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Research paper

Discomfort of the critically ill paediatric patient and correlated variables

Alejandro Bosch-Alcaraz, RN, PhD [a, b, *]
Iolanda Jordan, MD, PhD [c, d]
Llúcia Benito-Aracil, RN, PhD [e]
Mª Ángeles Saz-Roy, PNP, RN, PhD [b]
Anna Falcó-Pegueroles, RN, PhD [e, f]

[a] Pediatric Nurse, Hospital Sant Joan de Déu, Barcelona, Spain
[b] Department of Public Health, Mental Health, and Maternity/Childhood Nursing, School of Nursing, Faculty of Medicine and Health Sciences, University of Barcelona, Barcelona, Spain
[c] Pediatric Intensive Care Specialist, Hospital Sant Joan de Déu, Barcelona, Spain
[d] Medicine Unit of Training and Research, Faculty of Medicine and Health Sciences, University of Barcelona, Barcelona, Spain
[e] Department of Fundamental Care and Medical-Surgical Nursing, School of Nursing, Faculty of Medicine and Health Sciences, Spain
[f] Consolidated Research Group SGR 269 Quantitative Psychology, University of Barcelona, Barcelona, Spain

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ABSTRACT

Introduction: The care of critically ill children is usually invasive and aggressive, requiring numerous traumatic procedures that may cause fear, pain, and discomfort.
Objectives: The aim of this study was to analyse the level of discomfort of patients admitted to the paediatric intensive care unit of a specialist children's hospital and to determine the sociodemographic and clinical variables that influence the degree of discomfort experienced by critically ill paediatric patients.
Methods: We performed a descriptive observational cross-sectional study that included a total of 311 children with a median age of 5.07 y (interquartile range = 0.9–11.7). A team of 10 paediatric critical care nurses assessed the degree of discomfort once for each shift (morning, afternoon, and night) on 2 successive days using the COMFORT Behavior Scale—Spanish version.
Results: In total, 49.8% (n = 155) of the patients were free of discomfort (score ≤10 points) vs. 50.2% (n = 156) who experienced discomfort. There was a significant negative correlation between discomfort and the length of stay in days (Rho = 0.16; p = 0.02), that is, the longer the stay, the less discomfort the patient felt. The correlation between age and degree of discomfort was found to be both positive and significant (Rho = 0.230, p < 0.001); the greater the age, the greater the discomfort. In comparison of all children who received analgosedation (n = 205), with discomfort levels of 10.77 ± 2.94, with those who did not receive analgosedation (n = 106), with discomfort levels of 11.96 ± 2.80, we did find a statistically significant difference ($\chi^2 = -4.05$; p < 0.001).
Conclusions: Half of the patients admitted to the paediatric intensive care unit experienced discomfort. Age and analgosedation were the two most important variables involved with a high degree of discomfort. Clinical care practices must consider these factors and try to plan activities designed to relieve discomfort in all critically ill paediatric patients.

1. Introduction

The care of critically ill children is usually invasive and aggressive, requiring numerous traumatic procedures that may cause fear, pain, and discomfort.[1,2] Analgesia is a fundamental aspect of the

* Corresponding author. Paediatric Intensive Care Unit. Unit. Hospital Sant Joan de Déu, Pº Sant Joan de Déu, 2, 08950, Esplugues, Barcelona, Spain. . Tel.: +34.93.280.55.69; fax: +34 93.280.36.26.
E-mail address: abosch@sjdhospitalbarcelona.org (A. Bosch-Alcaraz).

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care of critically ill paediatric patients to avoid pain and discomfort.[3–5] Moreover, comfort related to distress is an essential aspect in the assessment of the paediatric critical care population, especially of sedated and mechanically ventilated patients who are unable to communicate effectively.[6] In this case, a correct level of sedation improves patient comfort, so sedation and analgesia together form a useful strategy for maintaining comfort related to distress.[7] Optimising care protocols to provide correct pain control and an optimal degree of sedation at intensive care unit (ICU) admission reduces the anxiety of children and has a positive impact on reducing the pain, distress, and discomfort of these patients.[8,9]

The most commonly used strategy for managing the comfort of critically ill paediatric patients is sedation and analgesia.[3,10,11] The optimal use of analgosedation allows for invasive procedures to be carried out safely by permitting synchronisation and patient tolerance of mechanical ventilation (MV),[11] preventing accidental extubation and reducing both metabolic[12] and oxygen consumption in the case of shock.[13]

