INTENS CRIT CARE NUR 85 (2024) 103788

Contents lists available at ScienceDirect

Intensive & Critical Care Nursing

journal homepage: www.sciencedirect.com/journal/intensive-and-critical-care-nursing

Research Article

Prevalence of use of physical restraints in pediatric intensive care units and correlated variables: A Spanish multicenter study

Alejandro Bosch Alcaraz [a,b,*], Sylvia Belda Hofheinz [c], Jesús Corrionero Alegre [d], José Miguel García Piñero [e], Sonia Gil Domínguez [c], Rocío Fernández Lorenzo [f], María Mata Ferro [f], Ainhoa Martín Gómez [f], Marta Serradell Orea [f], Patricia Luna Castaño [g,h], M. Ángeles Saz Roy [a,b,*], Esperanza Zuriguel Pérez [i,j], Marta Martínez Oliva [d], Susana González Rivas [d], Nerea Añaños Montoto [d], María José Espildora González [e], Elena Martín-Peñasco Osorio [e], Eva Carracedo Muñoz [c], Eduardo López Fernández [c], Gema Lozano Almendral [k], Maria Victoria Ureste Parra [k], Alicia Gomez Merino [k], Alexandra García Martínez [k], David Morales Cervera [k], Laura Frade Pardo [k], Ainhoa Díaz Lerma [l], Pedro Piqueras Rodríguez [k,m]

[a] *Department of Public Health, Mental Health and Maternal and Child Health Nursing, Faculty of Nursing, University of Barcelona (UB), Barcelona, Spain*
[b] *Mental Health, Psychosocial and Complex Nursing Care Research Group-NURSEARCH, University of Barcelona, Barcelona, Spain*
[c] *Pediatric Intensive Care Unit 12 de Octubre Hospital, Madrid, Spain*
[d] *Pediatric Intensive Care Unit, Vall Hebron Hospital, Barcelona, Spain*
[e] *Pediatric Intensive Care Unit Nursing Supervisor, Málaga Regional University Hospital, Spain*
[f] *Pediatric Intensive Care Unit, Sant Joan de Déu Hospital, Barcelona, Spain*
[g] *Alfonso X el Sabio University, Madrid, Spain*
[h] *Member of the Health Care and Services Research Unit (Investén-ISCIII), Spain*
[i] *Department of Knowledge Management and Evaluation, Vall d'Hebron Hospital, Barcelona, Spain*
[j] *Multidisciplinary Nursing Research Group. Vall d'Hebron Research Institute (VHIR), Barcelona, Spain*
[k] *Pediatric Intensive Care Unit, La Paz Hospital, Madrid, Spain*
[l] *Intensive Care Unit, Clinic Hospital, Barcelona, Spain*
[m] *Health Research Institute, La Paz Hospital – IdiPAZ, Madrid, Spain*

ARTICLE INFO

Keywords:
Physical restraint
Pediatrics
Intensive Care Units
Behavior

ABSTRACT

Objective: To calculate the prevalence of physical restraint (PR) use in Spanish PICUs and (2) to analyze the correlation between the prevalence of PR use and the sociodemographic, clinical variables of the patients and the PICU structural and organizational variables.

Methods: We conducted a multicenter prevalence study from January 2022 to January 2023 in Spanish PICUs. The method of data collection was by direct observation, review of the patient's medical history, and asking the professionals involved in the patient's care. Three weekly 24-hour prevalence observations (morning, afternoon, and night) were conducted for 6 months.

Results: A total of 336 patients were included in the study, obtaining an overall crude prevalence of PR use of 16 % (95 %CI: 15 %-17.7 %). Pediatric patients with respiratory pathology received the highest number of hours of PR, with significant differences observed when comparing respiratory cases with post-surgical cases. Statistical significance was also observed when comparing the mean scores of hours of PR according to admission diagnosis ($p = 0.01$), with respiratory patients being the ones who were restrained the longest (24 h [20–24]) and infectious patients the least (15 h [14–20]). Patients who receive PR upon admission remain in this situation for more hours (24 h [15–24] and in the PICUs that specifically recorded PR application, fewer hours of PR occurred (20 h [4–24]).

* Corresponding authors at: Department of Public Health, Mental Health and Maternal and Child Health Nursing, Faculty of Nursing, University of Barcelona (UB), Carrer de la Feixa Llarga, s/n, 08907 L'Hospitalet de Llobregat, Barcelona, Spain.
E-mail addresses: alejandrobosch@ub.edu (A. Bosch Alcaraz), masazroy@ub.edu (M. Ángeles Saz Roy).

https://doi.org/10.1016/j.iccn.2024.103788
Received 10 May 2024; Received in revised form 7 July 2024; Accepted 31 July 2024
Available online 7 August 2024

Conclusions: The use of PR is still present in the PICUs analyzed, with a crude prevalence of 16%. Factors such as the reason for admission, the use of respiratory support, and the reason for application of PR were linked to the hours of use of PR.
Implications for clinical practice: Knowing the prevalence of PR use will make professionals aware that it is still necessary to implement policies that avoid its use to prevent the side effects they have in pediatric patients.

Introduction

Intensive care units (ICUs) are areas dedicated to the care of patients whose pathology has become so severe that their lives are actually or potentially threatened. Comprehensive management is usually invasive, requiring numerous diagnostic and therapeutic procedures throughout the period of care [1]. As a result of clinical management, many critically ill patients develop behavioural disturbances such as agitation and delirium, making it difficult to provide safe medical care and to ensure the maintenance and continuity of life-sustaining devices such as endotracheal tubes or vascular catheters [2–5], justifying the use of pharmacological treatment or physical restraints [6]. The aim is to prevent unplanned adverse events related to patient safety. Since the effectiveness of these methods is uncertain and their use has not been found to prevent adverse events related to patient safety [7], PR should be used only when collaborative alternatives have been exhausted [8–10]. Some interventions to prevent the use of PR focus on the implementation of the Patient and Family Centred Care (PFCC) approach in PICUs, which includes working with families during the PICU stay and preventing agitation, pain management, promoting comfort and early mobilization [6].

