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Research paper

Investigating influencing factors of physical restraint use in China intensive care units: A prospective, cross-sectional, observational study

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ABSTRACT

Objective: In this study, we characterised the use of physical restraints in three intensive care units (ICUs) in a general hospital in Nantong, China. Additionally, we explored risk factors potentially related to physical restraint use.

Background: Despite their numerous harmful effects, physical restraints are frequently used in ICUs worldwide. Few studies have investigated the factors that contribute to physical restraint use in Chinese hospitals.

Methods: We conducted a prospective, cross-sectional, observational study of 312 patients in three ICUs at a general hospital in China. The quantitative data were collected during a 5-month period using a physical restraint observation form and patient records. The data obtained were analysed using descriptive statistics. The independent risk factors for physical restraint use were assessed using a logistic regression model.

Results: Of the 312 patients in the three ICUs, 191 (61.2%) were restrained, and physical restraints were used more than once for 46 (24.1%) patients during their ICU stay. The median length of physical restrain use was 20 shifts (interquartile range = 10–36 shifts). Physical restraints were applied in 6664 of 12374 (53.9%) nurse shifts. The most common time at which physical restraints were applied was the beginning of the evening shift. According to the forward stepwise logistic regression analysis, delirium ($P < 0.001$), mechanical ventilation ($P < 0.001$), and age ($P < 0.001$) were independent risk factors for physical restraint use. The use of analgesics ($P = 0.001$) exerted an independent protective effect against physical restraint use.

Conclusions: The overall prevalence of physical restraint use in Chinese ICUs was higher than that reported in previous investigations. The patients' nursing notes lacked complete physical restraint records, reflecting a need for standard guidelines and policies for physical restraint use in hospital ICUs in China. In addition, in this study, we explored the risk factors related to physical restraint use and found that age, delirium, mechanical ventilation, and analgesic use are associated with physical restraint use.

1. Introduction

When caring for critically ill patients in the intensive care unit (ICU), both chemical and physical restraints are frequently used to minimise patient discomfort and anxiety.[1] Chemical restraints are defined as any medication used for the specific purpose of

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restricting patients' movement that is not a standard treatment for the patient's medical or psychiatric condition.[2] A physical restraint is defined as the use of "any mechanical device or material attached or adjacent to a resident's body that she or he cannot remove easily, which limits the freedom of an individual's movement or normal access to one's body".[2] In ICUs, physical restraint is a fairly common method to the protect patients from adverse events[3] and to manage patients who may be deemed uncooperative.[4] The range of the use of physical restraint remains unclear, with the reported prevalence ranging from 0% to 100% in different hospital wards.[5–8] An increasing number of studies have reported the adverse effects of physical restraint. The harmful outcomes linked to physical restraint include restraint site complications, nerve injury, delirium, post-traumatic stress disorder, greater risks of self-extubation, and a prolonged length of stay in the ICU.[9–11] To reduce the inappropriate use of physical restraint, numerous guidelines and regulations aimed at minimising the use of restraints have been developed.[4,12,13] The British Association of Critical Care Nurses[12] released a position statement on the use of restraint in adult ICUs. This statement highlights that the use of restraint must not substitute for inadequate human and environmental resources and that restraint should be used only when alternative therapeutic measures have proven ineffective. The clinical practice guidelines produced by the American College of Critical Care Medicine Task Force[4] recommend limiting the use of physical restraints to "clinically appropriate" situations and emphasising the need to consider alternative methods in the ICU. A policy statement published by the Joanna Briggs Institute[13] recommended using restraints as little as possible, releasing the restraints as soon as possible and considering alternative treatments as much as possible. In previous studies, various risk factors for physical restraint use have been described and are primarily associated with patient demographic variables,[14,15] the attitudes of nurses,[16,17] the ratio of nurses to patients, and the environment.[14]

In China, no recommendations, standards, or legal policies have been developed regarding physical restraint use in the ICU. The lack of clear rules and requirements for restraint informed consent create ethical dilemmas for nursing staff in the course of carrying out physical restraint, frequently resulting in adverse events and further affecting the satisfaction of patients with nursing work. Studies investigating factors contributing to physical restraint use are rare. Most previous research in China on this matter focuses on the prevalence, reasons, and context for physical restraint use.[18,19] The literature indicates that the patient's age,[20] state of consciousness,[12] and treatment characteristics[7] are important factors in applying physical restraints. ICU nurses play an important role in the decision to apply physical restraint. Physical knowledge, attitudes, and behaviour of the nursing staff as well as the ratio of nurses to patients are associated with physical restraint use.[10] Therefore, we were specifically interested in the relationships among patient characteristics, clinical variables, and the use of physical restraint.

