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The Design and Application of a New Type of Bed Sheet Restraint Device: A Randomized Controlled Study

Jiamin YANG, Hairong HAN, Xianghong TIAN, Jing ZHANG, Yaping ZHU, Xueyan ZENG, and Baicha TANG*

Neurosurgical Intensive Care Unit, ZHUHAI PEOPLE'S HOSPITAL MEDICAL GROUP (Zhuhai hospital affiliated with Jinan University/ The First Affiliated Hospital of Faculty of Medicine Macau University of Technology), Kangning Road 79, Zhuhai, Guangdong, China. Hairong HAN is considered as a co-first author of the article

*Corresponding author. Email: 64597988@qq.com, <https://orcid.org/0000-0002-0807-0092>

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Abstract

[Objective] To observe the application effect of the new type of bed sheet restraint device in NICU. [Methods] A randomized controlled trial was carried out. A total of 100 patients randomly divided into observation group and control group, with 50 patients in each group. Patients in the observation group used the new type of bed sheet restraint device, while the control group used the conventional restraint device. The restraint-related adverse reaction, restraint time and ICU stay time were compared between the two groups. [Results] There was no fall from bed in the two groups of patients. The incidence of the change of skin color, temperature, texture and restraint devices break free, unplanned extubation of the observation group was significantly lower than that of the control group. The restraint time and ICU stay time of the observation group was significantly less than that of the control group. The difference was statistically significant. [Conclusion] The new type of bed sheet restraint device can effectively reduce the incidence of restraint-related adverse reactions of patients, and reduce the restraint time and ICU stay time of patients, which is worthy of clinical application.

Keywords: Design and application; New type of bed sheet restraint device; Neurosurgical intensive care unit; Physical restraint

1. Introduction

The neurosurgical intensive care unit (NICU) mainly treats medium and severe acute cerebrovascular diseases, severe acute craniocerebral injury and spinal cord injury,

central nervous system bacterial infection, status epilepticus, perioperative neurosurgical patients requiring life support, and other progressive nervous system severe patients[1]. These kinds of patients prone to disorders of consciousness, restlessness, delirium, thinking disorder, abnormal behavior and movement, etc. due to special factors such as brain disease, injury or surgery, which seriously affect the patients' treatment safety[2,3]. When patients develop delirium and restlessness, adverse events are prone to occur, such as unplanned extubation, falling from bed, etc. Patient safety is essential to provide effective, high-quality medical care, and is one of the core principles of medical care and one of the main goals of nursing care[4-6]. Clinically, restraint is often used to prevent the occurrence of unexpected events. Although the use of restraint in the current healthcare environment is a controversial practice, restraint is one of the most common methods to ensure patient safety, including physical restraint, chemical restraint and seclusion[7,8]. Chemical restraints have no obvious effect on neurosurgical patients and interfere with the judgment of the patients' condition[9]. Seclusion is used only for patients who are behaving in a violent or self-destructive manner[10]. Physical restraint is the most commonly used type. It is a specific intervention or device that prevents the patient from moving freely or restricts normal contact with the patients' own body, while preventing the patient from interfering with treatment and medical devices[10,11]. The use of physical restraints do not reduce falls or fall-related injuries, or successfully control challenging behavior, and may lead to decreased comfort, injuries, pressure ulcers, increased length of hospital stay, orthopedic, vascular, and peripheral nerve injuries, etc.[12,13]. To improve the safety and standardized use of physical restraints, and reduce the incidence of adverse reactions and complications after restraint, we designed a new type of sheet restraint device and evaluated the application effect of the new type of bed sheet restraint device.