Pharmacological therapy to control pain, induce comfort, and produce tolerance of an apparently hostile environment in critically ill patients is based on substances such as sedatives/hypnotics and analgesics. Among these, those most frequently used are benzodiazepines (midazolam), opioids (morphine chlorhydrate and fentanyl), nonsteroidal anti-inflammatory drugs (NSAIDs) (ibuprofen and ketorolac), and paracetamol.[14–16] When deciding which therapeutic agent to use in the analgosedation of critically ill paediatric patients, a number of factors need to be considered: the type and duration of the procedure, the depth of sedation required, the need for intravenous access, prior experiences of the patient with sedation and analgesia, the risk factors identified in pre-evaluation, and the experience of the professionals with the available medication.[17] Improper assessments of the required analgesia and sedation can lead to overdose. This in turn can set back the timetable for ventilator withdrawal because of over sedation and/or haemodynamic instability or lead to desynchronisation of the patient with the respirator or accidental extubation,[18] which increases morbidity. Because of these implicit risks, the continuous assessment of the degree of comfort of mechanically ventilated patients and those under analgosedation is of fundamental importance.

In the context of caring for critically ill patients, the concepts of comfort and discomfort are usually associated simply with sufficient or insufficient pain control by means of sedation and analgesia. The care provided to critically ill children involves numerous invasive procedures that, although therapeutically justified, can cause pain, fear, anxiety, stress, and discomfort, both physically and psychologically,[1] and which may on occasion become intertwined.[19] The complexity of managing the comfort of patients admitted to a specialised facility of this kind represents one of the greatest challenges for the personnel providing care.[7,20]

Nonetheless, there have been no studies carried out to analyse the sociodemographic and clinical variables that might need to be considered in determining the degree of discomfort experienced by critically ill paediatric patients. Knowing what these factors are would allow for the design of additional analgesic strategies and sedative treatment that would improve the overall comfort of critically ill paediatric patients. For this reason, we felt it necessary to determine what variables correlated with the levels of patient discomfort.

2. Aims

- To analyse the degree of discomfort of patients admitted to the paediatric intensive care unit (PICU) of a third-level hospital.
- To determine the sociodemographic and clinical variables that influence the degree of discomfort experienced by critically ill paediatric patients.

3. Methods

3.1. Study design and participants

This was a descriptive observational cross-sectional study performed in the 18-bed ICU of a specialist paediatric hospital in Barcelona, Spain. The study was conducted between January and September 2016.

The inclusion criteria were as follows: (i) patients admitted to the intensive care area during the study period and (ii) patients who provided informed consent signed by the legal representatives of those younger than 12 y and by patients aged 12 y or older. In sedated patients, consent for participation was obtained from the family or legal representatives. The exclusion criteria were as follows: (i) patients who were receiving palliative care and (ii) those with a language barrier.

For the selection process, we used a nonprobabilistic sampling technique because of its ease of use. To calculate the sample size, we used the online program GRANMO (Program of Research in Inflammatory and Cardiovascular Disorders. Institut Municipal d'Investigació Mèdica, Barcelona, Spain), version 7.12, for two independent averages. With a population of 1450 patients per year—the total number of admissions corresponding to the year before the study—it was estimated that a minimum sample size of 221 individuals (95% confidence interval and precision ± 5%) was needed. The population percentage needed for replacements was determined to be 5%.

Taking into consideration both clinical experience and clinical evidence, we selected the sociodemographic and clinical variables that might have an impact on the management of critically ill paediatric patients. A total of 11 variables were recorded: (i) admission unit (PICU/paediatric high-dependency unit), (ii) sex (male/female), (iii) age (in months), (iv) medical diagnosis at admission (respiratory/postsurgical/infectious/oncological/other), (v) administration of analgosedation (yes/no) and type, (vi) level of pain (determined using the Face, Legs, Activity, Cry and Consolability [FLACC], PAIN, and numerical pain scales, which classified pain as follows: no pain = 0; mild pain = 1-3 points; moderate pain = 4-7 points; and severe pain = 8-10 points,[21–23] (vii) patient temperature (normal, febrile, fever/mild hypothermia, and high fever/hypothermia), (viii) overall length of stay in the critical care area (in days), (ix) work shift (morning/afternoon/night), (x) patient accompaniment (yes/no), and (xi) family member present with the critically ill child (father/mother/legal guardian), and his or her age (in years), educational level, and profession