The aim of this study was to evaluate the prevalence of physical restraint use in three ICUs in a general hospital and to identify the factors that affect their use.

2. Methods

2.1. Study population and recruitment

A prospective, cross-sectional, observational study was conducted in three ICUs (general, respiratory and neurology) at the Second Affiliated Hospital of Nantong University from January 2017 to May 2017. The general ICU had 15 beds and 56 nurses. The respiratory ICU had 12 beds and was staffed by 42 nurses. The neurology ICU had 12 beds and was staffed by 45 nurses. During the study, the average monthly patient admission rate per ICU reached 95%. The nurse-to-patient ratio is generally 1:1.5 during the day and 1:3 during the evening and night shifts. From January 2017 to May 2017, all consecutively enrolled ICU patients who met the following criteria were included in this study: (i) complete medical data, which refers to complete patient medical files, including nursing documents, medical records, orders, etc. and (ii) age $\geq$18 years. The patients were excluded from the study if their stay in the ICU was less than 1 shift. Ultimately, 312 patients (general ICU, 143 patients; respiratory ICU, 89 patients; and neurology ICU, 80 patients) were eligible for investigation and entered the study.

After the patient entered the ICU, the author explained the purpose of the study and the method of investigation to the patient. For unconscious patients, the concept of the study was described to their legal representatives. The research team conducted data collection after obtaining their consent and signatures on the study's informed consent form. The study was approved by the Ethics Committee of the Second Affiliated Hospital of Nantong University in 2016 (Ethics No. 43).

2.2. Procedure and data collection

Two methods (direct observation and a review of patients' records) were used to collect data for the study. The research team was composed of research nurses and the first author.

Our physical restraint observation form was completed based on the research nurses' direct observations. The physical restraint observation form was based on the observation restraint form described in the Handbook of Nursing-Sensitive Quality Indicators.[21] The physical restraint observation form included physical restraint use (yes or no), the type and site of the physical restraints, the time of application and removal of physical restraints, the presence of mechanical ventilation (MV), sedative and analgesic use (yes or no), Glasgow Coma Scale scores (except during sedation protocols), and the use of the Richmond Agitation–Sedation Scale[22] to assess the level of sedation or agitation (while using sedatives). Each day was divided into three shifts. The day shifts occurred between 08:00 and 16:00, the evening shift occurred between 16:00 and 00:00, and the night shift occurred between 00:00 and 08:00. For each shift in each ICU, a research nurse was assigned to continuously and dynamically observe and record any change in the physical restraint data relating to each patient (i.e., occurrence, change in the type of physical restraint) until the restraint was removed or the patient was discharged from the ICU. A total of 312 patients were observed from the time they entered the ICU until ICU discharge for three shifts each day. During this period, the total number of observable nurse shifts was 12,374. The median number of shifts for which the patient was admitted was 22 (interquartile range [IQR] 12–44). Before the initiation of the formal investigation, the first author trained and educated all of the nurses in the three ICUs in subjects related to physical restraint use. There was an assessment at the end of the training to identify 18 nurses with similar assessment scores, age, years of experience, level of education, and job titles who were employed as the research nurses in the study. These 18 nurses were further trained in how to complete the physical restraint observation form. Lastly, these 18 nurses were able to fill the physical restraint observation form with unified standards before beginning the formal investigation.