2. Methods

2.1 Design

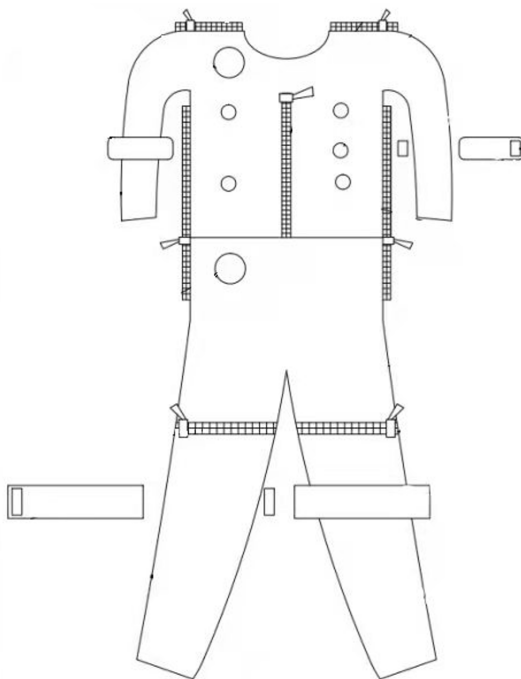
This was a randomized controlled trial conducted in the neurosurgical intensive care unit of a tertiary general hospital in Guangdong Province, China.

2.2 Participants

We selected 100 patients admitted to the neurosurgical intensive care unit between January 2020 and June 2021 who required physical restraint and met the inclusion and exclusion criteria. The researchers used a random number table to assign the research subjects to the observation group and the control group according to a set ratio of 1:1, with 50 cases in each group. Inclusion criteria: (a) Age > 18 years old; (b) The patient needs physical restraint and the restraint time is ≥ 24h; (c) The patients' guardian informed consent and signed the informed consent form; Exclusion criteria: (a) patients with red, swollen, damaged skin or rash at the restraint area at the time of admission. (b) Patients with mental retardation. (c) Patients who had hemiplegia in the restrained part of the limb. (d) Patients with a cast or splint.

2.3 Design of new type of bed sheet restraint device

The new bed sheet restraint device is a utility model patent (patent number: ZL2021 0670593.8) designed for team members, including a restraint suit and a bed sheet for fixing and connecting the restraint suit. The restraint suit includes a blouse and pants. (a) The blouse is provided with CVC holes on both sides of the neck and five ECG holes on the chest according to the position of the ECG monitoring electrodes, which is convenient for CVC nursing and monitoring of patients' vital signs. (b) The pants are provided with CVC holes on both sides of the groin. (c) There is no cloth at the buttocks of the pants, and the cloth at the knees are connected with zippers, which is convenient for operations such as perineal wiping and CVC dressing change. (d) The sheets are equipped with fixed belts for fixing the arms and legs. The blouse and pants are connected by zippers and the restraint suit is zippered to the sheet and can be secured in sections. Thick cotton pads are used for the cloth of each zipper to prevent skin damage. Details are shown in Figure 1.



2.4 Clinical application

For the two groups of patients with restraint indications, Nurses promptly informed the patients and their families of the purpose of the restraint and possible complications, and signed the informed consent form after obtaining the consent of the patients' families. (1) In the control group, the patients' palm was fixed with a table tennis restraint glove, and the opening position was tied tightly with a belt, leaving 2 fingers gap, and tied to the bed rail. While the patients' ankle was fixed with an

ankle restraint straps, and tie the tether to the bed rail. The blood supply and skin damage of the wrist and palm were observed every 2 hours. (2) In the observation group, a new type of bed sheet restraint device was used to restrain the patients. Put on the restraint suit for the patient, zip and fix the joint of the suit and the connection with the bed sheet. When the patient is extremely restless and uncooperative, use a fixing belt to fix the limbs, leaving 2 finger gaps to avoid skin damage. Evaluate the patients' consciousness, restlessness, cooperation, and blood circulation in the restraint every hour, and loosen and move the limbs every 2 hours.