3.2. Instruments

We used the COMFORT Behavior Scale—Spanish version (CBS-S) to assess the degree of discomfort of critically ill paediatric patients.[24] The CBS-S has adequate measurement properties in terms of reliability (Cronbach's alpha coefficient of 0.715), although the data obtained are weaker than those obtained from the psychometric studies of the COMFORT scale (Cronbach alpha coefficient of 0.90) and the COMFORT Behavior Scale (Cronbach alpha coefficient of 0.90–0.92).[25,26] The CBS-S comprises three dimensions with two factors each assessed by means of a Likert scale ranging from 1 to 5 points: (1) “Alertness and physical

movement"; (2) "Calmness/Agitation" and "Respiratory response/Flat", and (3) "Muscle tone" and "Facial tension". The scores established with the COMFORT Behavior Scale-Spanish version were classified as follows: ≤10 points, absence of discomfort; 11–22 points, discomfort; and ≥23 points, severe discomfort.[23] These cut-offs are similar to those reported by the authors of the original scale in relating COMFORT scores to pain.[27] To gather the other 11 variables, we used a form developed by the research team.

3.3. Data collection

With the aim of administering the instrument to the study sample, a team of 10 nurses with university education in the critical care area, each with a minimum of 5 y of experience in the management of critically ill patients, was assembled. The team received specific training for one week that included a brief explanation of the concept of comfort and of the use of the CBS-S. The tool was used in the PICU for one week before the study began. The degree of discomfort was determined by these trained professionals working the three shifts (morning, afternoon, and night). During training, any questions concerning the comprehension of items were resolved.

Afterwards, following the request for informed consent from the parents or guardians of paediatric patients younger than 12 y, the assessments of the level of discomfort were performed once each shift (morning, afternoon, and night) for two consecutive days during the hospital stay.

3.4. Statistical analysis

Descriptive and bivariate analyses were carried out. Numerical variables were described by means of descriptive statistics (mean, standard deviation, median, quartiles, and interquartile range).

To compare numerical values of comfort between samples matched according to scores by two professionals for each patient, the Wilcoxon test was used for two samples and the Friedman test was used for more than two samples. In the case of two independent samples, the Mann–Whitney U test was used, and for more than two samples, the Kruskal–Wallis test was used. To determine whether there was an association between two categorical variables, the chi-squared test was used, and in the case of two numerical variables, the Spearman correlation was used.

For all tests, a confidence level of 95% was established, while the data obtained were considered to be statistically significant when $p < 0.05$. For the statistical analyses, IBM SPPS® Statistics for Windows, version 23.0 (Armonk, NY: IBM Corp), was used.

3.5. Ethical considerations

The research team followed the bioethical principles and guidelines established by the Belmont Report (1979) and the Declaration of Helsinki (1964–2013). The study was approved by the clinical research and ethics committee (PIC-06-16) of the hospital where it was conducted and by the bioethics commission of a public university (IRB-00003099). The legal representatives of the participants were informed, as were the participants themselves, in accordance with their level of comprehension in light of the doctrine of the mature minor. The participants, parents, or guardians were also told that their informed consent was required. The data derived from the study were of a confidential nature, and the information was managed to protect the confidentiality and followed the Spanish regulations.

4. Results

4.1. Characteristics of the participants and their families

A total of 311 patients were included in the study, and 54 had missing data, representing 17.4% of the total sample. In total, 56.6% (n = 176) were male with a median age of 5.07 y (interquartile range = 0.9–11.7). Of the patients, 94.9% (n = 295) were in the PICU and the remaining 5.1% (n = 16) were in a paediatric high-dependency unit. The medical condition most frequently prompting PICU admission was surgical recovery, representing 60.1% (n = 187) of the patients; of these patients, heart surgery (14.4%, n = 44) and surgery for idiopathic scoliosis (10.9%, n = 34) were the most prevalent, followed by respiratory illness (11.9%, n = 37). Among all patients, 72.3% (n = 225) were normothermic and 65.9% (n = 205) were being administered some form of analgosedation, most frequently morphine chlorhydrate (22.5%, n = 70), fentanyl (8.7%, n = 27), or fentanyl and midazolam (7.4%, n = 23). A total of 240 (77.2%) patients included in the study were pain-free versus 19 (6.1%) patients who experienced pain.

