et al., (2022) compared evaluations of pain made by children, relatives and professionals and their results indicated that children scored higher than the other groups did, suggesting that professionals in ED may need more training in assessing pain in children.

In our context, the Sociedad Española de Urgencias en Pediatria (SEUP) considered effective pain control to be a quality-of-care indicator, and hence recommended a series of core competences that healthcare professionals need in order to successfully manage pain in ED [12–15]. Relevant studies on this matter include those published by Míguez-Navarro, Oikonomopoulou, Rivas, Mora, & Guerrero (2019) and Míguez-Navarro, Escobar-Castellanos, Guerrero-Márquez, Rivas-García, & Pascual-García (2022). The former assessed factors related to the effectiveness of sedation-analgesia and the adverse effects of drugs. Their findings suggest that PSA is a common practice in pediatric ED, and a safe one as a low rate of adverse effects was found. However, the results also demonstrate that PSA is only partially effective. The latter assessed the prevalence of pain in pediatric ED, and the interrater agreement between healthcare professionals and families regarding pain level. More than half of the sampled pediatric patients in ED suffered pain, thus highlighting the importance of correct, effective pain management.

Finally, the safety of these techniques has also been analyzed, examples being the recent research conducted by Lucich et al., (2020), Schlegelmilch et al. (2021) and Sirimontakan et al. (2020), which observed a low incidence of adverse effects, even in children <2 years. Only 3.9% of cases presented adverse effects, namely digestive (nausea), respiratory (desaturation, laryngospasm, apnea) and others (rash, hypotension, hypertension). Therefore, despite sedation-analgesia techniques always entailing certain risks [8,18,20], the low incidence of adverse events suggests that they could be safe in an pediatric ED.

Despite literature and evidence provided, the effective management of pain in children still seem to be a challenge in ED. We therefore decided to conduct this study in order to describe the sedation-analgesia techniques used in our pediatric ED, the focus being on assessing the effectiveness of sedation-analgesia and local anesthesia techniques, the degree of satisfaction among healthcare professionals (pediatric nurses and pediatricians) and relatives, and the interrater agreement between the satisfaction of healthcare professionals and relatives.

## Methods

### Design, setting and participants

This cross-sectional study is reported in accordance with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [21]. This study was conducted in an urban pediatric Spanish pediatrics ED of a secondary care hospital, with an annual attendance of 28.000 patients, and an average of 18 sedations per month.

Inclusion criteria were children aged 0 to 18 years old who required sedation-analgesia or local anesthesia techniques for painful or uncomfortable procedures, from October 2020 to July 2021. This age range was selected because in our hospital the patients up to 18 years of age are cared for by pediatricians. Parents and patients aged 12 years or

above (considered mature) signed informed consent forms. Patients whose parents did not issue their consent, patients that were hemodynamically unstable, and patients with major language barriers were excluded from the study.

**Sample size**

Calculation sample size was a priori, with a confidence level of 95%, precision of 10%, and prevalence of sedation-analgesia techniques of 50% (maximizing the sample size), with a total of 96 participants [22].

**Study variables**

Sociodemographic variables of age, sex and weight were recorded. Variables related to procedures, sedation-analgesia techniques, drug dosage and administration, adverse effects, and vital signs (oxygen saturation, heart and respiratory rate) were also recorded. The effectiveness of pharmacological techniques was assessed using the Face, Legs, Activity, Cry and Consolability scale (FLACC) [23,24], and the Wong-Baker FACES scale when infants were older than 4 years, conscious, and/or undergoing local anesthesia only. The satisfaction of healthcare professionals and relatives was evaluated by only one question, assessed on a 10-point Likert scale [25].

**Instruments**

***FLACC Scale (Face, Legs, Arms, Cry, Consolability)***

The FLACC is a validated behavioral scale for the assessment of procedural pain in children under 4 years undergoing mild, moderate or severe sedation-analgesia in intensive care, emergency, oncology, surgery and traumatology. An observer recorded the scores as (0) "no pain"; (1-3) "mild pain"; (4-6) "moderate pain"; and (7-10) "severe pain", assessing items related to facial expression, limb position, crying and comforting ability. The literature describes high interrater reliability, intra-class correlation coefficient ICC = 0.87 (0.84 – 0.89) [24].

