

Physical Restraints in Critically Ill Children: A Multicenter Longitudinal Point Prevalence Study*

OBJECTIVES: We elucidate to investigate the prevalence of and factors associated with the use of physical restraints among critically ill or injured children in PICUs.

DESIGN: This was a multicenter, longitudinal point prevalence study.

SETTING: We included 26 PICUs in Japan.

PATIENTS: Included children were 1 month to 10 years old. We screened all admitted patients in the PICUs on three study dates (in March, June, and September 2019).

INTERVENTION: None.

MEASUREMENTS AND MAIN RESULTS: We collected prevalence and demographic characteristics of critically ill or injured children with physical restraints, as well as details of physical restraints, including indications and treatments provided. A total of 398 children were screened in the participating PICUs on the three data collection dates. The prevalence of children with physical restraints was 53% (211/398). Wrist restraint bands were the most frequently used means (55%, 117/211) for potential contingent events. The adjusted odds of using physical restraint in patients 1–2 years old was 2.3 (95% CI, 1.3–4.0) compared with children less than 1 year old. When looking at the individual hospital effect, units without a prespecified practice policy for physical restraints management or those with more than 10 beds were more likely to use physical restraints.

CONCLUSIONS: The prevalence of physical restraints in critically ill or injured children was high, and significant variation was observed among PICUs. Our study findings suggested that patient age, unit size, and practice policy of physical restraint could be associated with more frequent use of physical restraints.

KEY WORDS: children; intensive care; Japan; physical restraints; prevalence

Physical restraints (PRs) are used to promote the safety of children and healthcare providers in the PICU. The conditions that lead to the use of PRs are based on a given children's underlying clinical conditions, such as their cognitive or neurologic status (1). However, we also recognize PR as an obstacle to the protection of basic human rights and human dignity, and it is recommended that the use of PRs should be minimized as much as possible (2). It has also been reported that PRs could be associated with adverse outcomes including physical or mental harm, infringement of rights, and even death (3–7). Hence, it is critically important and recommended to seek strategies for the use of PRs to maintain children's best interests (8).

Studies report that PRs are used in 20–30% of adult patients during their stay in the ICU, with higher rates of PR use with mechanical ventilation, and that PRs are associated with sedation status, unit size, and nurse-to-patient ratio (9). There are several guidelines on PRs targeting adult patients, and these are

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primarily in North America and Europe. However, those guidelines are not supported by substantial clinical evidence but are mainly based on expert opinions (1, 10, 11). There is very limited epidemiological evidence regarding the use of PRs in PICUs (12).

In this multicenter study led by bedside knowledge users including PICU registered nurses (RNs), we aimed to examine the prevalence of and factors associated with the use of PRs in critically ill or injured children in Japanese PICUs.

MATERIALS AND METHODS

Study Design and Population

This was a longitudinal point prevalence study conducted in Japanese PICUs, including children 1 month to 10 years old. We conducted screening and collected demographic information for all children admitted to participating PICUs on the three prespecified study dates/times. We then collected information about the characteristics and treatment items for the children with PRs. For this study, we defined PR as a measure used to control the physical activity of children or a portion of their body with specific equipment (13). Restraints such as high bed rails to prevent falls, and hand or ankle splints used in children with intravascular lines were excluded from the criteria of PR in this study, and the duration of PR was not considered in the definition.

Data Collection

First, we collected unit profiles of the participating sites, defined by the following components: number of beds, practice policy regarding PRs (Yes or No: Y/N), nurse-to-patient ratio, and dedicated pediatric unit (Y/N). On each study date, we collected administrative data such as the total number of patients in the units as of the study dates, as well as the patients' demographic and treatment data including medical devices used, for all admitted patients. We also assessed the patients' sedation level using the State Behavioral Scale (SBS) (14), and cognitive impairment was defined using the Pediatric Cerebral Performance Category (PCPC) scale (15) at the time of data collection (observation).

For the children with PRs, we also queried the reasons and modalities of PRs and the occurrence of medical device-related pressure ulcers (MDRPU) (Y/N).

MDRPU were defined as tissue damage to the skin caused by pressure from a medical-related device(s) (16).

We collected data on three prespecified dates, 3 months apart (March, June, and September 2019). All patients admitted to the PICUs on the three study dates were screened at 10 AM. We followed up the outcomes of all screened patients for up to 2 months by referring each medical chart. We contacted the site principal investigators if there were missing values in the dataset.