Overall, 96.2% (n = 299) of the patients were accompanied by a family member at the time of the discomfort assessment; for 63.7% (n = 198) of the patients, the family member was the mother. The average age of the accompanying family member or guardian was 39.41 y (standard deviation [SD] ± 7.31); 37.6% were university educated (n = 117), and 34.1% were trained professionals (n = 106).

The median length of stay in the PICU was 2 d (2–110). Table 1 presents the clinical and sociodemographic characteristics of the sample in detail.

4.2. Degree of discomfort and correlated variables

In total, 49.8% (n = 155) of patients were free of discomfort (score ≤10 points) versus 50.2% (n = 156) who experienced discomfort, as indicated by scores equal to or greater than 11 points. Fig. 1 presents the frequency of the discomfort scores obtained from the administration of the CBS-S to the 311 patients.

None of the assessed patients scored higher than 22 points on the CBS-S. The classifications according to the level of discomfort obtained from our sample are shown in Fig. 2. Of the 125 patients who were assessed during their 2 d of recorded stay, the degree of discomfort was 10.62 points (SD ± 3.08) on day 1 versus 11.06 (SD ± 3.92) on day 2; however, this difference was not statistically significant ($W = -0.97$; $p = 0.33$).

A comparative analysis was performed with the patients who were in the unit for less than 1 d (n = 103) and those admitted for more than 1 d (n = 208). There was a significant negative correlation between discomfort and the length of stay in days (Rho = 0.16; $p = 0.02$), that is, the longer the stay was, the less the discomfort the patient experienced (lower score on the CBS-S); see Fig. 3. An analysis was also performed in terms of the length of stay in hours, revealing that as the total hours of stay increased, the discomfort decreased ($\chi 2 = 19.20$; $p = 0.000$).

In analysing the data related to work shifts, it was noted that the average degree of discomfort observed in the 162 patients decreased with each of the three shifts. The first day, the discomfort was 10.87 points (SD ± 3.01) on the morning shift, 10.77 (SD ± 3.41) on the afternoon shift, and 10.19 points (SD ± 2.76) on the night shift. In comparing the levels of discomfort for the first day in the PICU, the scores were lower for the night shift than for the morning or afternoon shifts, but there were no statistically significant differences ($\chi 2 = 3.89$; $p = 0.14$). In determining the degree of discomfort of the 99 patients assessed three times on their second day in care, similar values were found for the levels of discomfort, with scores of 10.58 points (SD ± 3.79) during the morning shift, 10.53 points (SD ± 3.02)

Table 1
Clinical and sociodemographic characteristics of the sample (n = 311).

Characteristics	Values n (%)	Correlations and significance
Unit of admission[a]		
Intensive care unit	295 (94.9)	–
High-dependency unit	16 (5.1%)	
Length of stay[b]	2 (2–110)	Rho: 0.16; **p = 0.02**
Gender (n/%)[a]		χ2: 0.50; p = 0.97
Female	135 (43.4%)	
Male	176 (56.6)	
Age (years)[b]	5.07 (0.9–11.7)	Rho: 0.23; **p < 0.001**
Diagnosis at admission[a]		χ^2: 2.59; p = 0.27
Respiratory	37 (11.9%)	
Postsurgical	187 (60.1)	
Infectious	28 (9%)	
Oncological	4 (1.3%)	
Others: invasive procedures	55 (17.7)	
Sedoanalgesia[a]		χ^2: −4,05; **p < 0,001**
Yes	205 (65.9%)	
No	106 (34.1%)	
Type of sedoanalgesia[a]		–
Morphine chlorhydrate	70 (22.5%)	
Fentanyl	27 (8.7%)	
Fentanyl and midazolam	23 (7.4%)	
Propofol	22 (7.1%)	
Propofol and morphine ch.	17 (5.5%)	
Others	152 (48.8%)	
Pain[a]		–
No pain	240 (77.2%)	
Mild pain (1–3 points)	13 (4.2%)	
Moderate pain (4–7 points)	6 (1.9%)	
Severe pain (8–10 points)	0 (0%)	
Missing	52 (16,7%)	
Patient temperature[a] (in degrees Celsius: ºC)*		–
Normothermia (35.5–37 °C)	225 (72.3%)	
Febrile (37.1–38 °C)	15 (4.8%)	
Fever (38.1–39 °C)/mild hypothermia (35.4–35 °C)	16 (5.1%)	
High fever (>39.1 °C)/hypothermia (<34.9 °C)	1 (0.3%	
Missing	54 (17.4%)	
Accompanying family member[a]		
Yes	299 (96.1%)	
No	12 (3.9%)	
Which family member[a]		χ^2 = 2.85; p = 0.24
Father	101 (32.5%)	
Mother	198 (63.7%)	
Missing	12 (3.9%)	
Age of family member (years)[b]	39.41 ± 7.31	χ^2 = 0.91; p = 0.63
Educational level of family member[a]		χ^2 = 16.23; **p = 0.01**
No education	9 (2.9%)	
Basic	81 (26%)	
Vocational studies	91 (29,3%)	
University	117 (37.6%)	
Missing	4.2 (13%)	
Family member profession[a]		χ^2 = 22.28; p = 0.13
Skilled work	106 (34.1%)	
Technical work	33 (10.6%)	
Office work	40 (12.9%)	
Sales	26 (8.4%)	
Crafts/manual labour	26 (8.3%)	
Others	67 (21.5%)	
Missing	13 (4.2%)	