### *Wong-Baker FACES face scale*

The Wong-Baker FACES [26] is a validated self-assessment scale for the evaluation of pain in children over 3 years. It scores the degree of pain based on six different images of visual expressions that depict (0) "no pain"; (2) "hurts a little"; (4) "hurts a little more"; (6) "hurts a lot"; (8) "hurts a lot more"; (10) "hurts the most". The meaning of each face is explained to the children, who are asked to point to the one that best expresses their pain. This scale has been validated for the assessment of procedural pain, showing high correlation with the Visual Analog Scale (VAS) (r = 0.90; 95%CI 0.08 - 0.93) [27].

### *Likert scale to evaluate satisfaction*

A 10-point Likert scale [25] was used to evaluate the satisfaction of healthcare professionals and relatives. The question was “What is your level of satisfaction regarding the effectiveness of sedation technique used during the procedure?”. Answer ranged between 1= Not at all satisfied, and 10 = Totally satisfied.

## Procedure

Our ED exclusively attends pediatric patients with different pathologies. The care of pediatric patients undergoing sedation-analgesia and local anesthesia techniques is multidisciplinary, i.e. auxiliary nurses, pediatric nurses and pediatricians [28]. The pharmacological strategy is usually performed according to our Protocol (Table 1), based on recommendations of the Sociedad Española de Pediatria (SEUP)[14]. This Protocol is flexible and offers a wide variety of pharmacological strategies to be adapted to the procedure, intensity of pain and patient. The sedation strategy is always responsibility of the senior pediatrician, despite other professionals may collaborate (e.g., traumatologist).

----------Insert Table 1 here or near here----------

Pediatric nurses, together with auxiliary nurses and pediatricians, are responsible for patient monitoring, establishing peripheral venous access for drug administration, and controlling

possible adverse reactions, as well as enhancing patient and family comfort. Pediatric nurses assisted this study by informing parents, obtaining written consent, administrating different drug combinations, evaluating the effectiveness of sedation-analgesia and local anesthesia techniques using the FLACC scale or the Wong Baker FACES scale, respectively, and recording the satisfaction of health professionals and relatives. An ad hoc form was designed for data collection, where each sheet was identified with a number only in order to respect confidentiality and anonymity.

**Data analysis**

Data analysis was performed using STATA 16 and the results were reported in accordance with the "Statistical Analyses and Methods in the Published Literature" (SAMPL)[29] guidelines. Normality of data distribution was analyzed using the Shapiro-Wilk test. The descriptive analysis reported the means, standard deviation, medians, interquartile range, frequencies, and percentages. Differences between groups were analyzed using the Mann-Whitney test for quantitative non-normal data, and Chi-square for categorical variables.

The effectiveness of the most used pharmacologic techniques was evaluated by Analysis of Variance (ANOVA), with multiple comparisons counteracted by Bonferroni correction. Levene's test showed homogeneity of variances ($p=0.06$). Interrater agreement with regard to satisfaction was evaluated using Krippendorff's alpha coefficient for ordinal scales, using Landis & Koch (1977) scale criteria for interpretation (Gwet, 2014; Krippendorff, 2011). Significance was $p < 0.05$ for all statistics.

**Ethical aspects**

The present study was approved by the Ethics and Medicines Research Committee of the Consorci Sanitari de Terrassa, Barcelona, Spain (CEIM Ref. 01-20-103-067). It was conducted in accordance with the principles of the Helsinki Declaration of 1975 and

subsequent revisions, and in consideration of Spanish Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights, and Regulation (EU) 2016/679 on the protection of natural persons regarding processing of personal data and on the free movement of such data. Parents and patients aged 12 years and above (considered mature) signed the informed consent form.