With the same aims than ICU setting in pediatric intensive care units (PICUs), PR is applied to carry out specific painful procedures [5,8,11–14] and to ensure the upkeep and continuous use of life-support devices such as endotracheal tubes, vascular catheters, urinary and/or nasogastric tubes, and drainage systems (pericardial, pleural, and/or external ventricular shunts). As Mattiussi et al. note, 'the right to safe care is also a fundamental right for patients' [6], but this makes the goal of 'zero restraints' difficult to achieve. However, critically ill paediatric patients have different physiological, psychological and developmental needs than adults, particularly in relation to the information they receive to ensure their cooperation throughout the healthcare process. For this reason, the use of restraints in the paediatric setting is controversial as it may cause stress and violate children's rights, like independence and mobility [6,15–19].

The concept of physical restraint in the pediatric setting is ambiguous [8,15], and we can find names such as "clinical" or "supportive holding" or "restraint." Holding refers to "positioning a child so that a medical procedure can be carried out in a safe and controlled manner, wherever possible with the consent of child and parent/carer." In contrast, "restraint is used to administer medication or carry out a procedure to which the child objects and is carried out in what is considered to be in the child's best interest" [17,20]. At the same time, it is essential to differentiate between PR and punctual and specific physical restrictions, which are applied in pediatrics to carry out invasive procedures, such as placing a peripheral venous catheter. Although the duration of physical restriction is shorter than that of PR, studies conducted by Brenner et al. conclude that its use is very stressful and not beneficial for the child, in addition to leading to feelings of helplessness and vulnerability [21,22]. In this sense, the brevity of physical restriction does not seem to protect pediatric patients from adverse physical and psychological events.

Although the literature estimates the prevalence of PR use in the ICU to be 0–100 % [6], there is a lack of evidence in the PICU. However, the only recent study by Ikebe et al estimated a prevalence of 53 % (211/398) in children with physical restraints [23].

Given the obvious drawbacks of PR and the ongoing doubts about its benefits, experts promote strategies that reduce the use of PR as much as possible, turning instead to preventive and/or alternative interventions, with the goal of achieving "zero restraint" [2,3,8,12,24,25]. Prior to the implementation of these strategies, it is essential to identify the prevalence of PR use and the variables that are related to it. However, there are few studies that focus on the prevalence of PR in PICUs or the related factors.

Objectives

The general objective of the study was to describe the use of PR in five Spanish PICUs. The specific objectives were: (1) to calculate the prevalence of PR use in Spanish PICUs; (2) to analyze the correlation between the prevalence of PR use and the sociodemographic and clinical variables of the patients and (3) to analyze the correlation between the use of PR and the structural and organizational variables of the participating PICUs.

Methods

Design, study period and context of study

We conducted a multicenter prevalence study from January 2022 to January 2023 in PICUs from five Spanish tertiary-level maternity and paediatric hospitals (Sant Joan de Déu Hospital −24 beds-; Vall d'Hebron Hospital −20 beds-; La Paz University Hospital −20 beds-; 12 Octubre Hospital −16 beds- and Málaga Regional University Hospital −13 beds-), according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [26]. The five paediatric intensive care units included in the study are located in five of the most important paediatric hospitals in Spain. They care for paediatric patients suffering from any critical pathological process and receive admissions from other communities. All participating PICUs received patients for medical and post-operative admissions and maintained a policy of open visiting hours for family members 24 h a day. Two of them had an infrastructure consisting of open bays separated by curtains, one had individual rooms, and two had of them had a combination. None of them had an specific PR clinical guidelines.

Population and sample

All patients aged 0 to 18 years admitted to the selected PICUs during the study period were included, hence a sample size calculation was not performed. The sampling technique was non-probabilistic, consecutive, and age stratified. The sample was distributed according to the five pre-established age groups (see the classification established in the age variable). The patient selection criteria were as follows:

Inclusion criteria:

- Pediatric patients aged 0 to 18 years admitted to the PICUs under study.
- Acceptance and signing of the informed consent by the legal representatives and child aged 12 years or older.

Exclusion criteria:

- Patient at the end of life.

- Parents and child aged 12 years or older language barrier that hindered the comprehension of the study and/or obtaining informed consent.

Withdrawal criteria:

- Express verbalization by the family member or patient indicating a desire to withdraw from the study.

Study variables

Variables related to the sociodemographic and clinical characteristics of the patients were recorded: (i) age (in years and categorized for subsequent analysis into newborn and nursing (from 0 to 2 years), preschool-aged children (from 3 to 6 years), school-aged children (from 7 to 12 years) and teenagers (from 13 years to 18 years); (ii) sex (boy/girl); (iii) reason for admission: medical/surgical; (iv) chronic condition (yes (specify)/no); (v) use of sedation (yes (specify)/no); (vi) use of analgesics (yes (specify)/no); (vii) presence of family members at the time of the prevalence assessment (yes/no); (viii) type of family member (mother/father/primary caregiver/others); (ix) respiratory support (yes/no) and (x) type of respiratory support (oxygen therapy/mechanical ventilation/non-invasive ventilation/others).

In addition, the following variables related to the structure and organization of the participating PICUs were recorded: (i) type of PICU (medical/surgical/mixed); (ii) architectural layout (closed room/open bay/mixed); (iii) visitation policy (open 24 h/restricted to a set schedule) and (iv) nurse-patient ratio (specify).

Finally, data were obtained on the following variables related to the use of PR: (i) shift in which the prevalence assessment was carried out (morning/afternoon/night); (ii) total number of patients admitted to the PICU at the time of the prevalence assessment (specify); (iii) time of application of PR (upon admission/during stay/unknown); (iv) hours of PR (specify); (v) reason for PR (risk of falling, risk of treatment interruption, and/or risk of self-harm); (vi) specific protocol regulating the use of PR (yes/no); (vii) specific record related to the use of PR (yes/no); (viii) professional who indicates PR (nurse/pediatrician/both); (ix) written prescription for PR (yes/no); (x) verbal/written informed consent prior to PR (yes/no); (xi) experience of the professional indicating PR (<5 years experience, 5–10 years experience, >10 years experience); (xii) use of approved material (yes/no); (xiii) type of PR (wrist restraint/cuffs-splints/ankle restraint/ abdominal restraint); (xiv) removal of PR has been assessed (yes/no); (xv) complications (yes/no) and (xvi) type of complication (injury due to chafing or friction/bruising/agitation/edema/other).