Statistical Analyses

First, we summarized and described patients' demographic characteristics and outcomes. The prevalence of PRs was calculated as the number of children with PRs divided by that of all patients admitted as of the study dates and times. Second, we compared the two groups (PR vs non-PR) in terms of demographics and treatment characteristics. The distribution of each variable was described using its median and interquartile range (IQR). For instance, we presented medians of SBS for each group (PR and non-PR groups). The PCPC score was not collected at all sites at admission, so the values scored at the time of data collection were shown. The Mann-Whitney *U* test and chi-square test (or Fisher exact test, if appropriate) were used to compare continuous and nominal variables, respectively, between the two groups. We also explored factors potentially associated with PRs using multivariable regression models, including clinically relevant characteristics of both patients and units. For this analysis, we integrated all small-sized centers into the "other" group, which were the six units recruiting only five or fewer patients in total for the three data collection dates. We also generated the variable "total number of devices" by summing the number of devices for 18 different medical devices. All patients receiving extracorporeal membrane oxygenation (ECMO) were excluded from the analyses, given that the clinical relevance of ECMO on PRs was not equivalent. We did not include variables including medications or sedatives, and muscle relaxants in the regression models, considering the nature of the design of data collection. In other words, as this was a point prevalence study, we could not determine the temporal relationships between medications/sedation levels and PRs (i.e., whether the medication was necessary to do PR or not). We eventually included the following variables: age in years (we chosen the age

group based on previous pediatric studies) (14), invasive mechanical ventilation (Y/N), nurse-to-patient ratio (1:1 ratio: Y/N), and total number of devices placed, in the regression model. We adopted multivariable regression models with each participating unit as a random effect, instead including all the unit-associated variables such as dedicated pediatric unit (Y/N), preexisting PR policy (Y/N), and size of the unit in the model. We address those unit-associated factors in the figure representing the unit profile.

Considering the anonymous nature of the study data, the requirement for informed consent was waived. All data were analyzed using Stata version 13 (StataCorp LLC, College Station, TX). This study was approved by the Ethical Review Board of Osaka Women's and Children's Hospital, Japan, as of December 2018 (number 1095-2) and was registered in University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN000040589).

RESULTS

Demographics of the Participating Sites and Children

Twenty-six ICUs participated, including nine mixed ICUs (admitting adult and pediatric patients) and 17 dedicated PICUs. The median number of beds in the 26 PICUs was 12 (IQR, 8–18) (**Supplemental Table 1**, <http://links.lww.com/CCM/G509>). On the three data collection dates, a total of 398 patients were screened, among which the primary causes of PICU admission were cardiac disease in 45% (179/398) and respiratory illness in 31% (124/398) of patients. The median age of the 398 patients was 11 months old (IQR, 4–27); 53% (209/398) of patients were under 1 year old and 26% ($n = 105$) were 1–2 years old (**Table 1**).

Prevalence and Practice of PRs

The prevalence rate of children with PRs was 53% (211/398). The SBS score among the children with PRs was 0 (awake and able to be calmed) in 38% (81/211) and +1 (restless and difficult to calm) or +2 (agitated) in 19% ($n = 41$). The median PCPC score of the children with PRs was 2 (IQR, 1–3), and 1:1 nursing care was provided in 55% (117/211) (**Table 1**). The most frequently used PR method was wrist restraint bands (55%, 117/211), followed by body restraint bands (42%, 88/211), splint with

a clamp (18%, 39/211), and mittens (18%, 38/211). PRs were used to prevent potential contingent events for 57% of the children (120/211) (**Supplemental Table 2**, <http://links.lww.com/CCM/G510>).

Comparisons Between PR and Non-PR Groups

The median PCPC score was significantly lower in the PR group (PR: 2 [IQR, 1–3] vs non-PR: 3 [IQR, 1–4], $p < 0.001$), whereas the median SBS score was significantly higher (PR: 0 [IQR, –1 to 0] vs non-PR –1 [IQR, –2 to 0], $p < 0.001$), compared with those in the non-PR group. The PICU length of stay was significantly longer in the non-PR group (PR: 8 d [IQR, 4–25 d] vs non-PR: 17 d [IQR, 8–39 d], $p < 0.001$). The PICU mortality was significantly higher in the non-PR group (PR: 2% [5/211] and non-PR: 13% [24/211], $p < 0.001$) (**Table 1**). We found no differences for medications, medical devices used, and the proportion of mechanical ventilation between the two groups, except for the use of muscle relaxants and ECMO. We observed a trend that PRs were more often used when the assigned physician or RN had less clinical experience (**Table 2**).