Data were extracted from the patients' medical records, including patient age, sex, Acute Physiology and Chronic Health Evaluation II[23] score, diagnosis, smoking history, and alcohol use. Furthermore, when the author collected case data, the author assessed the presence of delirium using the Confusion Assessment Method for the Intensive Care Unit.[24]

2.3. Statistical analysis

All data were entered into the Statistical Package for the Social Sciences (version 21.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics were calculated for all measured variables. Data are reported as the means (standard deviations), medians (IQRs), or percentages. Univariate analysis was tested using independent *t* tests (continuous variables with a normal distribution), Chi-square tests (categorical variables), and Mann–Whitney tests (continuous variables with a skewed distribution). Statistical significance was set at $P < 0.05$ (two-tailed). The general data and clinical data of the patients were considered independent variables, and physical restraint use was considered the dependent variable in the univariate analysis. In accordance with the United Nations World Health Organization, age was stratified as follows: 18–45 years old, young; 45–60 years old, middle-aged; 60–75 years old, pre-elderly; and ≥75 years old, elderly. Regardless of whether the use of physical restraint was a dependent variable, a multivariate logistic regression model was established using the statistically significant factors in the univariate analysis as independent variables. Independent variables were analysed by dummy variables. The model used a maximum likelihood method to screen for independent factors related to physical restraints in ICU patients through a forward stepwise regression analysis (selection criteria of the variables were $P < 0.05$, excluding the standard $P > 0.10$).

3. Results

During the study, 312 enrolled patients were observed. The patients were observed from the time they entered the ICU until ICU discharge for three shifts each day. During this period, the total number of observable nurse shifts was 12 374. The median number of shifts for which the patient was admitted was 22 (IQR = 12–44). The observational outcomes of physical restraints are reported in Table 1. In 53.9% (6664) of these nurse shifts, some kind of physical restraint was applied. Bilateral upper limb restraints were used for the majority of patients in this study (56.5%), followed by four-point restraints (22.3%). The median length of physical restrain use was 20 shifts (IQR = 10–36 shifts). A total of 42.9% of the patients were continuously restrained for more than 24 h. Physical restraint was applied only once for most patients (145/19,175.9%), and the remainder had the physical restraint removed and reapplied at least once during their ICU stay. In 98 of the 191 restrained patients (51.3%), the observational data were documented in the patients' nursing notes. Nurses primarily recorded the time of application and sites and types of restraints, but none described the removal time, the patient responses, or complications associated with the restraint. Less than one-third of patients gave informed consent for physical restraint. In most cases, the purpose of applying the restraint was to prevent the accidental removal of the medical devices to decrease any threat to the airway.

As shown in Table 2, 191 of the 312 patients (61.2%) were restrained. The prevalence of physical restraint use was statistically higher in the general ICU than in other ICUs, a fact that may have been related to the number of patients and the characteristics of the patients admitted to each unit. The rate was higher in the general ICU than in the respiratory ICU (OR [odds ratio] = 8.016, 95% confidence interval = 4.370–14.703, $P < 0.001$) and neurology ICU (OR = 4.071, 95% confidence interval = 2.210–7.500, $P < 0.001$). In addition, significant associations were observed with nearly all the investigated factors that contributed to restraint use, with the exceptions of sex ($P = 0.268$) and being a current drinker ($P = 0.941$).

The final stepwise logistic regression analysis showed that the associations with several risk factors did not remain statistically significant. The variables of age, delirium, and MV were identified as independent risk factors for physical restraint use, whereas the use of analgesics was identified as an independent protective factor for physical restraint use. This model had good fit according to the Hosmer–Lemeshow goodness-of-fit test ($R^2 = 0.641$, $\chi^2 = 12.860\ 1$, $P = 0.117$), and the accuracy of the model was 83.3% (Table 3).

4. Discussion

In this study of three ICUs in a general hospital in China, more than half (61.2%) of the patients were physically restrained at least once during their ICU stay, with a mean length of physical restraint use of 20 nurse shifts. This rate is higher than the rates reported in other studies examining ICUs outside of China (30.0–50.0%)[6,7,25]

Table 1
Characteristics of the ICU patients examined in this study.