Data collection process and instruments

A group up of nurses and pediatricians with a minimum of 5 years of experience in the comprehensive management of critical pediatric patients was responsible for making prevalence observations during their work shift and recruiting a team to conduct observations in the remaining shifts. After each hospital's research group was established, a two-hour training session was conducted. This session covered the concept of PR, the research objectives, the data collection documents, and the procedures involved. To this end, a PowerPoint® presentation was used and the training was carried out either face-to-face or virtually, depending on the availability of the principal investigator. To ensure comprehension of this training, each staff member was given a verbal reminder of the data collection procedure and shown the ad hoc tool again just before assessing their first patient. At the same time, each staff member recorded their first prevalence data with the help of the principal investigator.

The method of data collection was by direct observation, review of the patient's medical history, and asking the professionals involved in the patient's care. Three weekly 24-hour prevalence observations (morning, afternoon, and night) were conducted for 6 months. The first assessment began on a Monday, with days rotating to a different one each week to mitigate recording biases. This means that in the first seven weeks of the research we collected data on different days of the week: Monday (first week), Tuesday (second week), Wednesday (third week) and Thursday, Friday, Saturday and Sunday for the remaining weeks. This procedure and alternative collection days were repeated during the prevalence study.

For patients subjected to PR, informed consent was obtained from the family members, and consent and/or assent were obtained from patients aged >12 years regarding their voluntary participation in the study. Once participation was accepted, the patient's sociodemographic and clinical data on PR were first recorded, as well as data related to the use of PR. A professional from each participating hospital provided the values for the variables related to the structural characteristics of the PICU.

To record all data derived from the study, a data collection notebook was developed ad hoc. This notebook included a brief explanation of the project and patient recruitment process, a grid to collect all data related to the study variables, as well as the informed consent form.

Statistical analysis

The collected data were stored in a database created using Microsoft® Excel software, preserving patient privacy. For the management and statistical analysis of the data, we used SPSS® v. 21.0 software (Armonk, NY: IBM Corp.) and Mplus v. 5.1 by Muthen&Muthen.

Numerical variables were described using descriptive statistics (mean, standard deviation, median and quartiles) and categorical variables were described using frequency tables with percentages. In order to compare the values of a numerical variable between paired samples, the Wilcoxon signed-rank 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 Student's *t*-test was used, and for more than two samples, the ANOVA test. To test whether two categorical variables were related, the chi-square test was performed, and in the case of two numerical variables, Spearman's correlation. Finally, the crude prevalence (number of patients with PR divided by the total number of patients admitted to the ICU during the 24-hour assessment period) was calculated for each day of the week. All data were considered statistically significant if $p \leq 0.05$.

Ethical considerations

Permission was received from nursing management and the ethics and clinical research committees of the participating hospitals. In addition, the principles set out in the Declaration of Helsinki (2013) as well as those of the Belmont Report (1979) were respected. Family members received information about the study orally, and they gave their written informed consent for their child to participate in the study. Children > 12 also provided their assent. Throughout the study, compliance with the Organic Law 1/1996 on the legal protection of minors, Law 41/2002 on patient autonomy and rights and obligations, and the provisions of Organic Law 8/2015 of July 22, which amended the child and adolescent protection system, was ensured. Additionally, we adhered to Regulation 2016/679 of the European Parliament and of the Council of April 27, 2016, as well as Organic Law 3/2018 of December 5, 2018, on the Protection of Personal Data and Guarantee of Digital Rights.

Results

Characteristics of patients, pediatric intensive care units, and the use of physical restraint

During the prevalence study period, a total of 345 patients were

physically restrained. Finally, 336 patients were included in the study, most of them male (59.8 %, n = 201). Post-surgical patients were the most common patient profile (37.8 %, n = 127). Of all subjects, 65.1 % (n = 213) had a chronic condition. A sedative drug was used in 74.6 % (n = 249), with dexmedetomidine being the most common, in 45.8 % of these patients (n = 114). Of the subjects, 89.9 % (n = 302) were receiving an analgesic, with paracetamol being the most commonly used, in 68.9 % (n = 208) of these patients. In addition, 79.8 % (n = 268) were ventilated, with mechanical ventilation, the most common type, being used in 58.7 % (n = 158). Finally, 78.9 % of the patients were accompanied by a family member (n = 265). Table 1.

In 65.3 % (n = 218) of patients, PR was applied during admission and in 85.3 % (n = 285). In 99.7 % (n = 335) of patients restrained, there was no protocol for PR and in 69.9 % (n = 234) there was no specific record of the use of PR. The nurse was the professional who most indicated PR (98.5 %, n = 331). In 92.8 % (n = 310) of the cases, approved material was used to perform PR, with wrist restraints (72.2 %, n = 241) being the most common type. In 99.4 % of the cases, no complications were detected. Table 2.

Finally, patients were admitted to the PICU for a median of 96 h (24–492) and had PR for a median of 20 h (14–24).

Prevalence of PR use and correlated variables

Among the five PICUs analysed, the overall crude prevalence of PR use was 16 % (95 %CI: 15.0 %-17.7 %). Tuesday being the day with the highest crude prevalence of PR use, 18 % (95 % CI: 15.2 %-21.1 %). Fig. 1. The prevalence of PR use by age group is shown in Table 1.

Pediatric patients with respiratory pathology received the highest number of hours of PR. This is particularly notable in cases requiring non-invasive mechanical ventilation support, where the primary aim was to prevent falls and the interruption of life-support treatment.

Upon analyzing the hours of physical restraint (PR) and various sociodemographic and clinical variables, no statistical significance was observed for age (p = 0.99), sex (p = 0.73), chronic condition (p = 0.78), sedation (p = 0.79), analgesia (p = 0.12), respiratory support (p = 0.40), and family accompaniment (p = 0.21).