Indications for physical restraint and release of restraint: Nurses evaluate whether the patient needs to be restrained according to the ICU Inpatient Physical Restraint Assessment Scale[14], which includes three aspects: MASS score, muscle strength grading score, and catheter risk level. The score range is 3-18 points, Complete restrained: score 17 points; Preventive restraint: 12-16 points; intermittent restraint: 9-11 points; no restraint: score 8 points or coma, muscle strength 1level. The nurses evaluate and record each shift. When the patient's consciousness, catheter placement or removal and other conditions change occur, the patients' physical restraint assessment will be carried out in time, and corresponding restraint measures will be taken.

2.5 Data collection

2.5.1 Individual Characteristics Form

The Individual Characteristics Form comprised patients' personal and clinical information including age, gender, disease type, education level, use of sedative hypnotics, Glasgow coma score (GCS), number of chronic diseases, number of indwelling tubes.

2.5.2 Restraint-related adverse reactions

The restraint-related adverse reaction including skin assessment[15] (color, temperature, texture and skin integrity), fall from bed, restraint devices break free; unplanned extubation (tracheal intubation/oxygen tube, nasogastric tube/ nasojejunal tube, head drainage tube, urinary catheter, arteriovenous catheter, etc.). If one of the above situations occurs, it will be counted as occurring, and will not be counted repeatedly.

2.5.3 Other clinical information

The other clinical information of patients including restraint time, ICU stay time.

2.6 Ethical approval

Informed consent was obtained from patients' relatives after informing them about the aim of the study. A written permission of the study protocol was obtained from the hospital Clinical Research Ethics Committee (No. LW-202202). Clinical Trial Registration Number: ChiCTR2200063718.

2.7 Data analysis

Research data were analysed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Patients' individual characteristics form were described with descriptive statistics such as means, standard deviations, and percentages. Whether relationships existed between each of the variables was determined by the χ^2 , ANOVA or *T* test. *P* values less than 0.05 were considered statistically significant.

3. Results

3.1 Patients' demographic and clinical characteristics

Recruitment were finished on 30 June 2021. All 100 patients' data were collected. The mean age of patients in the observation group and the control group were 67.16 ± 11.606 years and 66.98 ± 10.879 . The gender ratio was the same in both groups. The most common type of disease in both groups was cerebrovascular disease. 72% in the observation group used sedatives hypnotics, while 68% in the control group. There were no statistically significant differences between the two groups of patients in age, gender, disease type, education level etc. (all $P > 0.05$), which indicated comparability. Other characteristics of patients are described in Table 1.

3.2 The incidence of restraint-related adverse reactions of the two groups of patients

There was no fall from bed in the two groups of patients. The incidence of the change of skin color, temperature, texture and restraint devices break free, unplanned extubation in the observation group was significantly lower than that in the control group. The difference was statistically significant. The skin integrity of the two groups was not statistically significant, but the skin breakage and rash in the observation group were less than those in the control group. Other details are shown as Table 2.

3.3 The restraint time and ICU stay time of the two groups of patients

The restraint time of the observation group and the control group was 6.16 ± 2.289 days and 7.46 ± 2.082 days, respectively; and the ICU stay time was 7.68 ± 2.272 days and 8.72 ± 7.874 days, respectively. The restraint time and ICU stay time of the observation group was significantly less than that of the control group. The difference was statistically significant. Other details are shown as Table 3.

4. Discussion

4.1 The new bed sheet restraint device can reduce constraint-related adverse reactions in patients

Although there are several reports[16-18] that physical restraint is a controversial practice, it is clearly inappropriate for neurosurgical patients, especially those with neurological symptoms during treatment, to use sedatives in the long term. Therefore, as a preventive measure to maintain patient safety, physical restraint is still the most common way for patients to get the optimal treatment and care[19-22]. In this study, neither group of patients fell out of bed, indicating that both restraint devices

TABLE 1 Demographic and clinical characteristics.