Factors Associated With PRs

The adjusted odds for having PRs in children 1–2 years old was 2.3 (95% CI, 1.3–4.0), and this was 0.6 (95% CI, 0.3–1.3, $p = 0.23$) in children from 3 to less than 6 years old and 0.2 (95% CI, 0.1–0.6) in patients greater than or equal to 6 years old, compared with children less than 1 year old. There were no significant associations with the use of invasive mechanical ventilation, number of medical devices used, and a 1:1 nurse-to-patient ratio (**Table 3**). When looking at the individual hospital effect, we observed a tendency to use PRs more often in PICUs without a preexisting practice policy for PR management and in PICUs with more than 10 beds (**Fig. 1**).

DISCUSSION

We present a comprehensive description of PRs in critically ill or injured children, which revealed a high prevalence and several important findings of PRs in PICUs. There are several reports regarding the PR prevalence in adult ICUs, ranging from 23% to 39% (9, 17, 18), though only a few reports can be found in the pediatric

TABLE 1.
Comparisons of Patient Characteristics and Outcomes Between Physically Restrained and Nonphysically Restrained Groups

Variables	Total	Physically Restrained	Nonphysically Restrained	<i>p</i>
Patient characteristics	<i>n</i> = 398	<i>n</i> = 11	<i>n</i> = 187	
Sex, male, <i>n</i> (%)	195 (49)	111 (53)	84 (45)	0.13
Age, mo, median (IQR)	11 (4–27)	12 (5–22)	8 (3–40)	0.43
Pediatric Cerebral Performance Category score, median (IQR)	3 (1–4)	2 (1–3)	3 (1–4)	<0.001
Standard Behavioral Scale score, median (IQR)	0 (–2 to 0)	0 (–1 to 0)	–1 (–2 to 0)	<0.001
Primary reason for ICU admission				
Cardiac disease, <i>n</i> (%)	179 (45)	90 (43)	89 (48)	0.09 ^a
Respiratory insufficiency/failure, <i>n</i> (%)	124 (31)	76 (36)	48 (26)	
Neurologic disorder, <i>n</i> (%)	46 (12)	20 (9)	26 (14)	
Infectious/inflammatory disease, <i>n</i> (%)	18 (5)	11 (5)	7 (4)	
Gastrointestinal system disease, <i>n</i> (%)	14 (4)	8 (4)	6 (3)	
Renal disorder, <i>n</i> (%)	7 (2)	3 (1)	4 (2)	
Other, <i>n</i> (%)	14 (4)	3 (1)	11 (6)	
Postsurgical admission, <i>n</i> (%)	140 (35)	78 (37)	62 (33)	0.43
Presence of parents or family at bedside, <i>n</i> (%)	39 (10)	13 (6)	26 (14)	0.011 ^a
Outcomes				
ICU length of stay, d, median (IQR) ^b	12 (5–34)	8 (4–25)	17 (8–39)	<0.001
ICU mortality, <i>n</i> (%) ^b	29 (8)	5 (2)	24 (13)	<0.001 ^a
Medical device–related pressure ulcer, <i>n</i> (%)	5 (1)	5 (2)	0 (0)	NA

IQR = interquartile range, NA = not applicable.

χ^2 or Mann-Whitney *U* tests were applied.

^aFisher exact tests were applied.

^bData for 13 patients were missing.

acute care setting (12). However, the definitions of PRs used are not uniform among those studies; therefore, the results of those studies should be interpreted with caution (9, 17, 18). Nonetheless, the PR prevalence observed in our study was higher than in those previous reports. As our data suggested an association of patients' age with the use of PRs, we could infer that the age distribution in our study cohort might have led to the high prevalence of PRs observed in our results.

We found that most children with PRs were well sedated. It has been documented that sedation levels fluctuate more widely in younger children than in older children or adults. This can be explained by children's stages of development and differences in their cognitive levels (19, 20). The fact that there are few available options for analgesics and sedatives for critically ill or injured

children could also affect the practice of using PRs for children (20). A significant difference in SBS scores was observed between the non-PR and PR groups, with the non-PR group being more deeply sedated and more frequently given muscle relaxants. This may support that PR was used as a supplement to medical sedation.

The use of invasive mechanical ventilation and the number of medical devices was not significantly associated with PRs in this study. Although a causal relationship cannot be determined owing to the nature of the study design, we could assume that children with more medical devices were more deeply sedated and might not require PRs, and vice versa.

