Int J Clin Exp Med 2023;16(2):15-30
www.ijcem.com /ISSN:1940-5901/IJCEM0145852

Original Article

Clinical application of evidence for reduced physical restraint with ICU adult catheterized patients: a stepped-wedge randomized controlled trial

Yahui Yang, Juan Wu, Hailan Qian, Huifen Xu, Xiaoyan Chen, Lihua Lu, Yanghui Xu, Chenhui Wang, Yang Gao, Jingyi Li

Affiliated Hospital of Nantong University, Nantong 226001, Jiangsu, China

Received August 10, 2022; Accepted December 29, 2022; Epub February 15, 2023; Published February 28, 2023

Abstract: Background: In recent years, there have been many disputes about the validity and rationality of physical restraint. More and more nurses are beginning to pay attention to the pros and cons of restraint use, and rebalance the priority of restraint use. Aim: This study was performed to guide and standardize the practice of physical restraint by nurses and evaluate the effects of application. Methods: The trial was a stepped-wedge, cluster, randomized controlled trial. Four ICUs in the Affiliated Hospital of Nantong University were recruited, including the general ICU, Neurosurgery ICU, Neurology ICU and Cardiac Surgery ICU. Catheterized patients aged 18 years or older who were admitted to ICU and were willing to participate in the study were included. During the control phase, each ICU implemented nursing procedures and the management model as usual, and during the intervention phase implemented practical reform. Results: Compared with pre-implementation and post-implementation, the patient restraint time was shortened (682.16±370.81 vs 467.41±406.37; P=0.000) and the restraint rate was decreased (91.2% vs 73.7%; P=0.000). In the general ICU, the restraint time gradually decreased (P > 0.05). The restraint rate gradually decreased, but slightly increased in the fourth stage (P < 0.05). In the Neurosurgery ICU, restraint time was shortened in the fourth stage (P=0.000), and the restraint rate of the fourth stage was also decreased (P=0.000). In the Neurology ICU, the restraint time was extended during post-implementation (P=0.000) and the restraint rate increased during post-implementation (P < 0.05). In the Cardiac Surgery ICU, there was no significant difference of restraint time and rate in different implementation stages (P > 0.05). Linking evidence to action: The best evidence of reasonable physical restraint with ICU adult catheterized patients was transformed and applied to clinical practice. We believe that this study has evidence-based potential to help healthcare providers reduce the restraint rate and shorten the restraint time of ICU patients.

Keywords: ICU, catheterized patients, evidence-based practice, restraint

Introduction

Physical restraint is defined as the use of any mechanical device or material attached to or close to the human body that cannot be easily removed to limit the individual's freedom of movement or normal body contact [1]. As a protective medical auxiliary measure, it is mainly used in the intensive care unit to avoid or prevent injury to the patient and others when the patient is disturbed in consciousness or restless and has a high risk of removing the treatment channel by them self. After a comprehensive evaluation of the patient, physical restraint is used to maintain the patient's safety and prevent accidents such as falling out of bed. According to a Canadian study, most patients only had wrist restraint, and the utilization rate was 43.47% [2]. The utilization rate of physical restraint in ICU patients in Jordan was 35.8% [3] and 23% in the Netherlands [4]. Studies in China show that the physical restraint rate of ICU patients was 45.7% [5] and 69.4% [6].

In recent years, there have been many disputes about the validity and rationality of physical restraint. Physical restraint is a complex subject involving physiology, psychology, law and ethics. Some studies have shown that physical restraint has not been proven to be able to pre-

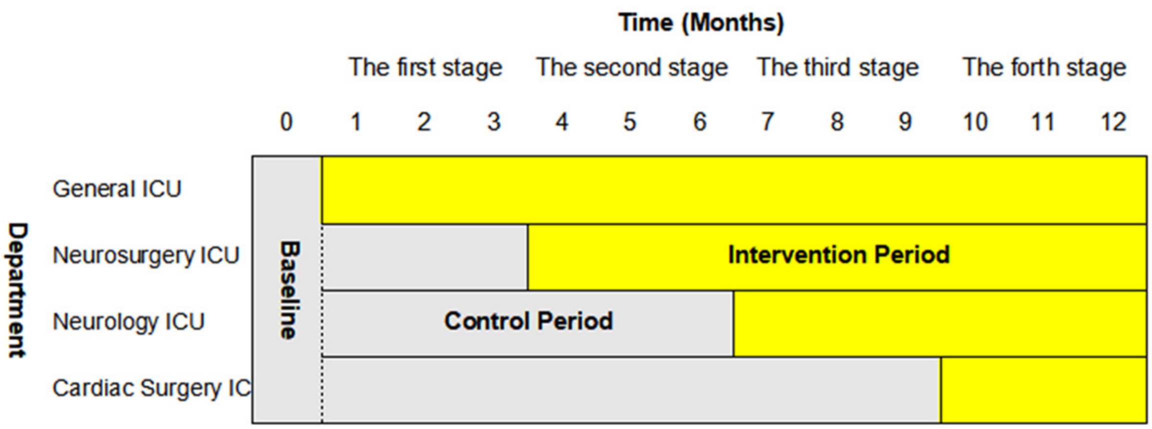

Figure 1. Baseline data were collected from July 17 to August 16, 2018. General ICU entered the intervention period in first month of the trial (September 17, 2018). Neurosurgery ICU entered the intervention period in month 4 (December 17, 2018). Neurology ICU entered the intervention period in month 7 (March 17, 2019). Cardiac Surgery ICU entered the intervention period in month 10 (June 17, 2019). All ICUs began the intervention by June 17, 2019.

vent falls and accidental injuries. On the contrary, it may have adverse effects on the physiological and psychological functions of patients, such as skin redness, breakage, ecchymosis and nerve damage, increasing the incidence of anxiety, depression, loneliness, fear and delirium, and even lead to post-traumatic stress disorder and other serious consequences [7-9].

Due to the differences in medical culture and concepts between China and the West, there are differences between Chinese and foreign medical staff in their perspective, behavior, and organization and management of physical restraint. In China, nurses play a dominant role in restraint decision-making, and most managers acquiesce that restraint is a conventional nursing measure, which is a contrast compared with the actions taken by other countries to reduce restraint by mandatory regulations. Although the amount of ICU patient restraint assessment and decision-making tools being developed is gradually increasing, nurses' attitude and behavior toward restraint, are important subjective factors, and still play a key role in the final decision of restraint use. At present, more and more nurses are beginning to pay attention to the pros and cons of restraint use, and rebalance the priority of restraint use. This study is part of a two-year nursing reform, which uses an evidence-based approach to construct a care program for ICU adult catheterized patients. The purpose is to guide and standardize the practice of physical restraint by nurses and evaluate the effects of application.