Variable	Overall sample	ICU			χ^2/t	P
		General	Respiratory	Neurology		
Number of beds, N (%)		15	12	12		
Patients, N (male/female)	312 (115/197)	143 (56/87)	89 (28/61)	80 (31/49)	1.563	0.458
Mean nurses per shift, N (morning/evening/night)[a]		8/5/5	6/3/3	6/3/3		
Total nurse shifts, N (%)	12 374	6302	3248	2824		
Restrained nurse shifts, N (%)	6664	4372	1213	1079		
Prevalence of physical restraint use,[b] P	53.9	69.4	37.3	38.2	1245.214	**<0.001**
Site of physical restraint, shifts, N (%)					1118.498	**<0.001**
Bilateral wrist	3763 (56.5)	2717 (62.1)	523 (43.1)	523 (48.5)		
Four-point restraints	1489 (22.3)	1122 (25.7)	162 (13.4)	205 (19.0)		
Unilateral wrist	1135 (17.0)	289 (6.6)	528 (43.5)	318 (29.5)		
Bilateral ankle	109 (1.6)	109 (2.5)	0 (0.0)	0 (0.0)		
Unilateral ankle	56 (0.8)	47 (1.1)	0 (0.0)	9 (0.8)		
Chest restraint	112 (1.7)	88 (2.0)	0 (0.0)	24 (2.2)		
Duration of physical restraint use,[c] patients, N (%)					1.129	0.890
≤50%	36 (18.8)	20 (17.1)	6 (18.7)	10 (23.8)		
50–100%	73 (38.2)	47 (40.2)	12 (37.5)	14 (33.3)		
=100%	82 (42.9)	50 (42.7)	14 (43.7)	18 (42.9)		

ICU = intensive care unit.
Bold values indicate statistically significant results ($P < 0.05$).
[a] Day shifts begin at 08:00 and end at 16:00; evening shifts begin at 16:00 and end at 00:00; and night shifts last 00:00 to 08:00.
[b] The prevalence of physical restraint was calculated by dividing the number of shifts in which patients were restrained by the total length of ICU stay (shifts) for all patients.
[c] The duration of physical restraint use was calculated by dividing the number of shifts in which each patient was restrained by the total length of ICU stay (shifts) for patients.

Table 2
Comparison of demographic and clinical factors contributing to the use of physical restraints.

Variable	Overall sample	Physical restraint		χ^2/t	P
		Used	Not used		
Total, N (%)	312	191 (61.2)	121 (38.8)		
Ward				52.046	**<0.001**
General	143 (45.8)	117 (61.3)	26 (21.5)		
Respiratory	89 (28.5)	32 (16.8)	57 (47.1)		
Neurology	80 (25.6)	42 (22.0)	38 (31.4)		
Sex, N (%)				1.227	0.268
Male	197 (63.1)	116 (60.7)	81 (66.9)		
Female	115 (36.9)	75 (39.3)	40 (33.1)		
Age (years), N (%)				64.158	**<0.001**
18–45	66 (21.2)	26 (13.6)	40 (33.1)		
45–60	70 (22.4)	26 (13.6)	44 (36.4)		
60–75	79 (25.3)	52 (27.2)	27 (22.3)		
≥75	97 (31.1)	87 (45.5)	10 (8.3)		
Current smoker (yes), N (%)	80 (25.6)	37 (19.4)	43 (35.5)	10.152	**0.001**
Current drinker (yes), N (%)	47 (15.1)	29 (15.2)	18 (14.9)	0.005	0.941
APACHE II score, mean (SD)	19.0 (6.1)	19.9 (5.7)	17.7 (6.5)	2.979[a]	**0.003**
GCS score, median (IQR)	12 (6–15)	12 (7–15)	15 (5–15)	−3.095[b]	**0.002**
MV (yes), N (%)	207 (66.3)	160 (83.8)	47 (38.8)	66.961	**<0.001**
Use of sedation (yes), N (%)	156 (50.0)	142 (74.3)	14 (11.6)	116.762	**<0.001**
RASS score, median (IQR)	−1 (−3 to 0)	−1 (−2 to 0)	−5 (−5 to −2)	−17.198[b]	**<0.001**
Use of analgesics (yes), N (%)	152 (48.7)	63 (33.0)	89 (73.6)	48.799	**<0.001**
Delirium (yes), N (%)	130 (41.7)	122 (63.9)	8 (6.6)	99.932	**<0.001**
Length of ICU stay (shifts), median (IQR)	22 (12–44)	28 (14–52)	15 (8–33)	−4.618[b]	**<0.001**

APACHE II = Acute Physiology and Chronic Health Evaluation; GCS = Glasgow coma scale; ICU = intensive care unit; IQR = interquartile range; RASS = Richmond agitation–sedation scale; SD = standard deviation.
Bold values indicate statistically significant results (P < 0.05).
[a] Independent *t* test.
[b] Mann–Whitney test.