Even so, overall, statistical significance was observed when comparing the mean scores of hours of PR according to admission diagnosis (p = 0.01), with respiratory patients being the ones who were restrained the longest (24 h [20–24]) and infectious patients the least (15 h [14–20]). When disaggregating the types of respiratory support, statistical significance was observed (p < 0.001), especially among patients receiving non-invasive ventilation (24 h [15–29]), followed by those on mechanical ventilation (22 h [15–24]). Table 3.

In relation to work shift, fewer hours of PR application were observed at night (20 h [12–24]) compared to the morning (24 h [8–24]) and afternoon (24 h [12–24]), with statistical significance (p = 0.00). Statistical significance (p = 0.01) was also observed when comparing the timing of PR application, indicating that patients who receive PR upon admission remain in this situation for more hours (24 h [15–24]). On the other hand, in the PICUs that specifically recorded PR application, fewer hours of PR occurred (20 h [4–24]) than in those that did not (24 h [1–432]), p < 0.000. Table 3.

Upon analyzing the variables associated with the infrastructure of the participating PICUs, we observed that in the PICUs with closed rooms, patients spent more hours in PR, with a median of 26.50 h [15–72], with statistical significance (p < 0.001), as shown in Table 3.

Discussion

The overall prevalence of PR use in the five PICUs analyzed was 16 % (95 %CI: 15.7 %-17.7 %). We obtained a prevalence of PR use of 16 %, a percentage much lower than the 53 % recorded in another longitudinal point prevalence study in PICU or the 0–100 %, depending on geographical location, recorded in adult ICUs [6,27]. Other research

Table 1
Sociodemographic and clinical characteristics of patients (n = 336).

Characteristic	Values	Prevalence data (%)
Sex (n/%)[a]		
Male	201 (59.8 %)	
Female	134 (39.9 %)	
Missing	1 (0.3 %)	
Age (years)[b]	2.2 ± 4.2	
Age category		
Newborn and nursing (0–2 years)	255 (75.9 %)	17.3 (95 %CI: 15.4–19.3)
Preschool (3–6 years)	36 (10.7 %)	2.4 % (95 %CI: 1.7 – 2.3)
School age (7–12 years)	21 (6.3 %)	1.4 (95 %CI: 0.9 – 2.1)
Teenage (>13 years old)	24 (7.1 %)	1.6 (95 %CI: 0.11 – 2.4)
PICU admission diagnosis (n/%)[a]		
Post-surgical	127 (37.8 %)	
Respiratory	92 (27.4 %)	
Infectious	14 (4.1 %)	
Oncological	11 (3.3 %)	
Other (liver failure, trauma, status epilepticus, cardiological)	92 (27.4)	
Chronic condition (n/%)[a]		
Yes	213 (63.4 %)	
No	114 (34.0 %)	
Missing	9 (2.6 %)	
Type of chronic condition (n/%)[a]		
Congenital heart disease	107 (50.2 %)	
Respiratory (cystic fibrosis, apneas, bronchopulmonary dysplasia, etc.)	23 (10.8 %)	
Neurological (congenital encephalopathy, epilepsy, tuberous sclerosis, hydrocephalus, etc.)	25 (11.7 %)	
Renal (hydronephrosis, renal insufficiency, hemolytic-uremic syndrome, etc.)	18 (8.5 %)	
Digestive and hepatic (short bowel syndrome, jejunal atresia, liver insufficiency, biliary atresia, etc.)	14 (6.6 %)	
Syndromes (Vacterl, Kabuki, Wiedemann Streiner, Koolen-Devries, cri du chat…)	26 (12.2 %)	
Respiratory support (n/%)[a]		
Yes	269 (80.1 %)	
No	66 (19.6 %)	
Missing	1 (0.3 %)	
Type of respiratory support (n/%)[a]		
Oxygen therapy	63 (23.4 %)	
Non-invasive mechanical ventilation	34 (12.7 %)	
Mechanical ventilation	158 (58.7 %)	
Other	14 (5.2 %)	

(*continued on next page*)

Table 1 (*continued*)

Characteristic	Values	Prevalence data (%)
Use of analgesia (n/%)[a]		
Yes	302 (89.9 %)	
No	33 (9.8 %)	
Missing	1 (0.3 %)	
*Type of analgesic drug (n/%)[a]		
Paracetamol	208 (68.9 %)	
Metamizole	159 (52.6 %)	
Morphine sulfate	73 (24.2 %)	
Fentanyl	65 (21.5 %)	
Remifentanil	17 (5.6 %)	
Methadone	22 (7.3 %)	
Use of sedative drugs (n/%)[a]		
Yes	249 (74.1 %)	
No	86 (25.6 %)	
Missing	1 (0.3 %)	
*Type of sedative drug (n/%)[a]		
Levomepromazine	17 (6.8 %)	
Diazepam	26 (10.4 %)	
Dexmedetomidine	114 (45.8 %)	
Midazolam	54 (21.7 %)	
Chloral Hydrate	21 (8.4 %)	
Propofol	74 (29.7 %)	
Ketamine	28 (11.2 %)	
Chlorpromazine	15 (6.0 %)	
Clonidine	54 (21.7 %)	
Others: quetiapine, phenobarbital, clonazepam, sevoflurane, isoflurane, pentobarbital, etc.	15 (6.0 %)	
Family accompaniment		
Yes	265 (78.9 %)	
No	71 (21.1 %)	
Person accompanying the patient		
Mother	164 (61.9 %)	
Father	55 (20.8 %)	
Both (father and mother)	38 (14.3 %)	
Others: grandmother, sibling, aunt, etc.	8 (3.0 %)	

a Frequency (percentage).
b Mean and standard deviation
*The same patient was being given more than one analgesic and sedative drug.

Table 2
Characteristics related to the use of PR in analyzed patients.