Material and methods

Trial design

The trial was a stepped-wedge, cluster, randomized controlled trial (RCT). Stepped-wedge RCTs require fewer clusters and provide the same level of evidence [10]. In a stepped-wedge trial, all clusters start under the control condition, and then develop to the intervention condition in a random order (**Figure 1**).

Recruitment

Four ICUs in the Affiliated Hospital of Nantong University were recruited, including the general ICU, Neurosurgery ICU, Neurology ICU and Cardiac Surgery ICU. The allocation of nursing human resources in the 4 departments is configured in accordance with the Implementation Opinions on the Position Setting of Nursing Staff in Jiangsu Province. The working years, professional titles and professional experience of the nursing staff were similar, and they all received hierarchical training typical of nursing staff in the hospital.

Randomization

The four ICU wards were numbered from high to low according to the floor (1, 2, 3, 4). An independent statistician wrote the four numbers into four pieces of paper with same size and put them into four identical blank envelopes. The intervention order was determined by drawing lots by the head nurse of each ICU.

Participants

Inclusion criteria: Patients eligible for inclusion were that (1) patients aged 18 years or older; (2) patients who had at least one tube (except peripheral venous catheterization); (3) patients who were admitted to the ICU and were willing to participate in the study.

Exclusion criteria: Criteria that made patients ineligible for inclusion were (1) patients who had mental disorders, history of mental illness, dementia or were accompanied by intellectual disability; (2) patients or their families who had a strong desire for and requested restraint.

Study interventions

During the control phase, each ICU implemented nursing procedures and management model as usual, making no changes to any part of their clinical care.

The establishment of reasonable physical restraint process for ICU adult catheterized patients is based on the systematic search and quality evaluation of the subjects related to the reasonable physical restraints of ICU adult patients. The best evidence was summarized. Combined with clinical scenarios and professional judgments, 18 evidence-based quality review standards were formulated. Relevant papers have been published in Chinese [11]. The content of the intervention phase implemented during practical reform included: (1) construction of the "Reasonable Physical Restraint Process for ICU Adult Catheterized Patients"; (2) production of a training manual of "Reasonable Physical Restraint"; (3) videos were made of "ICU Common Scores", "Physical Restraint", and "Use of Physical Restraint Assessment Tools"; (4) the doctors and nurses were trained in the relevant knowledge of restraint before the intervention; (5) revision of the informed consent form and health education manual. The original restraint communication records of the hospital were recorded in the nurse-patient communication records. The research team revised the special restrained informed consent form and the health education manual for patients' families; (6) restraint decision-making wheel, classification of the necessity of restraint, and ICU inpatient restraint assessment scale were selected as restraint assessment tools and the effectiveness of these three assessment tools has been evaluated [12]; (7) the hospital HIS system implanted the term "reasonable physical restraint" into the doctor's advice database. Before the implementation of the evidence, the clinical review of nursing practice was carried out at the baseline stage, the obstacle factors were analyzed according to the review results, and the corresponding improvement strategies were proposed [13]. The flow chart is shown in **Figure 2**.

Outcomes

Patient restraint time (Number of restraint days per 1000 days that patients were catheterized): To obtain a standardized length of restraint, from the time of admission to discharge, we separately recorded the time of patient catheterization and the time of physical restraint, calculating the number of days of restraint per 1000 days of catheterization. Patient restraint time = (restraint time/catheterization time) × 1000.

Patient restraint rate: The proportion of patients using physical restraints in the total number of patients during the observation period.

Blinding

Because of the nature of the intervention, it was not possible to blind the healthcare professionals providing the intervention or statisticians. Participants were blinded to treatment allocation.

Ethical considerations

Ethical approval was exempt as granted by the ethics committee of the Affiliated Hospital of Nantong University.

Statistical analysis

Statistical analysis was performed using SPSS 22.0. Quantitative data of normal distribution were expressed as mean ± standard deviation, and count data were expressed as percentage. The mean of two samples of normal distribution quantitative data was compared with t test, and the comparison of two independent samples of non-normal distribution quantitative data was conducted by the non-parametric Mann-Whitney U test, and $P < 0.05$ was consid-

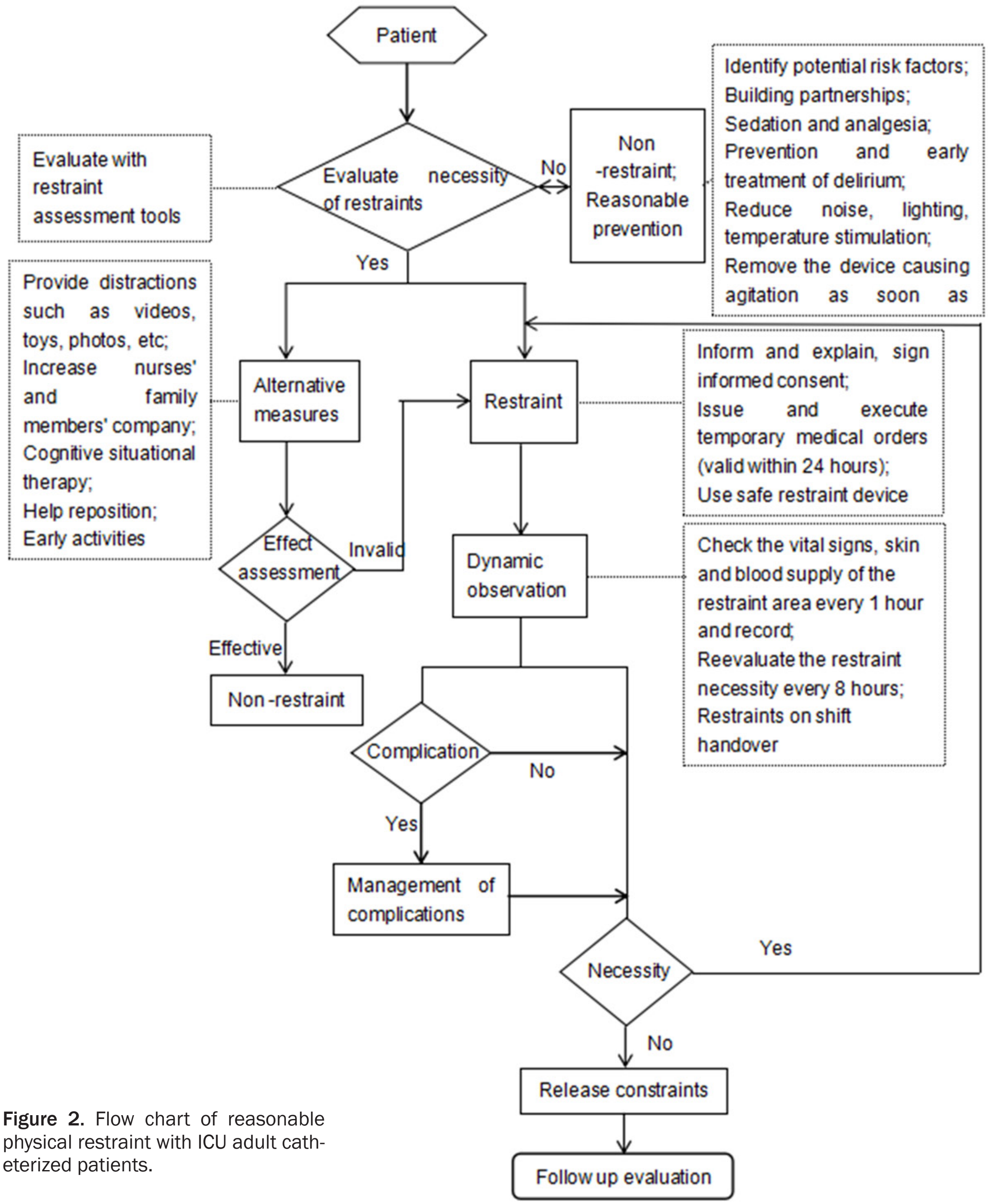

Figure 2. Flow chart of reasonable physical restraint with ICU adult catheterized patients.