Variables	Observation group (N=50)	Control group (N=50)	<i>F</i>	<i>P</i> values
Age (n, %)				
≤60	8 (16)	8 (16)	0.015	0.902
61-70	19 (19)	21 (42)		
71-80	21 (21)	18 (36)		
≥81	2 (4)	3 (6)		
Gender (n, %)				
Men	26 (52)	26 (52)	0.000	1.000
Women	24 (48)	24 (48)		
Disease type (n, %)				
Brain Injury	7 (14)	9 (18)	0.103	0.749
Intracranial tumor	13 (26)	8 (16)		
Spinal tumors	9 (18)	11 (22)		
Cerebrovascular disease	18 (36)	17 (34)		
Other	3 (6)	5 (10)		
Education level (n, %)				
Primary or below	5 (10)	3 (6)	0.244	0.622
junior	18 (36)	20 (40)		
senior	22 (44)	20 (40)		
University or above	5 (10)	7 (14)		
Use of sedative hypnotics (n, %)				
Yes	36 (72)	34 (68)	0.187	0.666
No	14 (28)	16 (32)		
GCS score ($\bar{x} \pm s$)	11.16±1.983	10.94±1.621	0.369	0.545
Number of chronic diseases ($\bar{x} \pm s$)	3.36±1.191	3.04±0.968	2.173	0.144
Number of indwelling tubes ($\bar{x} \pm s$)	3.78±0.840	3.88±0.746	0.396	0.531

could prevent patients from falling out of bed. Previous studies have shown that neurovascular complications such as edema, redness, limitation of movement, increase in temperature, color changes, etc. may occur due to prolonged physical restraint[18]. The results of this study showed that the incidence of skin color, temperature, texture and restraint devices break free, unplanned extubation in the observation group was significantly lower than that in the control group, with statistically significant differences. Patients are more likely to accept and cooperate with the new bed sheet restraint device. The possible reason is that the traditional restraint belt binds the patients' limbs to the bed, and the patients' limb movement is limited and cannot meet his daily activities, and the long-term restraint reduces the joint activity of the limbs and makes the joints stiff, the patients' comfort is reduced, and it is easy to produce conflict and anger, and is unwilling to understand and cooperate with constraints.

The restraint suit mainly restricts the patients' getting up and extubation. The

TABLE 2 Restraint-related adverse reactions.

Variables	Observation group (N=50)	Control group (N=50)	F/χ^2	P values
Colour (n, %)				
Normal	44 (88)	37 (74)	4.422	0.038*
Red	6 (12)	10 (20)		
Pale	0	3 (6)		
Temperature (n, %)				
Normal	48 (96)	42 (84)	4.506	0.036*
Hot	2 (4)	6 (12)		
Cold	0	2 (4)		
Texture (n, %)				
Normal	46 (92)	39 (78)	7.481	0.007*
Dry	4 (8)	2 (4)		
Moist	0	8 (16)		
Oedema	0	1 (2)		
Integrity (n, %)				
Normal	45 (90)	40 (80)	2.097	0.151
Breakage	4 (8)	7 (14)		
Rash	1 (2)	3 (6)		
Fall from bed (n, %)				
Yes	0	0	--	--
No	50 (100)	50 (100)		
Restraint devices break free (n, %)				
Yes	46 (92)	38 (76)	0.054	0.027*
No	4 (8)	12 (24)		
Unplanned extubation (n, %)				
Yes	47 (94)	39 (78)	0.041	0.020*
No	3 (6)	11 (22)		

*Significant difference between groups at $P < 0.05$.

TABLE 3 Restraint time and ICU stay time.

Variables	Observation group (N=50)	Control group (N=50)	F	P values
restraint time (day)	6.16 ± 2.289	7.46 ± 2.082	8.826	0.004**
ICU stay time (day)	7.68 ± 2.272	8.72 ± 7.874	6.236	0.014*

*Significant difference between groups at $P < 0.05$. **Significant difference between groups at $P \leq 0.01$.

patients wearing the restraint suit can carry out some daily activities and have relatively independent space for activities. The patients' comfort is improved, who feel a sense of dignity, and it is not easy to produce resistance. Therefore, the incidence of skin damage, restraint breaking, and unplanned extubation due to resistance to restraint was significantly reduced. The skin integrity of the two groups of patients was not statistically significant, indicating that the new bed restraint device could also lead to skin integrity impairment in patients. However, the skin breakage and

rash in the observation group were less than those in the control group, indicating that the new bed sheet restraint device can reduce the skin Breakage and rash of the patients compared with the traditional restraint belt, which may be related to the degree of cooperation of the patients. The restraint suit is not as tight as a traditional restraint strap, resulting in less damage to the skin.