- Not calculated: not focus of research/noncomparable groups.
* Ranges based on: V.E. del Bene. Chapter 218: Temperature. In: H.K. Walker, W.D. Hall, J.W. Hurst, editors. Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston: Butterworths; 1990.
Bold values correspond to statistically significant data.
[a] Frequency (percentage).
[b] Median and interquartile range.

during the afternoon shift, and 9.93 points (SD ± 2.60) during the night shift; there were no statistically significant differences among shifts (χ^2 = 2.89; p = 0.23). The paired analysis revealed that the discomfort levels during the night shift were significantly lower than those during the afternoon shift (W = −2.29; p = 0.022) and the morning shift (W = −4.34; p < 0.001) (Table 2).

Focussing on the relations between the degree of discomfort and sociodemographic variables, we found that 49.4% (n = 87) of the males and 50.4% (n = 68) of the females were free of discomfort, versus 50.6% (n = 89) and 49.6% (n = 67), respectively, who experienced discomfort. No statistically significant relation was found between sex and degree of discomfort (χ^2 = 0.50; p = 0.97).

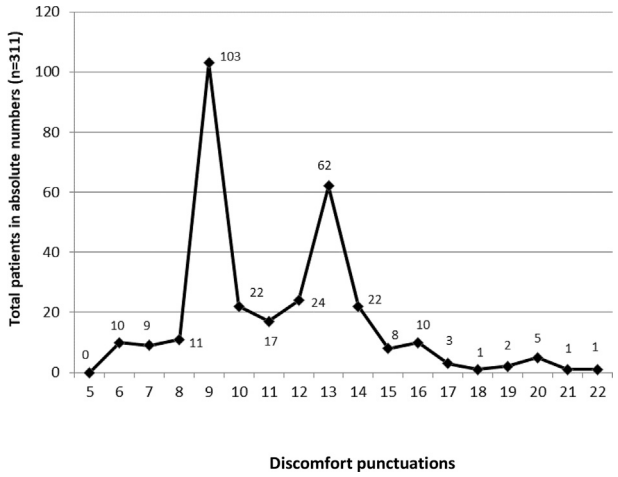

Fig. 1. Frequency of the obtained discomfort scores (n = 311).

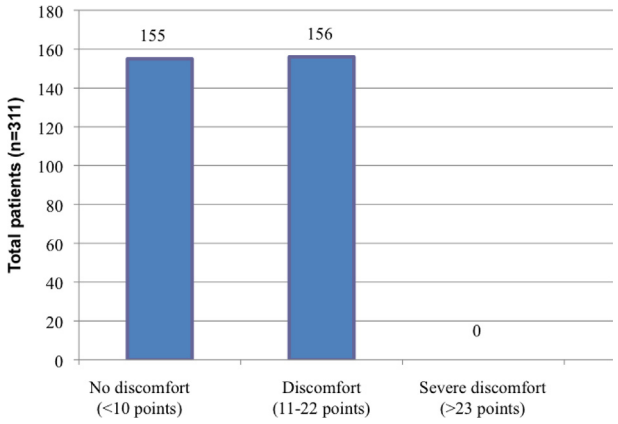

Fig. 2. Classification of degree of discomfort for the total sample (n = 311).