ered statistically significant. One way ANOVA was used to analyze the restraint time in different implementation stages of each ICU. F-test was used when the variances were uniform, and the Bonferroni method was used for multiple comparisons; Welch's approximate F-tests were used for uneven variances, and Donnett's T3 method was used for multiple comparisons. Chi-square test was used to evaluate the restraint rate in different implementation stages.

Results

Comparison of pre and post implementation

Because the time of each ICU entering the intervention was inconsistent, the comparison

Table 1. Comparison of participant characteristics in pre and post implementation (N=577)

	Pre-implementation (N=91)	Post-implementation (N=486)	t/χ^2	*p*
Age (x ± s, years)	64.57±16.68	63.05±16.49	-0.804	0.421
Gender (cases, %)			0.115	0.719
Male	59 (64.8%)	324 (66.7%)		
Female	32 (35.2%)	162 (33.3%)		
Length of ICU stay (x ± s, hours)	161.62±152.22	204.63±197.01	2.352	0.020
Diagnosis (cases, %)			36.065*	0.202
Coronary heart disease	5 (5.5%)	31 (6.4%)		
Cerebral apoplexy	15 (16.5%)	86 (17.7%)		
Traumatic brain injury	6 (6.6%)	37 (7.6%)		
Severe acute pancreatitis	2 (2.2%)	14 (2.9%)		
Multiple injuries	4 (4.4%)	16 (3.3%)		
Intracranial space occupying	0 (0.0%)	3 (0.6%)		
Pulmonary infection	1 (1.1%)	19 (3.9%)		
Respiratory failure	0 (0.0%)	11 (2.3%)		
Heart failure	0 (0.0%)	3 (0.6%)		
Lung tumor	2 (2.2%)	24 (4.9%)		
Aortic dissection	0 (0.0%)	16 (3.3%)		
Digestive tract tumor, etc.	22 (24.2%)	75 (15.4%)		
Valvular disease	4 (4.4%)	35 (7.2%)		
Mediastinal mass	0 (0.0%)	3 (0.6%)		
Shock	4 (4.4%)	7 (1.4%)		
Intracranial infection	0 (0.0%)	8 (1.6%)		
Motor neuron disease	0 (0.0%)	1 (0.2%)		
Epilepsy	2 (2.2%)	4 (0.8%)		
Femoral fracture	6 (6.6%)	9 (1.9%)		
Guillain-Barre Syndrome	3 (3.3%)	4 (0.8%)		
Atrial tumor	1 (1.1%)	4 (0.8%)		
Multiple organ failure	0 (0.0%)	1 (0.2%)		
Myocarditis	0 (0.0%)	2 (0.4%)		
Arrhythmia	0 (0.0%)	2 (0.4%)		
Congenital heart disease	2 (2.2%)	8 (1.6%)		
Infective endocarditis	0 (0.0%)	2 (0.4%)		
Myasthenia	0 (0.0%)	5 (1.0%)		
Renal failure	0 (0.0%)	6 (1.2%)		
Others	12 (13.2%)	50 (10.3%)		

Note: *means Fisher exact test was used.

between groups could not be conducted directly. The researchers used baseline data as the pre-implementation phase, and data from the fourth stage as the post-implementation stage for comparison.

There was no significant difference in age, gender and diagnosis between the two groups (P > 0.05). There was significant difference in length of ICU stay between the two groups (P < 0.05) (**Table 1**).

The patient restraint time was (682.16±370.81) days/thousand catheterized days, in 83 patients (91.2%) who had restraints during pre-implementation. The patient restraint time was (467.41±406.37) days/thousand catheterized days, in 358 patients (73.7%) who had

Table 2. Comparison of patient restraint time and rate in pre and post implementation (N=577)

	Restraint time/Catheterization time (x ± s, days/thousand catheterized days)	*t*	*p*	Restraint rate (no. of cases, %)	χ^2	*p*
Pre-implementation (N=91)	682.16±370.81	-4.992	0.000	83 (91.2%)	13.099	0.000
Post-implementation (N=486)	467.41±406.37			358 (73.7%)		

Table 3. Comparison of participant characteristics of general ICU in pre and post implementation (N=851)

	Pre-implementation (N=45)	Post-implementation (N=806)	t/χ^2	*p*
Age (x ± s, years)	67.20±18.80	67.79±17.63	0.216	0.829
Gender (cases, %)			0.208	0.754
Male	29 (64.4%)	492 (61.0%)		
Female	16 (35.6%)	314 (39.0%)		
APACHE II (x ± s, scores)	15.20±7.37	16.86±6.83	1.580	0.114
Length of ICU stay (x ± s, hours)	140.02±144.83	226.93±216.56	3.796	0.000
Diagnosis (cases, %)			25.692*	0.053
Coronary heart disease	0 (0.0%)	19 (2.4%)		
Cerebral apoplexy	1 (2.2%)	8 (1.0%)		
Traumatic brain injury	0 (0.0%)	7 (0.9%)		
Severe acute pancreatitis	2 (4.4%)	42 (5.2%)		
Multiple injuries	3 (6.7%)	55 (6.8%)		
Pulmonary infection	1 (2.2%)	79 (9.8%)		
Respiratory failure	0 (0.0%)	69 (8.6%)		
Heart failure	0 (0.0%)	14 (1.7%)		
Lung tumor	2 (4.4%)	20 (2.5%)		
Digestive tract tumor, etc.	20 (44.4%)	233 (28.9%)		
Valvular disease	0 (0.0%)	2 (0.2%)		
Shock	4 (8.9%)	21 (2.6%)		
Motor neuron disease	0 (0.0%)	14 (1.7%)		
Femoral fracture	6 (13.3%)	39 (4.8%)		
Multiple organ failure	0 (0.0%)	11 (1.4%)		
Myocarditis	0 (0.0%)	4 (0.5%)		
Myasthenia	0 (0.0%)	1 (0.1%)		
Renal failure	0 (0.0%)	17 (2.1%)		
Others	6 (13.3%)	151 (18.7%)		

Note: *means Fisher exact test was used.

restraints during post-implementation. The patient restraint time was significantly shortened (P=0.000) and the restraint rate was significantly decreased (P=0.000) (**Table 2**).