Variable	Values (n/%)
Time of application of PR (n = 331)	
On admission	112 (33.5 %)
During the hospital stay	218 (65.3 %)
Don't know / no answer	1 (0.3 %)
Reason for PR (n = 334)	
Risk of falling	10 (3.0 %)
Risk of treatment interruption	285 (85.3 %)
Risk of self-harm	1 (0.3 %)
All of the above	38 (11.4 %)
Specific protocol for the use of PR (n = 336)	
Yes	1 (0.3 %)
No	335 (99.7 %)
Specific record of PR use (n = 335)	
Yes	101 (30.1 %)
No	234 (69.9 %)
Professional indicating PR (n = 336)	
Nurse	331 (98.5)
Pediatrician	0 (0 %)
Both	5 (1.5 %)
Professional experience of professional indicating PR (n = 333)	
< 5 years	112 (33.6 %)
5–10 years	88 (26.4 %)
> 10 years	133 (39.9 %)
Specific written prescription for PR (n = 335)	
Yes	0 (0 %)
No	335 (100 %)
Informed consent for the use of CM (n = 333)	
Yes	12 (3.6 %)
No	321 (96.4 %)
Approved PR material use (n = 334)	
Yes	310 (92.8 %)
No	24 (7.2 %)
Type of PR applied (n = 334)	
Wrist restraints	241 (72.2 %)
Cuffs/splints	51 (15.3 %)
Abdominal restraint	16 (4.8 %)
Wrist restraint and splint	9 (2.7 %)
Wrist restraint and ankle restraint	10 (3.0 %)
Wrist restraint and abdominal restraint	7 (2.1 %)
PR withdrawal assessment (n = 335)	
Yes	207 (61.8 %)
No	128 (38.2 %)
Complications of PR use (n = 335)	
Yes	2 (0.6 %)
No	333 (99.4 %)
Type of complication associated with PR use (n = 2)	
Agitation	1 (50 %)
Bruising	1 (50 %)

with study populations different from ours reported prevalence data for patients with cognitive disability of 14 % in Canada [28,29], 29 % in adolescents with psychiatric disorders [15], 6.8 % in psychiatric units in Finland [30], and 0.81 % in adult/pediatric emergency units [31]. Notably, the international data are disparate, with rates of PR events per

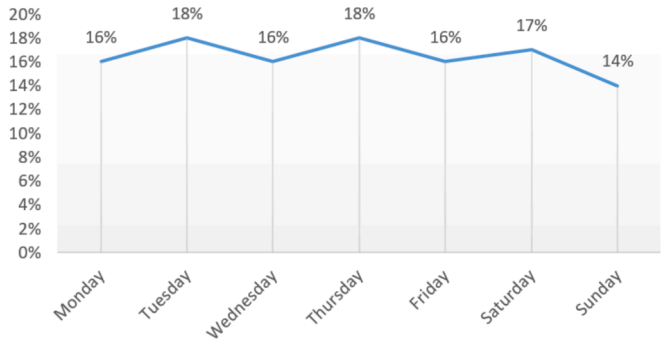

Fig. 1. Crude prevalence of use of physical restraints by day of the week*. *Confidence interval (95%): Monday: 13.9%-19.4%, Tuesday: 15.2%-21.1%, Wednesday: 13%-18.5%, Thursday: 14.9%-20.6%, Friday: 13.1–18.5%, Saturday: 13.9%-20.4%, Sunday: 10.8%-16.8%.

million inhabitants per day in 2017 of 0.03 in New Zealand, 0.17 in Australia, 0.37 in the United States, and 98.9 % in Japan [32].

In the context of PICUs, one study concludes that the use of physical is very common. A research documents that 68 % of PICUs use restraint techniques, either manually, with splints to prevent joint flexion, or with mechanical devices such as ankle braces [25]. At the international level, in 2005 Ofoegbu et al. in the United Kingdom recorded a use of PR in pediatrics that was around 68 % in all the units analyzed [25], data that coincide with another multicenter study carried out in 2017 by Zhang et al. on quality indicators in a PICU in China [14]. Adding to the previous studies, Demir et al., published in 2008 [12], also found widespread use of PR. They reported that wrist restraints were used in 96.7 % of patients, while ankle restraints were used in 81 % of cases, among other types of restraints. These findings are similar to ours, in which wrist restraints were the most commonly used type at 72.2 % of cases, followed by cuffs or splints, at 15.3 %.

In our research, respiratory pathology was related to more hours of PR. This aligns with research indicating that factors such as the patient's young age and the severity of the pathological process are predisposing factors for the application of PR [27,30,33–37]. In addition, having invasive life-support devices inserted makes the use of PR more likely [27]. As a result of this, the main justification for the use of PR in the research conducted by da Silva in 2019 was to prevent falls in 100 % of cases, whereas in our case, this share was 3 %. Additionally, in 57.9 % of cases, the reason was to prevent the accidental removal of life-support devices, compared to 85.3 % in our study [27]. This difference might be attributed to the presence of specific protocols in our environment aimed at preventing patients from experiencing accidental falls, as well as the use of protective barriers on beds. These factors may lead professionals to justify the use of PR more with the aim of preventing the accidental removal of life-support devices.

Another essential aspect when applying PR to critically ill patients is to protocolize the procedure. This ensures that patients' rights are protected by obtaining informed consent from the patient/legal guardian and continuously evaluating whether to apply, maintain and or withdraw PR. This aspect acquires greater relevance when we consider the research by Özdemir et al., in which it was found that family members felt poorly informed and concerned about possible complications related to the application of PR in their child [38]. However, PR protocols are not very common in ICUs. We see this in the present study, in that only 0.3 % had a specific protocol for recording the use of PR. These findings are consistent with the study by Arias et al., which collected data from 158 adult ICUs in Spain to assess the status of analgesia, sedation, PR, and delirium in hospitalized patients. It showed that 83.5 % of the units analyzed did not have specific protocols for PR in critical patients [24]. Furthermore, they also concluded that in 61.4 % of cases, PR measures were not prescribed in writing (100 % in our study). Additionally, the use of PR was recorded in 24.7 % of observations (compared to 30.1 % in

Table 3
Hours of PR and sociodemographic and clinical variables of the patients.