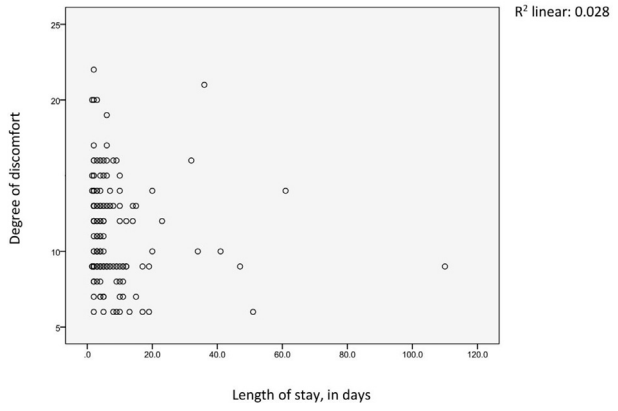

Fig. 3. Scatter plot of length of stay in days and degree of discomfort.

In contrast, there were significant differences according to the age groups analysed (p = 0.001). The patients who did not experience discomfort (≤10 points) had an average age of 5.04 months (SD ± 5.26), while those experiencing discomfort (≥11 points) had an average age of 7.68 months (SD ± 6.03) (W = −3.75; p < 0.001). In analysing the correlation between age and degree of discomfort, the correlation was found to be positive and significant (Rho = 0.230, p < 0.001); the greater the age, the greater the discomfort (Fig. 4).

In terms of other clinical parameters, it was observed that there was neither significant relationship between the degree of discomfort and the type of clinical diagnosis ($\chi^2 = 17.42$; p = 0.66) nor significant differences between patients admitted for medical conditions versus for surgery ($\chi^2 = 2.59$; p = 0.27).

We examined the shifts to determine in which shift the most patients received analgosedation, and the result was the morning shift on day 1 of the evaluation. In comparison of all children who received analgosedation (n = 205), with discomfort levels of 10.77 ± 2.94, with those patients who did not receive analgosedation (n = 106), with discomfort levels of 11.96 ± 2.80, we did find a statistically significant difference ($\chi^2 = -4.05$; p < 0.001). Furthermore, we found that 60.4% (n = 64) of the patients without analgosedation experienced discomfort (score ≥10 points) versus 36.6% (n = 75) of those who experienced discomfort but were given analgosedation ($\chi^2 = 1$; p < 0.001).

Finally, no statistically significant relationships were found between the presence of family members, sex, and the profession of the family member accompanying the patient. The variable of educational level of the accompanying family member was statistically significant between patients who experienced or did not experience discomfort ($\chi^2 = 16.23$; p = 0.01), that is, the children whose parents with no university education experienced greater levels of discomfort.

5. Discussion

The proportion of critically ill paediatric patients found to have high levels of discomfort in the PICU was considerable, despite the analgesia and sedation that most patients received. Although there was a reduction in discomfort in the hours following admission to the unit, this remains unacceptable.

Other studies have been carried out on postoperative paediatric patients, and low scores were recorded on the Comfort Behavior Scale, from which one may conclude that the patients had little pain and were therefore comfortable.[28,29]

The biopsychosocial model establishes that sex and age factors have a direct impact on the perception of pain and discomfort.[29] In the present study, we noted that the variable of age may influence the degree of discomfort of critically ill paediatric patients; the older the patient, the greater the discomfort. This is probably related in part to the conscious perception of the hostile environment in which the child is being treated. However, this observation has not been corroborated in other paediatric studies, although an investigation carried out in an adult sample did find greater pain and discomfort in younger patients.[30] This highlights the importance of comfort management in paediatric and adolescent populations.[8]

Another variable that plays a key role in managing the degree of comfort in critically ill paediatric patients is analgosedation, given the aggressive therapies that patients are subjected to for both clinical and critical-care reasons in a setting such as the intensive care unit. Correct sedation needs to be applied immediately at the start of the clinical management of patients admitted to the PICU to reduce the discomfort felt by children who find themselves in hostile surroundings and subjected to constant handling. Correct sedation would not only influence the comfort of the patient but also increase patient safety and security throughout the care process.[14]

In our study, 6.1% of patients experienced pain, lower values that in other investigations in which 55% of patients reported feeling acute pain.[31–36] Analgesia reduces the pain caused by invasive procedures.[37,38] Both sedation and analgesia are used to maintain an optimal and safe level of comfort for critically ill children.[14] This study has demonstrated that patients receiving incorrect analgosedation experience greater discomfort.