Comparison of participant characteristics of each ICU in pre and post implementation

In the general ICU, there was no significant difference in age, gender, APACHE II score and diagnosis between the two groups (P > 0.05). There was a significant difference in length of ICU stay between the two groups in the general ICU (P < 0.05) (**Table 3**). In the Neurosurgery ICU there was no significant difference in age, gender and diagnosis between the two groups (P > 0.05). There was significant difference in length of ICU stay between the two groups in the Neurosurgery ICU (P < 0.05) (**Table 4**). In the Neurology ICU there was no significant dif-

Table 4. Comparison of participant characteristics of Neurosurgery ICU in pre and post implementation (N=333)

	Pre-implementation (N=100)	Post-implementation (N=233)	t/χ^2	p
Age (x ± s, years)	59.20±13.30	60.15±14.79	0.553	0.580
Gender (cases, %)			0.002	1.000
Male	68 (68.0%)	159 (68.2%)		
Female	32 (32.0%)	74 (31.8%)		
Length of ICU stay (x ± s, hours)	198.32±153.08	260.76±194.25	3.137	0.002
Diagnosis (cases, %)			2.941*	0.830
Cerebral apoplexy	43 (43.0%)	96 (41.2%)		
Traumatic brain injury	38 (38.0%)	88 (37.8%)		
Multiple injuries	8 (8.0%)	25 (10.7%)		
Intracranial infection	2 (2.0%)	2 (0.9%)		
Intracranial space occupying	1 (1.0%)	6 (2.6%)		
Epilepsy	1 (1.0%)	1 (0.4%)		
Others	7 (7.0%)	15 (6.4%)		

Note: *means Fisher exact test was used.

Table 5. Comparison of participant characteristics of Neurology ICU in pre and post implementation (N=305)

	Pre-implementation (N=159)	Post-implementation (N=146)	t/χ^2	p
Age (x ± s, years)	63.69±15.92	65.03±17.23	0.707	0.480
Gender (cases, %)			1.837	0.216
Male	104 (65.4%)	106 (72.6%)		
Female	55 (34.6%)	40 (27.4%)		
Length of ICU stay (x ± s, hours)	286.03±208.19	306.32±226.93	0.812	0.418
Diagnosis (cases, %)			3.556*	0.878
Cerebral apoplexy	110 (69.2%)	103 (70.5%)		
Intracranial infection	9 (5.7%)	10 (6.8%)		
Guillain-Barre Syndrome	9 (5.7%)	6 (4.1%)		
Epilepsy	6 (3.8%)	7 (4.8%)		
Myasthenia	9 (5.7%)	6 (4.1%)		
Arrhythmia	2 (1.4%)	0 (0.0%)		
Intracranial space occupying	1 (0.6%)	1 (1.7%)		
Others	15 (9.4%)	11 (7.5%)		

Note: *means Fisher exact test was used.

ference in age, gender, diagnosis and length of ICU stay between the two groups (P > 0.05) (**Table 5**). In the Cardiac Surgery ICU there was no significant difference in age, gender, diagnosis and length of ICU stay between the two groups (P > 0.05) (**Table 6**).

Comparison of participant characteristics of each ICU in different implementation stages

In the general ICU there was no significant difference in age and gender among groups (P > 0.05). There was a significant difference in APACHE II score, length of ICU stay, and diagnosis among groups in the general ICU (P < 0.05) (**Table 7**). In the Neurosurgery ICU there was no significant difference in age, gender and diagnosis among groups (P > 0.05). There was significant difference in length of ICU stay among groups in the Neurosurgery ICU (P < 0.05) (**Table 8**). In the Neurology ICU there was no significant difference in age, gender, diagnosis and length of ICU stay among groups (P > 0.05)

Table 6. Comparison of participant characteristics of Cardiac Surgery ICU in pre and post implementation (N=502)

	Pre-implementation (N=378)	Post-implementation (N=124)	t/χ^2	p
Age (x ± s, years)	62.89±10.93	60.48±13.20	-1.831	0.069
Gender (cases, %)			0.412	0.589
Male	241 (63.8%)	83 (66.9%)		
Female	137 (36.2%)	41 (33.1%)		
Length of ICU stay (x ± s, hours)	85.58±100.91	84.68±65.60	-0.094	0.925
Diagnosis (cases, %)			12.020*	0.815
Coronary heart disease	72 (19.0%)	26 (21.0%)		
Cerebral apoplexy	10 (2.6%)	2 (1.6%)		
Traumatic brain injury	1 (0.3%)	0 (0.0%)		
Multiple injuries	2 (0.5%)	0 (0.0%)		
Heart failure	2 (0.5%)	0 (0.0%)		
Lung tumor	47 (12.4%)	17 (13.7%)		
Aortic dissection	41 (10.8%)	16 (12.9%)		
Valvular disease	97 (25.7%)	35 (28.2%)		
Digestive tract tumor, etc.	42 (11.1%)	7 (5.6%)		
Congenital heart disease	18 (4.8%)	8 (6.5%)		
Shock	1 (0.3%)	0 (0.0%)		
Atrial tumor	6 (1.6%)	4 (3.2%)		
Myasthenia	0 (0.0%)	1 (0.8%)		
Myocarditis	1 (0.3%)	0 (0.0%)		
Infective endocarditis	11 (2.9%)	2 (1.6%)		
Mediastinal mass	11 (2.9%)	3 (2.4%)		
Arrhythmia	1 (0.3%)	0 (0.0%)		
Others	15 (2.4%)	3 (2.4%)		

Note: *means Fisher exact test was used.

(**Table 9**). In the Cardiac Surgery ICU there was no significant difference in age, gender, diagnosis and length of ICU stay between the two groups (P > 0.05) (**Table 10**).

Comparison of patient restraint time and rate in each ICU during pre and post implementation

The patient restraint time was significantly shortened (P < 0.05) and the restraint rate was significantly decreased in the general ICU (P < 0.05). The patient restraint time was shortened (P > 0.05) and the restraint rate was decreased in the Neurosurgery ICU (P > 0.05). The patient restraint time was significantly extended (P < 0.05) and the restraint rate was significantly increased in the Neurology ICU (P < 0.05). The patient restraint time was shortened (P > 0.05) and the restraint rate was decreased in the Cardiac Surgery ICU (P > 0.05) (**Table 11**).

Comparison of patient restraint time and rate of each ICU in different implementation stages

In the general ICU, the patient restraint time of different implementation stages gradually decreased (P > 0.05). The restraint rate gradually decreased, and slightly increased in the forth stage, the difference was statistically significant (P < 0.05) (**Table 12**). There was no significant difference of restraint time between each stage (P > 0.05) (**Table 13**).