Table 3
Logistic regression model of risks factors for the use of physical restraints.

Variables	B	S.E.	Wald	OR	Exp (B) 95% CI		P value
					Lower bound	Upper bound	
Constant	−1.446	0.465	9.691	0.235			**0.002**
Age			32.305				**<0.001**
18–45	–	–	–	REF	–	–	–
45–60	−0.412	0.481	0.736	0.662	0.258	1.698	0.391
60–75	0.747	0.467	2.553	2.110	0.884	5.275	0.110
≥75	2.592	0.551	22.163	13.355	4.540	39.293	**<0.001**
MV	1.848	0.373	24.598	6.345	3.057	13.168	**<0.001**
Delirium	2.419	0.445	29.521	11.235	4.695	26.886	**<0.001**
Use of analgesics	−1.218	0.362	11.349	0.296	0.146	0.601	**0.001**

CI = confidence interval; MV = mechanical ventilation; OR = odds ratio; REF = reference group.
Bold values indicate statistically significant results (P < 0.05).

but similar to that in a previous study conducted in Canada.[11] This discrepancy could be attributed to nurses' heavy workloads and lack of knowledge about physical restraints. At present, because of a general lower ratio of nurses to patients and an insufficient nursing staff in China,[26] nurses are unable to fully and continuously observe the patients' behaviour. Thus, nurses implement physical restraints as a preventive measure instead of relying on clinical observations. Physical restraints are seen as a compensatory tool for the lack of manpower, which thereby potentially increases the use of physical restraints in ICUs[17]. Therefore, an increased nurse-to-patient ratio and an appropriate reduction in the nurses' responsibilities would give them more time to focus on the patient, which would reduce the use of physical restraint. As shown in the study by Voigtländer,[27] when the number of registered nurses increased by 22% and the assisting staff increased by 42%, the ratio of physically restrained patients decreased from 19% to 8%, and the total duration of restraint decreased from 3162 h to 781 h. Pellfolk's[28] 6-month education program on physical restraint for all nursing staff showed that increasing staff education can reduce the use of physical restraints. Therefore, changes in staffing levels and education can influence physical restraint rates. Furthermore, we observed that physical restraint was more frequently applied during the hours of 16:00 to 08:00 (evening shift, 62.3%; night shift, 16.2%), which is consistent with the results of previous studies.[29] The presence of fewer nurses on duty during the evening and night shifts may be the primary explanation for this high rate of physical restraint use.

In the multivariate logistic analysis, delirium was identified as an independent risk factor for the use of physical restraint (OR = 11.235), consistent with previous studies.[30,31] Some articles have reported an association between physical restraint use and delirium in the ICU. For example, in one study, patients with delirium received physical restraints more frequently and for longer durations than patients without delirium.[32] Simultaneously, the use of physical restraint was shown to contribute to the development of delirium,[11] thereby resulting in a vicious cycle.

Pharmacological treatment for delirium within 24 h has been shown to reduce the number of days in physical restraints (3 vs 6 days).[33] Other than delirium, MV was also associated with an increased risk of physical restraint use (OR = 6.345) in the logistic regression analysis. De Jonghe's[5] report shows that 82% of ICUs applied at least one physical restraint for more than 50% of patients with MV during their ICU stay. This finding suggests that physical restraint plays an important role in the management of patients with MV. The purpose of the use of physical restraint for patients with MV is to prevent self-extubation. However, according to recent studies, 25–87% of patients experience unplanned extubation while being physically restrained.[34] Several studies have even reported that physical restraint increases the risk of unplanned extubation.[35] Therefore, physical restraint use cannot help prevent self-extubation. Proper fixation, continuous observation and evaluation, and timely extubation are fundamental measures for the prevention of extubation. In addition, when we stratified patients by age (18–45 years old, young; 45–60 years old, middle-aged; 60–75 years old, pre-elderly; and ≥75 years old, elderly), we found that elderly patients had a 13-fold greater risk of physical restraint use than younger patients. The prevalence of physical restraint use was 13.6%, 13.6%, 27.2%, and 45.5%, respectively, in the successive age groups. Evans[20] also reported that the rate of physical restraint use gradually increased with patient age and was highest among patients ≥75 years. The high rate may be related to the decline in physiological function and cognitive function.