## Results

Table 2 shows the sample characteristics and procedures performed. The total number of sedation procedures were 162, and the sample was composed of 95 out of 162 (58.6%) participants, but one subject was removed due to missing data. No refusals were recorded.

In the final sample of 94 out of 162 (58.0%) participants, n=48 (52.1 %) were boys, mean age m=8.5 years SD (5.3), and n=46 (48.8 %) were girls, mean age m=8.4 years SD (5.1). We observed no differences between boys and girls with respect to age. A total of n=80 (85.1%) procedures were performed involving mild, moderate or severe sedation-analgesia, and n=14 (14.9%) procedures were performed involving local anesthesia only. The most frequent procedures were wound suturing n=30 (31.9%) and fracture reduction n=26 (27.7%). A total of n=91 (96.8%) participants were monitored with a pulse-oximeter, recording oxygen saturation, heart rate and respiratory rate. In addition, all children were accompanied by their relatives, with the exception of one mother who reported that she was sick.

----------Insert Table 2 here or near here----------

Table 3 shows the most commonly used drugs. The most frequent drug combination was midazolam (intravenous, iv) + ketamine (intravenous, iv) n=26 (28.6%). In 15 out of 94 cases (16.0%), anti-inflammatory drugs were also administered (e.g., metamizole, iv). Common adverse reactions were digestive reactions, vomiting and nausea n=1 (1.1%), and respiratory and desaturation difficulties, n=2 (2.2%). Digestive reactions were self-limited

and did not require intervention. Desaturation episodes required oxygen therapy support. Adverse events were associated to the combination of midazolam + ketamine only.

----------Insert Table 3 here or near here----------

Table 4 shows the scores for the FLACC and Wong-Baker FACES scales. The mean for the FLACC scale was m=2.1 SD (2.7), and the mean for the Wong-Baker FACES scale was m=5.9 SD (3.3). A total of n=36 (38.3%) procedures were scored as zero, i.e., no pain; and n=21 (22.3%) were scored as mild pain; while the remaining procedures were scored as moderate or severe pain. Moreover, in 16 cases out of 94 (17.0%), signs of pain, such as tachycardia, facial grimacing, moaning and crying were annotated by pediatric nurses. In all cases, drugs were administered according to the established protocol, with doses adjusted by weight; mean dose of midazolam was m=0.14 mg/kg SD (0.1); mean dose of ketamine was m=1.1 mg/kg SD (0.5); and mean dose of fentanyl was m=1.3 μg/kg SD (0.4). Drug administration was intravenous (iv), intramuscular (im), subcutaneous (sc), intranasal (in), or inhaled (inh), depending on the case.

----------Insert Table 4 here or near here----------

Table 5 shows the FLACC scores for sedation techniques, together with the analysis of variance to evaluate their effectiveness. Due to the wide variety of pharmacological techniques and the small sample, this analysis was conducted for the most used sedation techniques only, i.e., midazolam (iv) +ketamine (iv), midazolam (in), fentanyl (in), and nitrous oxide (inh). Multiple comparisons showed statistically significant differences between techniques. Midazolam (in) alone was not as effective as either the combination of ketamine (iv) + midazolam (iv) (p=0.008) or the use of nitrous oxide (inh) (p=0.033). It is noted that the combination of ketamine (iv) + midazolam (iv) was generally used for major procedures, such as fracture reduction or complicated wound sutures, whereas nitrous oxide (inh) or

midazolam (in) were generally used for minor procedures, such as peripheral access or wound sutures. No further differences between techniques were found.