In the Neurosurgery ICU, there were differences in the patient restraint time among implementation stages, and the forth stage was significantly shortened (P=0.000). The restraint rate of the forth stage significantly decreased (P=0.000) (**Table 14**). Comparison of patient restraint time between each stage shows that there were significant differences of restraint time between individual stages and the fourth

Table 7. Comparison of participant characteristics of general ICU in different implementation stages (N=851)

	Baseline (N=45)	The first stage (N=207)	The second stage (N=194)	The third stage (N=198)	The fourth stage (N=207)	$t/\chi^2/W$	*p*
Age (x ± s, years)	67.20±18.80	66.36±18.53	70.61±16.24	67.83±18.43	66.52±19.97	1.862	0.115
Gender (cases, %)						7.281	0.122
Male	29 (64.4%)	126 (60.9%)	133 (68.6%)	111 (56.1%)	122 (58.9%)		
Female	16 (35.6%)	81 (39.1%)	61 (31.4%)	87 (43.9%)	85 (41.1%)		
APACHE II (x ± s, scores)	15.20±7.37	17.36±5.03	17.63±7.96	15.96±6.90	16.50±7.09	2.493	0.044
Length of ICU stay (x ± s, hours)	140.02±144.83	204.40±198.65	248.21±234.90	228.99±227.01	227.57±204.66	4.478	0.002
Diagnosis (cases, %)						104.303*	0.001
Coronary heart disease	0 (0.0%)	4 (1.9%)	7 (3.6%)	3 (1.5%)	5 (2.4%)		
Cerebral apoplexy	1 (2.2%)	1 (0.5%)	4 (2.1%)	2 (1.0%)	1 (0.5%)		
Traumatic brain injury	0 (0.0%)	1 (0.5%)	2 (1.0%)	0 (0.0%)	4 (1.9%)		
Severe acute pancreatitis	2 (4.4%)	9 (4.3%)	7 (3.6%)	12 (6.1%)	14 (6.8%)		
Multiple injuries	3 (6.7%)	22 (10.6%)	18 (9.3%)	5 (2.5%)	10 (4.8%)		
Pulmonary infection	1 (2.2%)	14 (6.8%)	29 (14.9%)	17 (8.6%)	19 (9.2%)		
Respiratory failure	0 (0.0%)	15 (7.2%)	20 (10.3%)	23 (11.6%)	11 (5.3%)		
Heart failure	0 (0.0%)	5 (2.4%)	3 (1.5%)	3 (1.5%)	3 (1.4%)		
Lung tumor	2 (4.4%)	4 (1.9%)	4 (2.1%)	5 (2.5%)	7 (3.4%)		
Digestive tract tumor, etc.	20 (44.4%)	63 (30.4%)	44 (22.7%)	58 (29.3%)	68 (32.9%)		
Valvular disease	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	0 (0.0%)		
Shock	4 (8.9%)	2 (1.0%)	9 (4.6%)	3 (1.5%)	7 (3.4%)		
Motor neuron disease	0 (0.0%)	6 (2.9%)	4 (2.1%)	3 (1.5%)	1 (0.5%)		
Femoral fracture	6 (13.3%)	11 (5.3%)	12 (6.2%)	7 (3.5%)	9 (4.3%)		
Multiple organ failure	0 (0.0%)	2 (1.0%)	0 (0.0%)	8 (4.0%)	1 (0.5%)		
Myocarditis	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	2 (1.0%)		
Myasthenia	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)		
Renal failure	0 (0.0%)	3 (1.4%)	3 (1.5%)	5 (2.5%)	6 (2.9%)		
Others	6 (13.3%)	43 (20.8%)	27 (13.9%)	42 (21.2%)	39 (18.8%)		

Note: *means Fisher exact test was used.

Table 8. Comparison of participant characteristics of Neurosurgery ICU in different implementation stages (N=333)

	Baseline (N=15)	The first stage (N=85)	The second stage (N=70)	The third stage (N=78)	The fourth stage (N=85)	$t/\chi^2/W$	*p*
Age (x ± s, years)	56.00±14.93	59.76±13.01	61.10±13.10	61.49±14.11	58.14±16.57	0.862	0.490
Gender (cases, %)						3.494	0.479
Male	9 (60.0%)	59 (69.4%)	48 (68.6%)	48 (61.5%)	63 (74.1%)		
Female	6 (40.0%)	26 (30.6%)	22 (31.4%)	30 (38.5%)	22 (25.9%)		
Length of ICU stay (x ± s, hours)	182.40±123.02	201.13±158.25	262.83±184.52	291.59±210.66	230.78±183.78	3.389	0.013
Diagnosis (cases, %)						18.930*	0.722
Cerebral apoplexy	6 (40.0%)	37 (43.5%)	33 (47.1%)	25 (32.1%)	38 (44.7%)		
Traumatic brain injury	6 (40.0%)	32 (37.6%)	20 (28.6%)	35 (44.9%)	33 (38.8%)		
Multiple injuries	1 (6.7%)	7 (8.2%)	10 (14.3%)	9 (11.5%)	6 (7.1%)		
Intracranial infection	0 (0.0%)	2 (2.4%)	0 (0.0%)	1 (1.3%)	1 (1.2%)		
Intracranial space occupying	0 (0.0%)	1 (1.2%)	2 (2.9%)	1 (0.7%)	3 (0.0%)		
Epilepsy	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)		
Others	1 (6.7%)	6 (7.1%)	5 (7.1%)	6 (7.7%)	4 (4.7%)		

Note: *means Fisher exact test was used.

stage ($P < 0.05$) and no significant difference was found among any two other stages ($P > 0.05$) (**Table 15**).

In the Neurology ICU, the patient restraint time gradually shortened during pre-implementation and extended in the post-implementation, the

Table 9. Comparison of participant characteristics of Neurology ICU in different implementation stages (N=305)

	Baseline (N=15)	The first stage (N=48)	The second stage (N=96)	The third stage (N=76)	The fourth stage (N=70)	$t/\chi^2/W$	p
Age (x ± s, years)	65.53±15.87	66.04±13.74	62.22±16.89	66.59±16.30	63.33±18.15	0.958	0.431
Gender (cases, %)						7.948	0.093
Male	12 (80.0%)	28 (58.3%)	64 (66.7%)	50 (65.8%)	56 (80.0%)		
Female	3 (20.0%)	20 (41.7%)	32 (33.3%)	26 (34.2%)	14 (20.0%)		
Length of ICU stay (x ± s, hours)	285.47±201.77	348.52±227.01	254.86±194.01	296.00±214.92	317.53±240.34	1.784	0.140
Diagnosis (cases, %)						27.247*	0.382
Cerebral apoplexy	8 (53.3%)	34 (70.8%)	68 (70.8%)	58 (76.3%)	45 (64.3%)		
Intracranial infection	0 (0.0%)	4 (8.3%)	5 (5.2%)	3 (3.9%)	7 (10.0%)		
Guillain-Barre Syndrome	3 (20.0%)	0 (0.0%)	6 (6.3%)	2 (2.6%)	4 (5.7%)		
Epilepsy	1 (6.7%)	1 (2.1%)	4 (4.2%)	3 (3.9%)	4 (5.7%)		
Myasthenia	0 (0.0%)	4 (8.3%)	5 (5.2%)	2 (2.6%)	4 (5.7%)		
Arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.9%)		
Intracranial space occupying	0 (0.0%)	0 (0.0%)	1 (1.0%)	1 (1.3%)	0 (0.0%)		
Others	3 (20.0%)	5 (10.4%)	7 (7.3%)	7 (9.2%)	4 (5.7%)		

Note: *means Fisher exact test was used.