Variable	Hours of PR[a]	P value
Age group		
Newborn and nursing (0–2 years)	20 (14–24)	
Preschool (3–6 years)	20.5 (12–24)	0.99
Primary school (7–12 years)	20 (10–120)	
Teen (>13 years)	20 (12–24)	
Sex		
Male	20 (12–24)	0.72
Female	20 (14–24)	
Diagnosis at PICU admission (n = 331)		
Respiratory	24 (20–24)	
Post-surgical	20 (10–24)	
Infectious	15 (14–20)	**0.01**
Oncological	22 (16–312)	
Other	20 (15–24)	
Chronic condition		
Yes	20 (14–24)	0.78
No	20 (11–24)	
Respiratory support		
Yes	20 (14–24)	0.4
No	20 (12–24)	
Type of respiratory support		
Oxygen therapy	16 (10–24)	
Non-invasive mechanical ventilation	24 (15–29)	
Mechanical ventilation	22 (15–24)	**<0.001**
ECMO	16 (6–16)	
Combination of various therapies	20 (12–24)	
Use of sedation		
Yes	20 (13–24)	0.79
No	21.5 (14–24)	
Use of analgesia		
Yes	20 (14–24)	0.12
No	20 (13–20)	
Family accompaniment		
Mother	20 (15–24)	
Father	20 (10–24)	0.21
Mother and father	20 (10–24)	
Other: grandmother, aunt, volunteer, etc.	18.5 (6–24)	
Work shift when PR is applied		
Morning	24 (8–24)	
Afternoon	24 (12–24)	**0.04**
Night	20 (12–24)	
Timing of PR application		
On admission	24 (15–24)	**0.01**
During the hospital stay	20 (12–24)	
Reason for application of PR		
Risk of falling	22 (15–24)	
Risk of treatment interruption	20 (12–24)	**0.01**
Both	24 (20–60)	
Specific recording of use of PR		
Yes	20 (14–20)	**<0.001**
No	24 (13–24)	

Note: ECMO=extracorporeal membrane oxygenation. P values given in **bold** indicate a significant relationship.
[a] Median and interquartile range.

our study), and their withdrawal was assessed in 18.9 % of cases (compared to 61.8 % in our research) [24]. Finally, unlike studies where the decision to apply PR is made by the physician [30], one study points to the nurse as the main agent in 53.2 % of the cases [24], while in our study, the share of PR indicated by nurses was 98.5 %. The literature makes clear that the decision to apply PR should be made by professionals with knowledge, skills, and experience in evaluating the risks it may pose to the child. Furthermore, if PR is applied, constant observation and reassessment of the patient's condition should be encouraged [27].

These issues must be taken into account to ensure compliance with current regulations. In Catalonia, with the aim of guaranteeing the highest quality of health services through the development of a safe health practice that moves towards zero physical restraints, the Department of Health of the Generalitat de Catalunya, in line 8 of the Pla de Salut de Catalunya 2016–2020, and the Parliament of Catalonia, in its Resolution 314/XI of 13 October 2016, have approved "the creation of a mandatory and common protocol for all health centres in Catalonia, regulating the justification, standards, approved materials, procedure and subsequent evaluation that must be followed when physical restraint or immobilisation is used ", although work is still underway to implement it. These premises are in line with those proposed by the American Medical Association, which states in its Code of Medical Ethics that all patients' fundamental rights must be respected, but if PR is to be performed, it must be ordered by a trained professional, informed consent must be obtained from the patient or proxy if the patient is unable to give it, and the need for PR must be regularly reassessed Ethics [39].

An important aspect to consider is the alternative methods of avoiding the use of PR in the PICU. The literature suggests that aspects such as cooperation of the paediatric patient, involvement of the family in their care, prevention and control of agitation by promoting child orientation, as well as adequate pharmacological management of pain, sedation, withdrawal syndrome and early mobilisation influence the intention to use PR [6,40,41]. In addition, the development of multicomponent interventions that include educational modules for professionals that address the negative effects of PR use, as well as systematised protocols that include alternatives to PR use, can promote a culture of safety to encourage zero PR use [6,40,41].

Finally, in our study, nurses were the most likely professionals to report PR, with those with more than 10 years' experience accounting for 39.9 % (n = 133). This is consistent with the literature which suggests that professional experience, changes in the health status of critically ill paediatric patients and increases in nurse-to-patient ratios mean that increased use of PR is needed to ensure that quality of care is not compromised by workload [1,4].

Limitations

The main limitation of our study is that we did not record the characteristics of the patients who were not in PR at the time of the PR observations. This would have allowed for a more comprehensive profiling of patients to whom PR is applied and could have guided more specific interventions for preventing its use. At the same time, it is important to note that more than 75 % of the patients included were newborn and nursing, which limited the ability to determine the prevalence of PR use by age. Therefore, future research should focus on this aspect and include more samples of different age groups.

Conclusions

The use of CM is still present in the PICUs analyzed, with a crude prevalence of 16 %. Factors such as the reason for admission, the use of respiratory support, and the reason for application of PR were linked to the hours of use of PR.

The assessment of the need for PR, the exploration of alternatives, decision-making involving the entire interdisciplinary team, obtaining informed consent, the use of approved materials, continuous recording and review of the necessity of PR, and ongoing training of healthcare professionals are key aspects that should be taken into consideration when deciding to apply PR to pediatric patients.

Pediatric patients shouldn't be treated like miniature adults. Instead, we should adapt to their needs and cognitive abilities. Developing effective communication and negotiation skills is crucial for safely executing medical procedures while respecting their rights and promoting humane care. Involving strategies such as play and enlisting the support of their families can help minimize the need for PR and ensure a more patient-centered approach to care.

Ethical statement

Permits by the nurse manager and by the Ethics and Research Committee from the five hospitals where the study was carried out were obtained: Sant Joan de Déu Children's Hospital (ethical approval number: PIC-176–21; approved date: 04 November 2021); Vall d'Hebron Hospital (ethical approval number: PR(AMI)07/2022; approved date: 28 January 2022); La Paz University Hospital (ethical approval number: PI-5146; approved date: 10 February 2022); 12 October Hospital (ethical approval number: 22/016; approved date: 17 January 2022) and Carlos Haya Regional University Hospital (ethical ratification/acceptance of the coordinating centre (Sant Joan de Déu Hospital) on 24 November 2021).