----------Insert Table 5 here or near here----------

Table 6 shows the satisfaction of health professionals and relatives, as well as interrater agreement. Satisfaction was assessed using the Likert scale and the agreement using Krippendorff´s alpha coefficient for ordinal scales. Satisfaction with all techniques was good: nurses m=7.9 (CI95% 7.4 – 8.4); pediatricians m=8.0 (CI95% 7.5 – 8.5); family m=8.1 (CI95% 7.6 – 8.6). Satisfaction with sedation-analgesia techniques was also good: nurses m=8.1 (CI95% 7.6 – 8.7); pediatricians m=8.3 (CI95% 7.8 – 8.8); relatives m=8.4 (CI95% 7.9 – 8.8). However, satisfaction with local anesthesia techniques was only acceptable: nurses m=6.4 CI95% (4.6 – 8.4); pediatricians m=6.0 (CI95% 3.9 – 8.1); relatives m=6.3 (CI95% 4.3 – 8.4). Interrater agreement among pediatric nurses, pediatricians and relatives was substantial for all techniques according to the established criteria, alpha=0.79 (CI95% 0.71 – 0.87). However, agreement per pairs of raters were slightly lower when sedation-analgesia techniques were evaluated; agreement among pediatric nurses and relatives was alpha=0.68 (CI95% 0.51-0.83), and between pediatricians and relatives it was alpha=0.63 (CI95% 0.46-0.80). Although the alpha values suggested substantial agreement, the CI95% suggested that this agreement might be moderate.

----------Insert Table 6 here or near here----------

## Discussion

As far as we are aware, this is the first study to have assessed the effectiveness of sedation-analgesia and local anesthesia techniques together with satisfaction and interrater agreement between healthcare professionals and relatives. Our results showed that we usually use pharmacological techniques to manage pain in our pediatric emergency ED, in order to

promote patient comfort and well-being during painful procedures, in accordance with the recommendations of the AAP [3,4] and the SEUP [12,13,32].

Our findings describe a wide variety of techniques and, in line with previous studies, midazolam together with ketamine was the most used drug combination (Míguez-Navarro et al., 2017, 2019; Sahyoun et al., 2021). In addition, and despite the small sample size, it is noteworthy that we observed a low incidence of adverse effects, occurred in the combination of ketamine plus midazolam only. Our results also indicate that these techniques were effective or mildly effective in only half of the cases. Despite the different evaluation method, these results seem to be similar to those reported by Míguez et al. (2019) in which two thirds of evaluated techniques were considered good (patient collaboration and lack of recall) or partially good (some degree of pain and anxiety), and one third were classified as poor (no collaboration and poor recall). When effectiveness of the most used techniques was compared, our findings suggested that midazolam (in) alone may be less effective than other regimes, despite it only being used in minor procedures, as recommended [14].

In general, sedation-analgesia and local anesthesia techniques were not as effective as expected, supporting the notion that the experience of pain in children in ED is often poorly treated, as Benini et al. (2016) and Rybojad et al. (2022) also noted. This may be associated to several factors. One of these could be the lack of professional training in the management of these techniques, as reported by Sahyoun et al. (2021) and Rybojad et al., (2022), and another might be the fear of certain adverse effects, as reported by Márquez et al. (2021). To this concern, it should be noted that in spite of training courses of sedation are conducted in our ED, these are less frequent as desirable. In this line, it is noteworthy that the proper management of pain may be related to expertise in PSA, which is considered a core competency in Emergency Medicine (EM) and Pediatric Emergency Medicine (PEM) in different countries, such as the United States, Canada, Australia and Switzerland [6]. These

countries formally recognize this specialty, so professionals are trained to have specific skills to provide adequate levels of sedation-analgesia, and to manage the possible adverse effects [6].

Finally, our results showed a generally acceptable degree of satisfaction. These findings were also in line with previous research (Míguez-Navarro et al., 2019). Interrater agreement between health professionals and relatives was moderate when general techniques were considered, while for local anesthesia it was substantial, almost perfect. The higher-than-expected scores for the Wong-Baker scale suggest that agreement was related to dissatisfaction rather than to satisfaction. Future research should conduct qualitative studies with a view to understanding the causes for the ineffectiveness of some techniques, and the reasons for the differences between the healthcare professionals' and relatives' perspectives.