Table 10. Comparison of participant characteristics of Cardiac Surgery ICU in different implementation stages (N=502)

	Baseline (N=16)	The first stage (N=131)	The second stage (N=97)	The third stage (N=134)	The fourth stage (N=124)	$t/\chi^2/W$	p
Age (x ± s, years)	64.31±9.75	62.53±12.33	62.14±10.13	63.60±10.21	60.48±13.20	1.331	0.257
Gender (cases, %)						1.701	0.791
Male	9 (56.3%)	88 (67.2%)	61 (62.9%)	83 (61.9%)	83 (66.9%)		
Female	7 (43.7%)	43 (32.8%)	36 (37.1%)	51 (38.1%)	41 (33.1%)		
Length of ICU stay (x ± s, hours)	86.75±47.20	77.82±79.64	103.55±159.55	80.04±60.92	84.68±65.60	0.644	0.633
Diagnosis (cases, %)						82.658*	0.059
Coronary heart disease	5 (31.3%)	24 (18.3%)	20 (20.6%)	23 (17.2%)	26 (21.0%)		
Cerebral apoplexy	0 (0.0%)	0 (0.0%)	7 (7.2%)	3 (2.2%)	2 (1.6%)		
Traumatic brain injury	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)		
Multiple injuries	0 (0.0%)	0 (0.0%)	2 (2.1%)	0 (0.0%)	0 (0.0%)		
Heart failure	0 (0.0%)	0 (0.0%)	1 (1.0%)	1 (0.7%)	0 (0.0%)		
Lung tumor	0 (0.0%)	22 (16.8%)	8 (8.2%)	17 (12.7%)	17 (13.7%)		
Aortic dissection	0 (0.0%)	18 (13.7%)	10 (10.3%)	13 (9.7%)	16 (12.9%)		
Valvular disease	4 (25.0%)	27 (20.6%)	30 (30.9%)	36 (26.9%)	35 (28.2%)		
Digestive tract tumor, etc.	2 (12.5%)	20 (15.3%)	7 (7.2%)	13 (9.7%)	7 (5.6%)		
Congenital heart disease	2 (12.5%)	5 (3.8%)	4 (4.1%)	7 (5.2%)	8 (6.5%)		
Shock	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)		
Atrial tumor	1 (6.3%)	1 (0.8%)	0 (0.0%)	4 (3.0%)	4 (3.2%)		
Myasthenia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)		
Myocarditis	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)		
Infective endocarditis	0 (0.0%)	2 (1.5%)	4 (4.1%)	5 (3.7%)	2 (1.6%)		
Mediastinal mass	0 (0.0%)	3 (2.3%)	2 (2.1%)	6 (4.5%)	3 (2.4%)		
Arrhythmia	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Others	2 (12.5%)	8 (6.1%)	1 (1.0%)	4 (3.0%)	3 (2.4%)		

Note: *means Fisher exact test was used.

difference was statistically significant (P= 0.000). The restraint rate gradually decreased during pre-implementation and increased during post-implementation, the difference was statistically significant (P < 0.05) (**Table 16**). Comparison of patient restraint time between

Table 11. Comparison of patient restraint time and rate of each ICU in pre and post implementation

	General ICU (N=851)		Neurosurgery ICU (N=333)		Neurology ICU (N=305)		Cardiac Surgery ICU (N=502)	
	Pre-implementation (N=45)	Post-implementation (N=806)	Pre-implementation (N=100)	Post-implementation (N=233)	Pre-implementation (N=159)	Post-implementation (N=146)	Pre-implementation (N=378)	Post-implementation (N=124)
Restraint time/catheterization time (x ± s, days/thousand catheterized days)	619.61±347.93	470.94±483.72	630.47±462.81	540.05±533.72	769.09±398.15	883.55±306.13	452.85±363.92	393.35±323.99
t	-2.032		-1.559		2.827		-1.720	
p	0.042		0.121		0.005		0.087	
95% CI	-292.27~-5.07		-204.74~23.91		34.78~194.13		-127.66~8.66	
Restraint rate (cases, %)	41 (91.1%)	586 (72.7%)	71 (71.0%)	140 (60.1%)	130 (81.8%)	133 (91.1%)	316 (83.6%)	107 (86.3%)
χ^2	7.446		3.590		5.586		0.510	
p	0.005		0.063		0.020		0.570	

Table 12. Comparison of patient restraint time and rate of general ICU in different implementation stages (N=851)

	Restraint time/Catheterization time (x ± s, days/thousand catheterized days)	*F*	*p*	Restraint rate (no. of cases, %)	χ^2	*p*
Baseline[a] (N=45)	619.61±347.93	2.327	0.055	41 (91.1%)	16.052	0.003
The first stage[b] (N=207)	527.90±400.28			161 (77.8%)		
The second stage[b] (N=194)	477.30±406.14			137 (70.6%)		
The third stage[b] (N=198)	453.01±693.47			131 (66.2%)		
The fourth stage[b] (N=207)	425.18±366.07			157 (75.8%)		

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 13. Comparison of patient restraint time in general ICU between every two stages (N=851)

	Baseline[a] (N=45)	The first stage[b] (N=207)	The second stage[b] (N=194)	The third stage[b] (N=198)
The first stage[b] (N=207)	1.000			
The second stage[b] (N=194)	0.717	1.000		
The third stage[b] (N=198)	0.347	1.000	1.000	
The fourth stage[b] (N=207)	0.134	0.288	1.000	1.000

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 14. Comparison of patient restraint time and rate of Neurosurgery ICU in different implementation stages (N=333)

	Restraint time/Catheterization time ($\overline{x}$ ± s, days/thousand catheterized days)	*F*	*p*	Restraint rate (no. of cases, %)	χ^2	*p*
Baseline[a] (N=15)	729.11±465.91	7.963	0.000	11 (73.3%)	42.767	0.000
The first stage[a] (N=85)	613.06±462.84			60 (70.6%)		
The second stage[b] (N=70)	694.76±545.17			54 (77.1%)		
The third stage[b] (N=78)	649.71±526.79			57 (73.1%)		
The fourth stage[b] (N=85)	312.02±452.23			29 (34.1%)		

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 15. Comparison of patient restraint time in Neurosurgery ICU between every two stages (N=149)

	Baseline[a] (N=15)	The first stage[a] (N=85)	The second stage[b] (N=70)	The third stage[b] (N=78)
The first stage[a] (N=85)	1.000			
The second stage[b] (N=70)	1.000	1.000		
The third stage[b] (N=78)	1.000	1.000	1.000	
The fourth stage[b] (N=85)	0.028	0.001	0.000	0.000

Notes: [a]means pre-implementation, [b]means Post-implementation.

each stage shows that there were significant differences of restraint time between baseline and the first stage, the second stage and the third stage, the second stage and the third stage, and the fourth stage ($P < 0.05$) and no significant difference among any two other stages ($P > 0.05$) (**Table 17**).