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CRediT authorship contribution statement

Alejandro Bosch Alcaraz: Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Sylvia Belda Hofheinz:** Writing – review & editing, Supervision, Investigation, Data curation. **Jesús Corrionero Alegre:** Writing – review & editing, Investigation, Data curation. **José Miguel García Piñero:** Writing – review & editing, Supervision, Investigation, Data curation. **Sonia Gil Domínguez:** Writing – review & editing, Supervision, Investigation, Data curation. **Rocío Fernández Lorenzo:** Writing – review & editing, Supervision, Investigation. **María Mata Ferro:** Writing – review & editing, Supervision, Investigation. **Ainhoa Martín Gómez:** Writing – review & editing, Data curation. **Marta Serradell Orea:** Writing – review & editing, Investigation. **Patricia Luna Castaño:** Writing – review & editing, Supervision, Investigation. **M. Ángeles Saz Roy:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Esperanza Zuriguel Pérez:** Writing – review & editing, Methodology, Investigation. **Marta Martínez Oliva:** Writing – review & editing, Investigation. **Susana González Rivas:** Writing – review & editing, Investigation. **Nerea Añaños Montoto:** Writing – review & editing, Investigation. **María José Espildora González:** Writing – review & editing, Investigation. **Elena Martín-Peñasco Osorio:** Writing – review & editing, Investigation. **Eva Carracedo Muñoz:** Writing – review & editing, Investigation. **Eduardo López Fernández:** Writing – review & editing, Investigation. **Gema Lozano Almendral:** Writing – review & editing, Investigation. **Maria Victoria Ureste Parra:** Writing – review & editing, Investigation. **Alicia Gomez Merino:** Writing – review & editing, Investigation. **Alexandra García Martínez:** Writing – review & editing, Investigation. **David Morales Cervera:** Writing – review & editing, Investigation. **Laura Frade Pardo:** Writing – review & editing, Investigation. **Ainhoa Díaz Lerma:** Writing – review & editing, Data curation. **Pedro Piqueras Rodríguez:** Writing – review & editing, Supervision, Investigation, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] Bosch Alcaraz A, Corrionero Alegre J, Gol Domínguez S, Luna Castaño P, Piqueras Rodriguez P, Belda Hofheinz S, et al. Intention to use physical restraint in paediatric intensive care units and correlated variables: a multicentre and cross-sectional study. Intens Crit Care Nurs 2024;83:103690. https://doi.org/10.1016/j.iccn.2024.103690.

[2] Acevedo Nuevo M, González Gil M-T, Martín Arribas C, Solís Muñoz M. Mechanical restraints in Critical Care: situational mapping, professional conceptualization and recommendations for practice. Metas De Enfermería 2019;22(2):63–8.

[3] Acevedo Nuevo M, Via Clavero G. Reducing the use of physical restraints, a pending and emerging matter at the ICU. Med Intensiva 2019;43(5):299–301. https://doi.org/10.1016/j.medin.2018.09.005.

[4] He S, Meng Y, Liu F, Wang X, Qiu H, Zuo Z. Nurses' knowledge, attitude, and practice regarding the use of physical restraints in children in the intensive care setting in China: a crosssectional multicentre study. Austr Crit Care 2023;36:515–20. https://doi.org/10.1016/j.aucc.2022.04.007.

[5] Via Clavero G, Guàrdia Olmos J, Gallart Vivé E, Arias Rivera S, Castanera Duro A, Delgado Hito P. Development and initial validation of a theory of planned behaviour questionnaire to assess critical care nurses' intention to use physical restraints. J Adv Nurs 2019;75(9):2036–49. https://doi.org/10.1111/jan.14046.

[6] Mattiussi E, Rosset M, Danielis M. Do we care? Physically restrained patients in the intensive care unit. Intens Crit Care Nurs 2022;70:103221. https://doi.org/10.1016/j.iccn.2022.103221.

[7] Via Clavero G, Sanjuán Naváis M, Romero García M, de la Cueva Ariza L, Martínez Estalella G, Plata Menchaca E, et al. Eliciting critical care nurses' beliefs regarding physical restraint use. Nurs Ethics 2019;26(5):1458–72. https://doi.org/10.1177/0969733017752547.

[8] Bosch Alcaraz A, Via Clavero G. Can we justify the use of physical and mechanical restraint in pediatric patients admitted to the Intensive Care Unit. Med Intensiva 2020;44:192–5. https://doi.org/10.1016/j.medine.2019.05.008.

[9] Burry L, Rose L, Ricou B. Physical restraint: time to let go. Intensive Care Med 2018;44:1296–8. https://doi.org/10.1007/s00134-017-5000-0.

[10] Devlin J-W, Skrobik Y, Gélinas C, Needham D-M, Slooter A-J-C, Pandharipande P, Alhazzani W. Clinical practice guidelines for the prevention and management of pain, agitation / sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. Crit Care Med 2018;46:e825–73. https://doi.org/10.1097/CCM.0000000000003299.

[11] Crutchfield P, Gibb T-S, Redinger M-J, Ferman D, Livingstone J. The conditions for ethical application of restraints. Chest 2019;155(3):617–25. https://doi.org/10.1016/j.chest.2018.12.005.

[12] Demir A. The use of physical restraints on children: practices and attitudes of pediatric nurses in Turkey. Int Nurs Rev 2007;17(12):367–74. https://doi.org/10.1111/j.1466-7657.2007.00547.x.

[13] Kangasniemi M, Papinaho O. Nurses' perceptions of the use of restraint in pediatric somatic care. Nurs Eth 2014;21(5):608–20. https://doi.org/10.1177/0969733013513214.

[14] Zhang Y, Liu L, Hu J, Zhang Y, Lu G, Li G, et al. Assessing nursing quality in paediatric intensive care units: a cross-sectional study in China. Nurs Crit Care 2017;22(6):355–61. https://doi.org/10.1111/nicc.12246.

[15] De Hert M, Dirix N, Demunter H. Prevalence and correlations of seclusion and restraint use in children and adolescents: a systematic review. Eur Child Adolesc Psychiatry 2011;20(5):221–30. https://doi.org/10.1007/s00787-011-0160-x.

[16] Folkes K. Is restraint a form of abuse? Paediatr Nurs 2005;17(6):41–8. https://doi.org/10.7748/paed2005.07.17.6.41.c1033.

[17] Hull K, Clarke D. Restraining children for clinical procedures: a review of the issues. Br J Nurs 2010;19(6):346–9. https://doi.org/10.12968/bjon.2010.19.6.47233.