**Limitations and strengths**

Our findings should be interpreted in the light of certain limitations. First, there is possible bias derived from work overload in certain shifts, making difficult the register of all procedures realized during these nine months. For this reason, most of these records were made in the morning, which limited the sample size and the type of procedures. Second, no record was made of non-pharmacological interventions, such as distraction and sucrose. Finally, because the data were collected in a regional hospital, generalization of our results may be limited. However, it is important to stress that our findings were very similar to those reported by some multicenter studies.

On the other hand, this study has some strengths. First, it highlighted the importance of using sedation-analgesia and local anesthesia in pediatric ED. Second, it has assessed and compared the effectiveness of the most used sedation techniques, noting the need to improve pain management. And third, it has assessed the satisfaction interrater agreement between healthcare professionals and relatives, which no similar studies were found to have done. The findings indicate different perspectives with regard to the effectiveness of the sedation-

analgesia and local anesthesia techniques, noting the need for relatives to be involved in these procedures, and for their opinions and perspectives to be considered.

**Implications for emergency nursing**

The perspective, knowledge and experience of nurses should be considered in this context, as the enhancement of patient comfort is a core competency [34,35]. Comfort is a holistic concept, including ease and relief in physical, social, psychospiritual and environmental contexts. Because patients need and want to be comforted, nurses require an efficient framework in which to facilitate this in the context of the their emergency daily practice [34,35]. Actions such as meeting family needs and/or applying non-pharmacological techniques (e.g., distraction) are crucial for improving both patient comfort and family satisfaction. The literature reported a wide variety of such non-pharmacological strategies for use either in isolation or together with sedation-analgesia techniques [36]. The inclusion of these strategies in daily practice may be beneficial for improving pain management in pediatric ED.

## Conclusions

Pain management is considered an indicator of quality of care. However, proper pain management is still a challenge in pediatric ED. Based on findings, we recommend a review of sedation-analgesia and local anesthesia training programs to provide healthcare professionals with specific skills and competencies in pain management. Formal recognition of this specialty may be crucial to improve our quality of care in ED. Moreover, we recommend routine assessment of the effectiveness of these techniques using validated scales, which will enable comparison of results between different pediatric emergency departments. We also recommend taking into account relatives' assessments of the effectiveness of sedation-analgesia and local anesthesia techniques. The role of pediatric nurses may be crucial during this process for ensuring that family needs are met, and non-

pharmacological techniques are properly employed. Further research lines should also analyze possible interactions between pharmacological and non-pharmacological techniques. These strategies may improve the effectiveness of sedation-analgesia and local anesthesia techniques, as well as the comfort of pediatric patients.

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Table 1

*Protocol of Sedation-analgesia in our pediatric Emergency Department*

| PROCEDURES | **Not painful procedures** | **Moderate painful procedures** | **Substantial painful procedures** |
|---|---|---|---|
| | Radiography (Xray)<br>Ultrasound scan... | Wound suture<br>Lumbar punction… | Fracture reduction<br>Burns care… |
| RECOMMENDED DRUGS COMBINATIONS | Midazolam (iv, in) | Midazolam (iv, in)<br>Nitrous oxide (inh)<br>Propofol (iv)<br><br>Anesthetic gel<br>Anesthetic cream<br>Lidocaine (sc) | Nitrous oxide + another drug (iv)<br>Midazolam +Fentanyl<br>Midazolam +Ketamine<br>Propofol +Fentanyl<br>Propofol +Ketamine<br>Ketamine<br><br>Midazolam (in) +Fentanyl (sc, im)<br>Midazolam (in) +Ketamine (im) |
| Non-pharmacological techniques: distraction, sucrose | | | |

Note: iv= intravenous, in= intranasal; o= oral; inh= inhaled; sc= subcutaneous; im= Intramuscular; Anesthetic gel= lidocaine 1,5%; adrenaline, 0,1%; y tetracaine, 1%; Anesthetic cream= 25 mg de lidocaine and 25 mg de prilocaine.