In the Cardiac Surgery ICU, there was no significant difference of restraint time and rate in the

Table 16. Comparison of patient restraint time and rate of Neurology ICU in different implementation stages (N=305)

	Restraint time/Catheterization time (x ± s, days/thousand catheterized days)	*W*	*p*	Restraint rate (no. of cases, %)	χ^2	*p*
Baseline[a] (N=15)	996.45±13.73	18.183	0.000	15 (100%)	16.308	0.003
The first stage[a] (N=48)	857.12±320.18			43 (89.6%)		
The second stage[a] (N=96)	689.56±440.95			72 (75.0%)		
The third stage[b] (N=76)	857.20±327.19			68 (89.5%)		
The fourth stage[b] (N=70)	912.16±281.04			65 (92.9%)		

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 17. Comparison of patient restraint time in Neurology ICU between every two stages (N=305)

	Baseline[a] (N=15)	The first stage[a] (N=48)	The second stage[a] (N=96)	The third stage[b] (N=76)
The first stage[a] (N=48)	0.041			
The second stage[a] (N=96)	0.000	0.099		
The third stage[b] (N=76)	0.004	1.000	0.046	
The fourth stage[b] (N=70)	0.137	0.982	0.001	0.958

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 18. Comparison of patient restraint time and rate of Cardiac Surgery ICU in different implementation stages (N=502)

	Restraint time/Catheterization time ($\overline{x}$ ± s, days/thousand catheterized days)	*F*	*p*	Restraint rate (no. of cases, %)	χ^2	*p*
Baseline[a] (N=16)	519.42±355.19	2.227	0.065	16 (100%)	4.809	0.307
The first stage[a] (N=131)	391.50±352.11			106 (80.9%)		
The second stage[a] (N=97)	489.76±361.65			83 (85.6%)		
The third stage[a] (N=134)	478.15±373.77			111 (82.8%)		
The fourth stage[b] (N=124)	393.35±323.99			107 (86.3%)		

Notes: [a]means pre-implementation, [b]means Post-implementation.

Table 19. Comparison of patient restraint time in Cardiac Surgery ICU between every two stages (N=502)

	Baseline[a] (N=16)	The first stage[a] (N=97)	The second stage[a] (N=134)	The third stage[a] (N=124)
The first stage[a] (N=131)	1.000			
The second stage[a] (N=97)	1.000	0.384		
The third stage[a] (N=134)	1.000	0.465	1.000	
The fourth stage[b] (N=124)	1.000	1.000	0.447	0.547

Notes: [a]means pre-implementation, [b]means Post-implementation.

different implementation stages (P > 0.05) (**Table 18**). There was no significant difference of restraint time between each stage (P > 0.05) (**Table 19**).

Discussion

Our previous study had constructed a care program for ICU adult catheterized patients using an evidence-based approach [11]. After the implementation of the program, the physical restraint time and rate of ICU adult catheterized patients in the implementation group were significantly lower than those in the control group ($P < 0.05$). In this study, the restraint rate and restraint time were selected as the evaluation indexes to overcome the issue that no matter how long the restraint time was, it was recorded as one case: the idea was not only to see whether the patients are restrained or not, but also to evaluate the length of the restraint. The results of this paper showed that the application of the best evidence of reasonable physical restraint in adult ICU catheterized patients could reduce the restraint rate and length. Although the constraint rate of ICU adult catheterized patients is still high (73.7%), overall, the physical restraint rate of patients decreased by 17.5% after implementation.

Zhuang Xiaoyan [14] carried out the physical restraint safety management project guided by the healthcare failure mode and effect analysis (HFMEA) in the Neurosurgery ICU. After the implementation, the physical restraint rate decreased by 17.1%. Liu Ying [15] explored the effect of project-based quality control circle (QCC) activities in reducing the restraint rate of patients with mechanical ventilation in ICU. The result showed that the physical restraint rate decreased by 21.95%. These are similar to our result.

Although each ICU implemented the same program, due to differences in the types of diseases in the admitted patients, there were also differences in restraint time and restraint rate, and the effects in pre and post implementation were also different. This is the reason why we carried out a stepped wedge design rather than a parallel design. Most ICUs showed a downward trend in the restraint duration and restraint rate after the implementation, while the restraint rate of the general ICU rebounded in the fourth stage, indicating that it takes 6-9 months to achieve the maximum effect after the new program implementing, and there will be some rebound phenomena after the satisfactory effect is achieved. This may be due to the fact that the supervision of managers had decreased with the extension of time, and the implementation of intervention measures had been gradually slackened by staff. However, the overall final stage is lower than the baseline stage. Actually, the ultimate goal of this study was to replace the previous imperfect restraint system with a new and complete restraint program. Therefore, it is very important to maintain a strong supervision and cultivate the restraint concept of medical staff. Only by doing this can we avoid the occurrence of the rebound phenomenon.

In addition, in different intensive care units in the same hospital, in order to ensure safety during the practice of reform, a stepped-wedge trial is a better research design to gradually promote the program. Since the institute has the goal of reducing the restraint rate of inpatients in the hospital nursing department plan of 2018, the purpose of this research is consistent with the planning of the hospital's general goal. Therefore, even if there is no specific reform plan, the idea of reducing constraint certainly exists in the departments that have not implemented the reform program, and they might actively seek methods to unconsciously obtain related knowledge and strategies to reduce constraints from the research and implementation of this approach, and consciously or unconsciously change their behavior, so the nursing units that had not entered the implementation stage may also present corresponding effects (Neurology ICU). This phenomenon has been described as "a rising tide" [16]. Because it was a strategy that was beneficial to promote patient health outcomes, it was consistent with the research objective of reducing restraints, and the results were considered acceptable. In the stage of accepting promotion, the results of the Neurology ICU were contrary to the expectation. The restraint time and restraint rate increased. It may have been a rebound effect that was caused by the previous ideas. The manifestation was the same in the general ICU and Neurosurgery ICU. It may also be because the head nurse of the department changed in August 2019, and the training and supervision of new team members were not consistent enough. In the future research, we will pay attention to similar problems and train the relevant personnel as soon as possible to avoid the influence of confounding factors.