[18] Robinson S, Collier J. Holding children still for procedures. Paediatr Nurs 1997;9(4):12–4. https://doi.org/10.7748/paed.9.4.12.s20.

[19] United Nations. Declaration of the rights of the child. Geneva: UN; 1959.

[20] Jeffery K. Supporting holding or restraint: terminology and practice. Paediatr Nurs 2010;22(6):24–8. https://doi.org/10.7748/paed2010.07.22.6.24.c7841.

[21] Brenner M. Child restraint in the acute setting of pediatric nursing: an extraordinarily stressful event. Compr Child Adolesc Nurs 2007;30(1–2):29–37.

[22] Brenner M. A need to protect: parents' experiences of the practice of restricting a child for a clinical procedure in hospital. Compr Child Adolesc Nurs 2013;36(1–2):5–16. https://doi.org/10.1080/01460860701366658.

[23] Ikebe R, Kawaguchi A, Kawasaki T, Miura N, Matsuishi Y, Takesuishi Y, et al. Physical restraints in critically Ill children: a multicenter longitudinal point prevalence study. Crit Care Med 2021;49(11):1955–62. https://doi.org/10.1097/CCM.0000000000005111.

[24] Arias Rivera S, López López C, Frade Mera M-J, Via Clavero G, Rodríguez Mondéjar J-J, Sánchez Sánchez MM, et al. Assessment of analgesia, sedation, physical restraint and delirium in patients admitted to Spanish intensive care units. Proyecto ASCyD Enferm Intensiva 2020;31(1):3–18. https://doi.org/10.1016/j.enfi.2018.11.002.

[25] Ofoegbu B-N, Playfor S-D. The use of physical restraints on paediatric intensive care units. Pediatr Anesth 2005;15(5):407–11. https://doi.org/10.1111/j.1460-9592.2004.01551.x.

[26] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC. Strengthening the reporting of observational studies in epidemiology (STROBE): explanation and elaboration. Int J Surg 2014;12(12):1495–9. https://doi.org/10.1016/j.ijsu.2014.07.014.

[27] Da Silva Souza L-M, Ferreira Santana R, da Silva Gabriel Capeletto C, Kassiadou Menezes A, Delvalle R. Factors associated with mechanical restraint in the hospital environment: a cross-sectional study. Rev Esc Enferm USP 2019;53:e03473.

[28] Feldman M-A, Atkinson L, Foti-Gervals L, Condillac R. Formal versus informal interventions for challenging behaviour in persons with intellectual disabilities. J Intellect Disabil Res 2004;48(1):60–8. https://doi.org/10.1111/j.1365-2788.2004.00578.x.

[29] Iffland M, Xu J, Gillies D. Organisational interventions for decreasing the use of restrictive practices with children or adults who have an intellectual or developmental disability (Protocol). Cochrane Database of Systematic Reviews 2021;(1). Art. No.: CD013840.

[30] Mårtensson S, Schepelern Johansen K, HjorthØj C. Dual diagnosis and mechanical restraint – a register based study of 31,793 patients and 6562 episodes of mechanical restraint in the Capital region of Denmark from 2010–2014. Nord J Psychiatry 2019;73(3):169–77. https://doi.org/10.1080/08039488.2019.1582695.

[31] Beysard N, Yersin B, Carron P-N. Mechanical restraint in an emergency department: a consecutive series of 593 cases. Intern Emerg Med 2018;13(4):575–83. https://doi.org/10.1007/s11739-017-1697-6.

[32] Newton Howes G, Savage M-K, Arnold R, Hasegawa T, Staggs V, Kisely S. The use of mechanical restraint in Pacific Rim countries: an international epidemiological study. Epidemiol Psuchiatr Sci 2020;29:e190.

[33] Beghi M, Peroni F, Gabola P, Rosetti A, Cornaggia C-S. Prevalence and risk factors for the use of restraint in psychiatry: a systematic review. Riv Psichiatr 2013;48:10–22. https://doi.org/10.1708/1228.13611.

[34] Flammer E, Steinert T, Eisele F, Bergk J, Uhlmann C. Who is subjected to coercive measures as a psychiatric inpatient? A multi-level analysis. Clin Pract Epidemiol Ment Health 2013;9:110–9. https://doi.org/10.2174/1745017901309010110.

[35] Knutzen M, Bjørkly S, Eidhammer G, Lorentzen S, Mjøsund N-H, Opjordsmoen S, et al. Mechanical and pharmacological restraints in acute psychiatric wards-why and how are they used? Psychiatry Res 2013;209:91–7. https://doi.org/10.1016/j.psychres.2012.11.017.

[36] Luciano M, Sampogna G, Del Vecchio V, Pingani L, Palumbo C, De Rosa C, et al. Use of coercive measures in mental health practice and its impact on outcome: a critical review. Expert Rev Neurother 2014;14:131–41. https://doi.org/10.1586/14737175.2014.874286.

[37] Thomsen C, Starkopf L, Hastrup L-H, Kragh Andersen P, Nordentoft M, Bernos M-E. Risk factors of coercion among psychiatric inpatients: a nationwide register-based cohort study. Soc Psychiatry Psychiatr Epidemiol 2017;52:979–87. https://doi.org/10.1007/s00127-017-1363-3.

[38] Özdemir ÖF, Keçeci A. Evaluation of patient relatives' opinions on physical restraint. Journal of Patient Safety and Risk Management 2022;27(3):100–10. https://doi.org/10.1177/2516043522110243.

[39] American Medical Association. Code of Medical Ethics, 2024. Available from: https://code-medical-ethics.ama-assn.org/ethics-opinions/use-restraints.

[40] Acevedo Nuevo M, González Gil M-T, Martín Arribas C. Physical restraint use in intensive care units: exploring the decision-making process and new proposals. A multimethod study. Int J Environ Res Public Health 2021;18(22):11826. https://doi.org/10.3390/ijerph182211826.

[41] Alostaz Z, Rose L, Mehta S, Johnston L, Dale C. Implementation of non-pharmacologic physical restraint minimization interventions in the adult intensive care unit: a scoping review. Intens Crit Care Nurs 2021;69:103153. https://doi.org/10.1016/j.iccn.2021.103153.