Table 2

*Sample characteristics. Age, sex and procedures.*

| Sample | **n=94** | | | | | |
|---|---|---|---|---|---|---|
| | | Boys | | Girls | | ***p*** |
| Age | | **n** | **(%)** | **n** | **(%)** | |
| | <4 years | 15 | (31.3) | 14 | (30.4) | |
| | 4-8 years | 7 | (14.6) | 7 | (15.2) | |
| | 8-12 years | 11 | (22.9) | 13 | (14.9) | |
| | 12-18 years | 15 | (21.3) | 12 | (26.1) | |
| | Total | 48 | (52.1) | 46 | (48.8) | .92[£] |
| Age | | **m (SD)** | **Md (P25-P75)** | **m (SD)** | **Md (P25-P75)** | |
| | | 8.5 (5.3) | 9.1 (3.4 – 13.1) | 8.4 (5.1) | 8.3 (3.3 – 13.0) | .86[$] |
| | | **Sedation-analgesia** | | **Local anesthesia** | | **Total** |
| **One procedure only** | | **n** | **(%)** | **n** | **(%)** | **n (%)** |
| | **Total** | **80** | **(85.1)** | **14** | **(14.9)** | **94 (100)** |
| | Fracture reduction | 21 | (26.3) | | | 21 (27.7) |
| | Wounds suture | 19 | (23.8) | 10 | (71.4) | 29 (30.1) |
| | Burns care | 9 | (11.3) | 1 | (7.1) | 10 (10.6) |
| | Peripheral access | 5 | (6.3) | | | 5 (12.3) |
| | Wounds care | 2 | (2.5) | | | 2 (2.2) |
| | Lumbar puncture | 1 | (1.3) | | | 1 (1.1) |
| | Abscesses care | | | 2 | (14.2) | 2 (2.2) |
| **One or more procedures** | | | | | | |
| | Peripheral access + fracture | 5 | (6.3) | | | 5 (12.3) |
| | Burns+ ophthalmic care | 1 | (1.3) | | | 1 (1.1) |
| | Peripheral access + wounds | 1 | (1.3) | | | 1(1.1) |
| | Peripheral access + suture | 1 | (1.3) | | | 1(1.1) |
| | Other situations | 15 | (18.7) | 2 | (14.2) | 16 (17.0) |

Note: m=mean; SD= standard deviation; Md= median; P25= Percentile 25; P75= Percentile 75; n= sample; % = percentage per column; p= p value; Other (Xray, ophthalmic examination…) £ Chi Square test for proportions. $ Mann-Whitney test for means

Table 3

*Sedation-analgesia techniques and local anesthesia*

| **One drug only** | | | **Drugs combinations** | | |
|---|---|---|---|---|---|
| | **n** | **(%)** | **Two drugs** | **n** | **(%)** |
| Midazolam in | 8 | (8.8) | Midazolam iv+ Ketamine iv | 26 | (28.6) |
| Fentanyl in | 7 | (7.7) | Midazolam in + Nitrous oxide inh | 4 | (4.4) |
| Nitrous oxide inh | 6 | (6.6) | Fentanyl in + Nitrous oxide inh | 4 | (4.4) |
| Anesthetic gel | 6 | (6.6) | Mepivacaine sc + Anesthetic gel | 3 | (3.3) |
| Lidocaine sc | 2 | (2.2) | Midazolam in + Anesthetic gel | 2 | (2.2) |
| Mepivacaine sc | 2 | (2.2) | Propofol in + Morphine sc | 1 | (1.1) |
| Morphine sc | 1 | (1.1) | **Three drugs** | | |
| | | | Midazolam iv +Ketamine iv +Fentanyl iv | 4 | (4.4) |
| | | | Midazolam in +Ketamine iv + Nitrous oxide | 2 | (2.2) |
| | | | Midazolam in + Ketamine iv + Mepivacaine sc | 2 | (2.2) |
| | | | **Other combinations less frequent (3 drugs)** | 14 | (15.0) |