Limitations

The short collection time of baseline data in this study leads to a difference of sample size between the two groups during the pre and post implementation, which may lead to a bias. We will improve it in future research design.

Besides, this study used a single research site, and participants were recruited from one hospital in Nantong, China. There are cultural and demographic sociological differences with other regions and countries, so the results should be popularized with care. We hope that more multi center and larger sample randomized controlled trials can be conducted in the future to verify the results of this study.

Conclusion

In this study, the best evidence of reasonable physical restraint with ICU adult catheterized patients was transformed and applied to clinical practice. It was implemented in 4 ICUs and the results showed that this program can reduce the restraint rate and shorten the restraint time. The high rate of restraint in ICUs is still an issue worthy of attention in China, and we expect that the program constructed by our research can be considered for use in other ICUs.

Linking evidence to action

- The restraint rate of ICU patients in China is still at a high level.

- Applying the best evidence of reasonable physical restraint could effectively reduce the restraint rate and shorten the restraint time of patients.

- ICU medical staff can improve their awareness of reasonable physical restraint and recognize the necessity of reducing restraint.

- ICU medical staff can strengthen the evaluation of restraint indications in their work to minimize restraint.

Acknowledgements

We are grateful to Chief Yan Zhang, Hongji Qian, Hongsheng Zhao, Yan Hu, Hongwu Sheng, Xujuan Xu, Hong He and Xiuqun Xu, Nurse-in-Charge Linli Wang, Xuemei Zhou and Jinmei Shi for their guidance and participation in the process of program construction. We are grateful to all the staff in the general ICU, Neurosurgery ICU, Neurology ICU and Cardiac Surgery ICU for their dedicated support and all the patients and families who generously participated in this study. This work was supported by Nantong Science and Technology Bureau [MS-12018017] and Affiliated Hospital of Nantong University [Tfh2104]. The funding body provided financial support in the design of the study, data collection and in writing the manuscript.

Disclosure of conflict of interest

Juan Wu and Hailan Qian were funded by Nantong Science and Technology Bureau. Huifen Xu was funded by Affiliated Hospital of Nantong University. The funders did not influence the design of the study, the acquisition of data, the analysis, drafting of the manuscript or the decision to publish. Yahui Yang, Xiaoyan Chen, Lihua Lu, Yanghui Xu, Chenhui Wang, Yang Gao and Jingyi Li have disclosed that they do not have any conflicts of interest.

Address correspondence to: Juan Wu and Huifen Xu, Affiliated Hospital of Nantong University, Nantong 226001, Jiangsu, China. Tel: +86-1386190-1841; E-mail: texu1910@163.com (JW); Tel: +86-13813716296; E-mail: yhf8861@163.com (HFX)

References

[1] Gu T, Wang X, Deng N and Weng W. Investigating influencing factors of physical restraint use in China intensive care units: a prospective, cross-sectional, observational study. Aust Crit Care 2019; 32: 193-198.
[2] Pérez de Ciriza Amatriain AI, Nicolás Olmedo A, Goñi Viguria R, Regaira Martínez E, Margall Coscojuela MA and Asiain Erro MC. Physical restraint use in critical care units. Perceptions of patients and their families. Enferm Intensiva 2012; 23: 77-86.
[3] Suliman M. Prevalence of physical restraint among ventilated intensive care unit patients. J Clin Nurs 2018; 27: 3490-3496.
[4] van der Kooi AW, Peelen LM, Raijmakers RJ, Vroegop RL, Bakker DF, Tekatli H, van den Boogaard M and Slooter AJ. Use of physical restraints in dutch intensive care units: a prospective multicenter study. Am J Crit Care 2015; 24: 488-495.
[5] Chen L, Xi X and Chen XY. The current status and analysis of physical restraint usage in intensive care unit. Chin Nurs Manage 2014; 14: 1022-1024.
[6] Gu T, Weng WQ, Wang X and Deng N. Characteristics and current situation of physically restrained patients in ICU in a third-level hospital. J Clin Med Prac 2018; 22: 118-121.

[7] Pan Y, Jiang Z, Yuan C, Wang L, Zhang J, Zhou J, Tao M, Quan M and Wu Q. Influence of physical restraint on delirium of adult patients in ICU: a nested case-control study. J Clin Nurs 2018; 27: 1950-1957.
[8] Via-Clavero G, Sanjuán-Naváis M, Romero-García M, de la Cueva-Ariza L, Martínez-Estalella G, Plata-Menchaca E and Delgado-Hito P. Eliciting critical care nurses' beliefs regarding physical restraint use. Nurs Ethics 2019; 26: 1458-1472.
[9] Suliman M, Aloush S and Al-Awamreh K. Knowledge, attitude and practice of intensive care unit nurses about physical restraint. Nurs Crit Care 2017; 22: 264-269.
[10] Hemming K, Haines TP, Chilton PJ, Girling AJ and Lilford RJ. The stepped wedge cluster randomized trial: rationale, design, analysis, and reporting. BMJ 2015; 350: h391.
[11] Wu J, Qian HL, Hu Y, Li JY, Xu HF, Zhang Y, Wang CH, Qian HJ, Zhou XM, Shi JM, Chen XY, Lu LZ and Xu YH. Clinical application of best evidence for reasonable physical restraint with ICU adult catheterized patients. Chin Nurs Manage 2019; 19: 1395-1402.
[12] Xu HF, Wang LL, Wu J, Qian HL, Wang CH, Ji JF, Hu HP, He AX, Chen X and Ge HB. Effect evaluation of three restraint assessment tools in ICU adult catheterized patients. Med J of Communications 2020; 34: 310-313.
[13] Zhang Y, Wu J, Hu Y, Shi JM, Shen HW, He H, Xu XQ, Xu XJ, Xu HF, Qian HJ, Qian HL and Li JY. Application investigation and obstacle analysis on the best evidence for reasonable physical restraints in ICU adult patients with catheter. Chin Nurs Res 2019; 33: 3732-3736.
[14] Zhuang XY, Xu Q, Zhu SQ and Tong ZR. Failure risk assessment and countermeasures of physical restraints. Chin J Nurs 2014; 49: 816-820.
[15] Zhuang XY, Xu Q, Zhu SQ and Tong ZR. Project-based quality control circle activities in reducing the restraint rate of patients with mechanical ventilation in ICU. J Nurs Sci 2019; 34: 54-57.
[16] Bion J, Richardson A, Hibbert P, Beer J, Abrusci T, McCutcheon M, Cassidy J, Eddleston J, Gunning K, Bellingan G, Patten M and Harrison D; Matching Michigan Collaboration & Writing Committee. 'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Qual Saf 2013; 22: 110-123.