4.2 The new bed sheet restraint device can reduce the restraint time and ICU stay time

This study found that the restraint time and ICU stay in the observation group were significantly shorter than those in the control group, and the difference was statistically significant. It shows that the new restraint device can improve the patient's agitation and promote the patient's recovery compared with the traditional restraint, which may be related to the high-quality restraint reducing the occurrence of adverse events and complications, improving the clinical prognosis, and facilitating the patient's recovery. Protective restraint is still the main means of clinical management of agitation, and scientific and reasonable restraint measures can reduce the occurrence of restraint accidents. The new bed sheet restraint device restricts the removal of important pipes such as mechanical ventilation, drainage tubes, gastric tubes, etc., which effectively guarantees the safety of patients' treatment and nursing, and reduces the occurrence of delayed illness and delayed treatment caused by accidental extubation. The connection of the new restraint device is set with a zipper at a position that the patient cannot touch, which avoids the occurrence of accidents caused by improper restraint, and reduces the restraint time and the ICU stay time of the patient.

4.3 Limitations

There were some limitations in the study. First, although the new bed sheet restraint device has achieved better results than the traditional restraint device, there are still adverse reactions. Long-term use of physical restraint on patients should be avoided, and the international "physical restraint reduction action" should be followed in clinical work. Wherever possible, alternative treatments should be sought to prevent adverse consequences of restraint. Second, due to the small number of patients included in this study and the fast turnaround of neurosurgical ICU patients, it is not entirely clear whether the reduction in ICU stay is due to the use of the new bed restraint device or other factors, which may bias the results of the study, it is necessary to expand the sample and continue to track it to further verify its application effect. Finally, the study did not examine the accuracy of nurses in judging the timing of physical restraint and release, which should be addressed in the future to ensure the rigor of research. In addition, ICU nurses should strengthen the training of knowledge about physical restraint and the management of physical restraint, correctly evaluate the necessity of physical restraint of patients, and master the indications of physical restraint and release of restraint, so as to prevent adverse consequences caused by irregular restraint.

5. Conclusion

Physical restraint is recognized as a major issue globally affecting the quality of long-term care services. This study aiming at the defect of common physical restraints in clinical, designed the new type of bed sheet restraint device for NICU patients, which effectively reduced the incidence of skin damage, restraint device break free and unplanned extubation, and reduced the average restraint time and ICU stay time of patients. There was no increase the incidence of fall from bed, and achieved good results. The device is simple to use and easy for nurses to operate, and is worthy of clinical application.

The results of this study indicate that the design of the new type of bed sheet restraint device provides another choice and reference for clinical nurses, and may also provide a new idea for the next design of restraint devices to reduce patient damage. More importantly, nurses should first assess whether the patient needs restraint, so as to avoid unnecessary restraint causing psychological and physical harm, and correctly master restraint skills to avoid physical harm to the patient due to human reasons and affect its prognosis.

Clinical Trial Registration Number

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Conflict of Interest Statement

We declare that we have no competing or potential conflicts of interest.

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AUTHORS' CONTRIBUTIONS

Y-JM, T-BC and Z-XY: made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; Y-JM, T-BC, H-HR, and T-XH: involved in drafting the manuscript or revising it critically for important intellectual content; Y-JM, T-BC, H-HR, T-XH Z-J, Z-YP, and Z-XY: Given final approval of the version to be published. Y-JM, T-BC, H-HR, T-XH, Z-J, Z-YP and Z-XY: Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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