Note: n= sample, %= percentage. Percentages with respect to the total of procedures (n=94); iv= intravenous; in=intranasal; sc= subcutaneous; inh= inhaled

Table 4

*FLACC y Wong-Baker FACES scoring*

| Scales | FLACC | | | Wong-Baker FACES | | | Total | |
|---|---|---|---|---|---|---|---|---|
| | **Scoring** | **n (%)** | **Cum (%)** | **Scoring** | **n (%)** | **Cum (%)** | **n** | **(%)** |
| | 0 | 35 (43.8) | 43.8 | 0 | 1 (7.1) | 7.1 | 36 | 38.3 |
| | 1-2 | 19 (23.8) | 67.6 | 2 | 2 (14.3) | 21.4 | 21 | 22.3 |
| | 3-4 | 13 (16.3) | 83.9 | 4 | 3 (21.4) | 42.8 | 16 | 17.0 |
| | 5-6 | 6 (7.5) | 91.4 | 6 | 2 (14.3) | 57.1 | 8 | 8.5 |
| | 7-8 | 1 (1.3) | 92.7 | 8 | 3 (21.4) | 78.5 | 5 | 5.3 |
| | 9-10 | 5 (6.3) | 100 | 10 | 3 (21.4) | 100 | 8 | 8.5 |
| | **Total** | **80 (100%)** | **100** | **Total** | **14 (100)** | **100** | **94** | **100** |
| | | **m (SD)** | **Md (P25- P75)** | | **m (SD)** | **Md (P25-P75)** | | |
| | | 2.1 (2.7) | 1 (0-3) | | 5.9 (3.3) | 6 (4-8) | | |

Note: n= sample; %= percentage; Cum= cumulative percentage; m= mean; SD= standard deviation; Md= Median: P25= Percentile 25; P75= Percentile 75.

Table 5

*Analysis of variance. Effectiveness of the most used sedation-analgesia techniques.*

| FLACC | Midazolam iv +ketamine iv | Midazolam in | Fentanyl in | Nitrous oxide inh | ANOVA (F 4.60, df 3) | | |
|---|---|---|---|---|---|---|---|
| **n=47** | | | | | **p** | **$R^2$** | **$R^2$Adj** |
| | | | | | **.007** | .24 | .20 |
| **n (%)** | 26 (55.3) | 8 (17.0) | 7 (14.9) | 6 (12.8) | | | |
| **m (SD)** | 1.8 (2.3) | 5.5 (3.7) | 3.4 (3.1) | 1.3 (1.6) | | | |
| **Md (P25-P75)** | 1 (0 – 3) | 4.5 (2.5 – 9.5) | 3 (1 – 4) | 1 (0 – 2) | | | |

Multiple comparisons by Bonferroni

| Sedation-analgesia techniques | Contrast | Std Err | IC 95% | p |
|---|---|---|---|---|
| Midazolam (in) vs. (Ketamine iv + Midazolam iv) | 3.7 | 1.10 | 0.69 – 6.60 | **.008** |
| Fentanil (in) vs. (Ketamine ev + Midazolam iv) | 1.6 | 1.13 | -1.53 – 4.70 | >.99 |
| Nitrous oxide (inh) vs. (Ketamine iv + Midazolam iv) | -0.5 | 1.20 | -3.82 – 2.80 | >.99 |
| Fentanil (in) vs. Midazolam in | -2.1 | 1.40 | -5.90 – 1.71 | .824 |
| Nitrous oxide (inh) vs. Midazolam (in) | -4.2 | 1.42 | -8.11 – -0.22 | **.033** |
| Nitrous oxide (inh) vs. Fentanil (in) | -2.1 | 1.50 | -6.20 – 1.97 | .969 |

Note: n= sample; %= percentage; iv= intravenous; in= intranasal; inh= inhaled; Cum= cumulative percentage; m= mean; SD= standard deviation; Md= Median: P25= Percentile 25; P75= Percentile 75; ANOVA= Analysis of variance; F= F of Snedecor; df= degree of freedom; p= p value; $R^2$ = R squared; $R^2$ adj= $R^2$ adjusted.; Std Err= Standard error; IC95% = Confidence Interval 95%.