However, based on our results, the use of analgesics is a significant independent protective factor against physical restraint use, which may be associated with a high incidence of pain in ICU patients. The incidence and intensity of pain in ICU patients are greater than those in patients hospitalised in normal wards.[36] The proportion of patients who experience agitation and delirium due to pain is significantly increased.[37] In our study, delirium was identified as a risk factor for the use of physical restraint. Additionally, agitation is associated with an increased risk of physical restraint use.[14] However, analgesics are commonly used to reduce agitation, anxiety, and pain in ICU patients[1]; thus, using analgesics can reduce the use of physical restraints. One study found that nurses used analgesia instead of physical restraint to reduce the rate of physical restraint.[38] Martin[7] compared the use of physical restraints in the United States to that in Norway. Physical restraints were used in 40% of cases in the United States, whereas physical restraints were not used in the cases from Norway. The reason for this difference was that Norwegian patients were more frequently administered analgesics. Although analgesics can reduce the rate of physical restraint, they may have more side-effects. Furthermore, analgesics are also considered chemical restraints and may be used concurrently with physical restraints. The choice between physical restraints and chemical restraints may depend on the disease, the treatment involved, and the resources available.

5. Study limitations

First, because the study was conducted in three ICUs in a single hospital in China, the results are not considered representative of other hospitals in China. Second, this study compared only the frequency of physical restraint use among different ICUs. Considerable differences were observed, but we did not determine the reasons for these differences. Third, the data were collected by directly observing patients and reviewing patient records. As this was a prospective study, data on patient characteristics and clinical condition were collected at the time of hospitalisation to avoid the bias inherent in a retrospective review of patient records. Physical restraint use data were observed and recorded in a timely manner every day in three shifts by research nurses. Our group used 18 trained research nurses to reduce differences stemming from subjective observation. Fourth, the characteristics of ICU nurses, the treatments the patients received, and the ICU environment were not considered.

6. Conclusions

This study provides a picture of physical restraint practices in three ICUs in one hospital in China. The data on the high prevalence of physical restraint use in the study illustrate that physical restraint is a commonly used practice in ICUs in China. The patients' nursing notes contained incomplete records on physical restraint, indicating that the behaviours of nurses performing physical restraint are not standardised. This situation reflects the need to strengthen the training of nurses with respect to the use of physical restraint. Some cases lacked informed consent regarding physical restraint indicating that restrained patients or their families did not receive notification or sign informed consent for physical restraint before its application, further illustrating that the clinical notification of physical restraint is not yet perfect. This situation reflects the need for standard guidelines and policies for physical restraint use in ICUs in China. In this study, we explored the risk factors related to physical restraint use, and these data can serve as an objective basis for developing and implementing physical restraint use policies with the aim of minimising physical restraint use in Chinese clinical practice. Our findings are clinically important for critical care managers and clinicians who provide patient care. It is suggested that upgrading the original institutions, updating the details of the process on physical restraint implementation, and clarifying the use of physical indicators, assessment requirements, and release indications would limit the use of physical restraint. Moreover, more efforts should be made to educate nursing staff about the harmful effects of using physical restraint and to suggest alternatives to physical restraint. Future studies must also investigate physical restraint use in ICUs in other areas in China to increase the sample size and to make the samples more representative. In addition, the development of guidelines and recommendations for the use of physical restraint should be adopted in Chinese ICUs.

Authors' contributions

Weiqun Weng designed the study. Ting Gu and Xu Wang acquired and analysed the data. Ting Gu wrote the article. In addition, Nan Deng helped to modify the format for submission. All authors reviewed the manuscript.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.aucc.2018.05.002

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