Prevention of potential contingent events was the most common reason for PRs, and PRs were not necessarily implemented based on the presence of invasive

TABLE 2.
Comparison of Treatments Provided Between Physically Restrained and Nonphysically Restrained Groups

Variables	Total	Physically Restrained	Nonphysically Restrained	<i>p</i>
Treatments	<i>n</i> = 398	<i>n</i> = 211	<i>n</i> = 187	
Sedatives and analgesics, <i>n</i> (%)				
Benzodiazepines	111 (28)	61 (29)	50 (27)	0.66 ^a
Dexmedetomidine	133 (33)	77 (36)	56 (30)	0.20 ^a
Fentanyl	97 (24)	53 (25)	44 (24)	0.73 ^a
Morphine	40 (10)	21 (10)	19 (10)	1.00 ^a
Ketamine	2 (1)	1 (1)	1 (1)	1.00 ^a
Muscle relaxants ^b	21 (5)	2 (1)	19 (10)	<0.001 ^a
Invasive mechanical ventilation, <i>n</i> (%)	184 (46)	94 (46)	90 (48)	0.48
Tracheostomy, <i>n</i> (%)	56 (14)	31 (15)	25 (13)	0.77 ^a
High-flow nasal therapy, <i>n</i> (%)	42 (11)	27 (13)	15 (8)	0.14 ^a
Noninvasive mechanical ventilation, <i>n</i> (%)	27 (7)	13 (6)	14 (7)	0.69 ^a
Standard supplemental oxygen, <i>n</i> (%)	68 (17)	42 (20)	26 (14)	0.14 ^a
Clinical experience of physician, yr, <i>n</i> (%)				
≤1	95 (24)	62 (29)	33 (18)	<0.001 ^a
2–3	89 (22)	63 (30)	26 (14)	
4–9	129 (32)	46 (22)	83 (44)	
≥10	85 (21)	40 (19)	45 (24)	
Clinical experience of nurse, yr, <i>n</i> (%)				
≤1	50 (13)	31 (15)	19 (10)	0.044 ^a
2–3	123 (31)	70 (33)	53 (28)	
4–9	153 (38)	82 (39)	71 (38)	
≥10	72 (18)	28 (13)	44 (24)	
1:1 nurse-to-patient ratio, <i>n</i> (%)	213 (54)	117 (55)	96 (51)	0.41
Room type, private, <i>n</i> (%)	96 (24)	56 (27)	40 (21)	0.23
Devices, yr, <i>n</i> (%)				
Central venous catheter	133 (33)	73 (35)	60 (32)	0.60
Arterial line	214 (53)	108 (51)	106 (57)	0.27
Peripheral IV	307 (77)	170 (80)	137 (73)	0.08
Peripherally inserted central catheter	83 (21)	38 (18)	45 (24)	0.14 ^a
Nasogastric tube	300 (75)	161 (76)	139 (74)	0.65
Endotracheal tube	75 (19)	41 (19)	34 (18)	0.80 ^a
Extracorporeal membrane oxygenation	8 (2)	1 (0.5)	7 (4)	0.029 ^a
Bladder catheter	168 (42)	89 (42)	79 (42)	0.99

χ^2 or Mann-Whitney *U* tests were applied.

^aFisher exact tests were applied.

^bIncluding all types of administration, such as continuous and intermittent IV.

TABLE 3.
Factors Associated With Physical Restraints

Variables	Adjusted OR (95% CI)	p
Age, yr		
<1	Reference	NA
1 to <3	2.3 (1.3–4.0)	0.005
3 to <6	0.6 (0.3–1.3)	0.23
≥6	0.2 (0.1–0.6)	0.001
Invasive mechanical ventilation, yes	1.1 (0.6–1.8)	0.78
Nurse:patient ratio 1:1, no	0.7 (0.4–1.3)	0.31
Number of medical devices	0.9 (0.5–1.6)	0.78

NA = not applicable, OR = odds ratio.

devices including invasive mechanical ventilation. RNs might be more concerned with the patient’s age and sedation level rather than the number of invasive devices being used on the child.

Another interesting finding was the lack of association between PRs and the nurse-to-patient ratio, which has been well documented in adult studies (17, 21, 22). Instead, our results suggested that other factors, such as the clinical experience of the bedside physician and RN, were more likely to use PRs.

We also observed that a preexisting practice policy of PR management and the unit size could be associated with the prevalence of PRs, although we could

not quantitatively analyze this to make a causal inference in the profiling owing to our study design and the small sample size. A survey of adult patients in European ICUs reported that bedside practitioners in ICUs with a preexisting practice policy were less likely to implement PRs (9). In other words, we can assume that if there is no practice policy, bedside healthcare providers might perceive a need for PRs based on their experience and might judge that PRs are needed for the sake of safety, which can potentially lead to unnecessary use of PRs (23). The European survey also described that PRs were more likely to be used in larger size ICUs (9). This may be because of indirect factors such as nursing staff shortages with revolving-door staff turnover and severe illness among admitted patients (24).