Table 6

*Satisfaction and Interrater agreement.*

| General Satisfaction. All techniques | | | | |
|---|---|---|---|---|
| | **m** | **CI 95%** | **Md** | **P25 - P75** |
| Nursing | 7.9 | 7.4 – 8.4 | 8.5 | 7 – 10 |
| Pediatricians | 8.0 | 7.5 – 8.5 | 9.0 | 7 – 10 |
| Relatives | 8.1 | 7.6 – 8.6 | 9.0 | 7 – 10 |
| Satisfaction with sedation-analgesia techniques only | | | | |
| | **m** | **CI 95%** | **Md** | **P25 - P75** |
| Nursing | 8.1 | 7.6 – 8.7 | 9.0 | 7 – 10 |
| Pediatricians | 8.3 | 7.8 – 8.8 | 9.0 | 7 – 10 |
| Relatives | 8.4 | 7.9 – 8.8 | 9.0 | 8 – 10 |
| Satisfaction with local anesthesia techniques only | | | | |
| | **m** | **CI 95%** | **Md** | **P25 - P75** |
| Nursing | 6.4 | 4.6 – 8.4 | 6.5 | 4 – 10 |
| Pediatricians | 6.0 | 3.9 – 8.1 | 6.0 | 4 – 9 |
| Relatives | 6.3 | 4.3 – 8.4 | 6.5 | 4 – 10 |

| Interrater Agreement[δ]. All techniques | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Nursing vs Ped vs Relatives** | | **Nursing vs Ped** | | **Nursing vs Relatives** | | **Ped vs Relatives** | |
| | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** |
| Percent agreement | 0.97 | 0.95-0.98 | 0.97 | 0.95 -1.00 | 0.95 | 0.94-0.98 | 0.95 | 0.93-0.98 |
| Krippendorff´s alpha[δ] | 0.79 | 0.71-0.87 | 0.88 | 0.82-0.94 | 0.75 | 0.63-0.86 | 0.72 | 0.60-0.85 |
| Interrater Agreement with sedation-analgesia techniques only | | | | | | | | |
| | **Nursing vs Ped vs Relatives** | | **Nursing vs Ped** | | **Nursing vs Relatives** | | **Ped vs Relatives** | |
| | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** |
| Percent agreement | 0.96 | 0.95-0,97 | 0.98 | 0.97-0.99 | 0.95 | 0.94-0.97 | 0.95 | 0.93-0.97 |
| Krippendorff´s alpha[δ] | 0.72 | 0.61-0.84 | 0.87 | 0.79-0.94 | 0.68 | 0.51-0.83 | 0.63 | 0.46-0.80 |
| Interrater Agreement with local anesthesia techniques only | | | | | | | | |
| | **Nursing vs Ped vs Relatives** | | **Nursing vs Ped** | | **Nursing vs Relatives** | | **Ped vs Relatives** | |
| | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** | **Coef.** | **IC95%** |
| Percent agreement | 0.97 | 0.95-0.99 | 0.96 | 0.80-1,00 | 0.97 | 0.95-0,99 | 0.97 | 0.80-1.00 |
| Krippendorff´s alpha[δ]. | 0.91 | 0.83-0.99 | 0.87 | 0.75-0,99 | 0.92 | 0.85-0,99 | 0.90 | 0.79-1.00 |

Note: Ped= Pediatricians; m= mean; CI95%= Confidence Interval 95%; %= percentage; SD= standard deviation; Md= Median; P25= Percentile 25; P75= Percentile 75.

**δ** Landis& Koch scale: <0.0 poor; 0.0 – 0.20 slight; 0.20 – 0.40 fair; 0.40 –0.60 moderate; 0.60 – 0.80 substantial; 0.80 – 1.00 almost perfect