Table 2
Comparison of degrees of discomfort between shifts.

Pairs		Average	N	Typical deviation	Z[a]	Asymptotic signed (bilateral)[b]
Pair 1	Morning	10.91	174	3.031	−0.590[a]	0.555
	Afternoon	10.95	174	3.449		
Pair 2	Afternoon	10.80	169	3.353	−2.287[a]	**0.022**
	Night	10.14	169	2.724		
Pair 3	Morning	11.05	205	3.016	−4.338[a]	**0.000**
	Night	10.05	205	2.563		

Bold values correspond to statistically significant data.
[a] Based on positive ranges.
[b] Range test with Wilcoxon signed-rank.

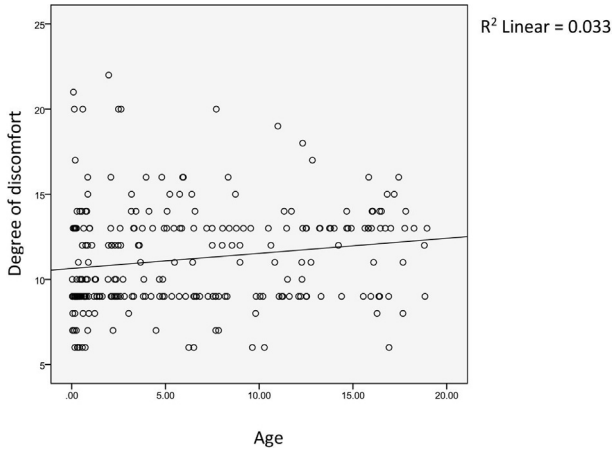

Fig. 4. Spearman correlation between degree of discomfort and age variable.

The relationship between comfort and correct/incorrect analgosedation was demonstrated in an experimental study in a PICU in Seoul, South Korea, of 21 children in an experimental group with an average age of 20.1 months (SD ± 30.7) and 20 participants in a control group with an average age of 21.7 months (SD ± 25.2), finding that guiding the sedation of these patients under a comfort protocol and using the COMFORT Scale reduced the time MV was needed, the length of stay in the critical care unit, the need for sedatives, as well as the incidence of adverse pharmacological events.[7] The importance of monitoring analgosedation is critical, and it can directly influence the correct use of the available medication to maintain the comfort of the patient, the time spent on MV, the length of stay in the ICU, the presence of nosocomial complications, and even mortality.[32,39–45]

5.1. Limitations

Despite the large sample size used for the present study (n = 311), the main limitations were that the data were obtained in the critical care unit of a single centre and inter-rater reliability was not assessed. Future studies should be designed and carried out in several centres to enable comparisons of the degree of comfort in the PICU across diverse hospitals, both nationally and internationally, to observe whether the degree of discomfort might be determined in part by dynamics and protocols specific to paediatric critical care and attention offered in different centres. Furthermore, it is important to note that comfort is a very broad term and not all elements and factors contributing to comfort were measured.

6. Conclusions

In our study, 50.2% (n = 156) of patients admitted to the PICU experienced discomfort, as indicated by scores equal to or greater than 11 points, and we noted that age and analgosedation were the two most important sociodemographic and clinical variables affecting discomfort. For this reason, comfort in paediatric critically ill patients should be assessed by all health professionals involved in their care. Assessment and management of comfort as well as adequate control of pain in daily practice will help improve the attention offered to patients.

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Conflict of interest

The authors declare that they have no conflicts interest.

CRediT authorship contribution statement

Alejandro Bosch-Alcaraz: Methodology, Writing - original draft, Writing - review & editing. **Iolanda Jordan:** Writing - original draft, Writing - review & editing, Methodology. **Llúcia Benito-Aracil:** Writing - original draft, Writing - review & editing. **Mª Ángeles Saz-Roy:** Writing - original draft, Writing - review & editing. **Anna Falcó-Pegueroles:** Writing - original draft, Writing - review & editing, Methodology.

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