This study has several limitations. First, owing to the study design, the findings might not represent the intrinsic intent of PRs in PICUs, and we could not draw causal inferences in this study. For instance, it was impossible to know if PRs were used just for temporal or for a long-term application, between which the purpose of PRs could be different. In addition, we could not infer whether SBS and family presence assessed at a single point of time at data collection might have affected the use of PR or not in this study. Second, we did not collect information about patient severity of illness at screening, which could be an important factor when considering PRs in practice. Instead, we applied the

number of medical devices used as an indirect substitute measurement. Third, a bias could be introduced by including different types of PICUs, such as cardiac PICUs and mixed PICUs. Finally, the multi-center study design could cause unexpected inconsistency in the data collection. To mitigate this, we developed a structured data collection procedure with clear definitions and repeatedly reminded the site collaborators to follow the procedure.

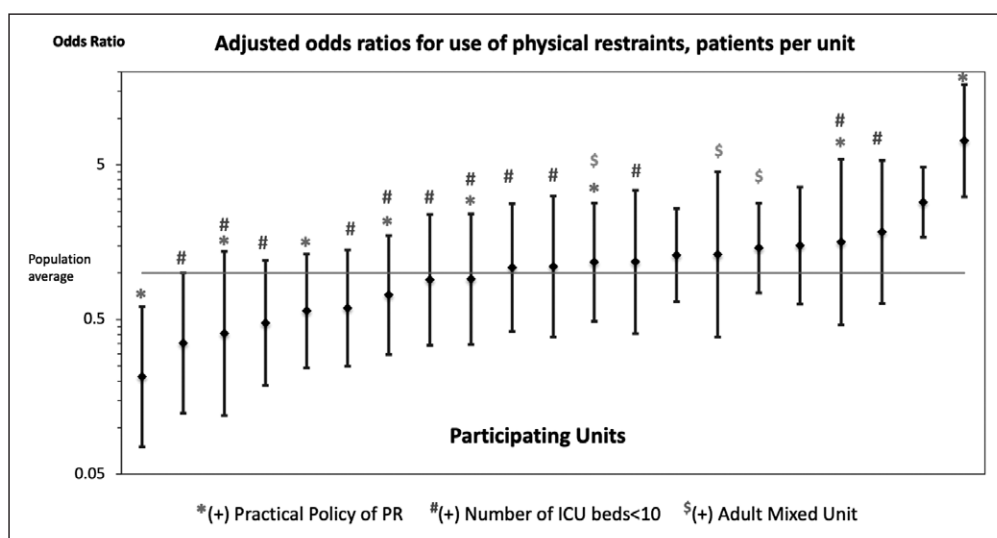


Figure 1. Adjusted odds ratio estimates to have physical restraint cases per units. An inclination in the profiles of participating sites as to their existing physical restraints policy (negative) and unit size (positive). PR = physical restraint.

CONCLUSIONS

The use of PRs in critically ill or injured children is common in Japan. Our study suggested that patient age, unit size, and PR practice policy could be associated with the prevalence of PR use in PICUs. Further examination is needed to elucidate the complexity of PR practices using such as an observational study design, which will be helpful in developing a standard of practice for PRs, to improve the quality of care for critically ill or injured children.

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The board members for PRINCE Study Group are listed in **Appendix 1** (<http://links.lww.com/CCM/G598>).

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Mr. Ikebe conceptualized and designed the study, built the database, conducted data collection and cleaned the data, carried out the initial analyses, drafted the initial article, revised the initial article, and approved the final article, as submitted. Dr. Kawaguchi conceptualized and designed the study, carried out analyses, drafted the initial article, revised the initial article, and approved the final article, as submitted. Drs. Kawasaki and Takeuchi conceptualized and designed the study, revised the initial article, and approved the final article, as submitted. Mr. Miura, Dr. Matsuishi, Dr. Nittsu, Dr. Matsuoka, Dr. Fujiwara, Dr. Shimoyama, Dr. Nakayama, Dr. Akita, Dr. Munekawa, Dr. Kajinishi, Ms. Sasaki, and Ms. Sakamoto contributed to conceptualizing and designing the data collection form, revised the initial article, and approved the final article, as submitted. All authors approved the final article as submitted and agree to be accountable for all aspects of the work.

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