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Original Article

Study on the effectiveness, safety and comprehensive evaluations of novel medical restraint gloves in patients with consciousness disorders

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Abstract: Objective: To develop novel medical restraint gloves and investigate their application effect in patients with consciousness and cognitive disorders. Methods: The clinical data of 63 patients with consciousness or cognitive impairment admitted to The First People's Hospital of Lin'an District from June 2021 to January 2022 were retrospectively analyzed. According to the different type of restraint gloves used for treatment, patients were divided into a control group and an observation group. Thirty-one patients from the observation group were treated with the novel medical restraint gloves, and 32 patients in the control group underwent conventional restraint gloves. The effectiveness, safety as well as the comprehensive evaluations of the gloves were detected and compared between the two groups. Results: In the term of effectiveness of gloves, the outcomes of protective performances, treatment operations, the fixed gloves/rings, the flexible fingers and overturned gloves in the observation group were significantly better than those in the control group (all $P<0.05$). In the term of safety of gloves, there was significant difference regarding the local skin redness ($P<0.05$) between the control group and the observation group, while there was no remarkable difference regarding strangulation marks, local skin damage and local skin swelling. The results of comprehensive evaluation showed the qualified outcome in the observation group was 100%, which was significantly higher than that in the control group (50%) ($P<0.05$). Conclusion: Compared with the traditional restraint gloves, the outcomes of effectiveness, safety and comprehensive evaluation results from the observation group were better, indicating that the novel medical restraint gloves better meet the requirements of clinical practices and thus have more clinical application value.

Keywords: Restraint, novel medical gloves, unplanned extubation, catheter, effects

Introduction

Patients with consciousness and cognitive disorders are usually accompanied by mental disorders, delirium, agitation, self-injury, injury, damage, unplanned extubation and other behaviors, which not only affects the treatment of patients, but also endangers their lives. Unplanned extubation, also known as accidental extubation, refers to the extubation caused by the patient's intention or any accident. Previous studies [1-6] showed that the incidence of unplanned extubation was between 3.9% and 14.0%. It may cause damage to the patient's body tissue, increase the patient's pain, prolong the length of hospitalization, lead to medical and nursing conflicts, and even endanger the patient's life [7].

In clinical practices, the restraint belt is used to restrict the patient's movement by fixing certain parts of the patient's body, which belongs to the mandatory protection for the patients. Effective restraint and protection measures can reduce the occurrence of adverse events in patients, and also ensure the smooth progress of treatment and nursing in patients [5]. In order to reduce the unplanned extubation rates in patients, there are currently a variety of restraint gloves available for application [8-12],

such as transparent restraint protective gloves, special safety restraint gloves, improved structural restraint gloves, anti-scratch restraint gloves, plug-in restraint gloves, fingers and thick palm restraint gloves, medical clamp-type restraint gloves, new restraint finger set and so on. Conventional table tennis gloves are not only easily broken free from during use, but also affect blood circulation. Moreover, improper restraint is often accompanied by defects such as skin bruising, poor comfort, untimely detection of saline extravasation, unplanned extubation, injuries, which increase the psychological burden on patients and their families [10]. Some studies showed that 68% of patients with unplanned extubation had received constraints, but the desired results were not achieved [13]. Other reports revealed that most of the restrictive gloves were easy to turn over in use and could not completely solve the problem of accidental extubation. However, at present the optimal restraint gloves are not available in clinical practices. Therefore, protective restraint of patients' limbs has become a common auxiliary treatment method in clinical practice, and it is necessary to create the novel medical restraint gloves to improve the effects.

Aiming at the shortcomings of current restraint gloves, our center developed a new type of medical restraint gloves [National Utility Model Patent: (ZL 2021 2 0394582.1)], which can be used for patients with consciousness disorders, effectively making up for the limitations of traditional restraint gloves and good results have been achieved. It is worthy of clinical promotion. The application results of these novel medical restraint gloves are not yet reported so far. This study will provide better clinical evidence for management of these patients with consciousness and cognitive disorders.

Materials and methods

General information

In this retrospective study, 63 patients requiring physical restraint from Departments of General Medicine and Comprehensive ICU, the First People's Hospital of Hangzhou Lin'an District from June 2021 to January 2022 were enrolled. These patients were divided into two groups according to different methods of physical restraints. Inclusion criteria: (1) Patients aged over 18 years old. (2) Patients with consciousness and cognitive disorders who were not able to fully cooperate with treatment and required protective restraints. (3) Patients with at least one or more kind of tubes, such as nasogastric tube, urethral catheter, peripherally inserted central catheter (PICC), central venous catheter, endotracheal tube. (4) Patients who had not participated in other clinical trials within one month. (5) Written informed consent was signed. Exclusion criteria: (1) Patients with skin diseases. (2) Patients with blood coagulation dysfunction. (3) The skin of the intubation-involved part had been damaged before the performance of protective restraint. (4) Patients in deep coma. (5) Patients with severe upper limb edema. (6) The muscle strength of the upper limb was below grade two. (7) The patient's family refused to conduct the protective restraints.

For the control group, 32 patients received traditional restraint gloves. For the observation group, 31 patients were treated with the novel medical restraint gloves. The confinement time was three days. This study was approved by the Ethics Committee of the First People's Hospital of Hangzhou Lin'an District (Approval No. 2021-026).

Methods

Patients in the control group were treated with the traditional restraint gloves, with hard pads in the double-layer cotton cloth and the restraint rings inside the palm surface of the gloves.

Patients in the observation group were treated with the novel medical restraint gloves. The structure of the novel medical restraint gloves [National Utility Model Patent: (ZL 2021 2 0394582.1)] is shown in **Figure 1**: the materials include thickened cotton cloths, mesh cotton cloth, hard liner, white canvas belt, zipper, white hook and loop fasteners and thin cotton cloths. The shell of novel medical restraint gloves is formed by the upper cloth and the lower cloth. The upper cloth, also named the back of the hand glove, is made of the mesh cotton cloth. The lower cloth, also named the palm of the hand glove, is made of the hard pad wrapped with a double layer of cotton. The accommodating cavity of the glove shell contained a cotton half-finger protective part. The protective gloves include a protective back part and a protective finger part. These two parts

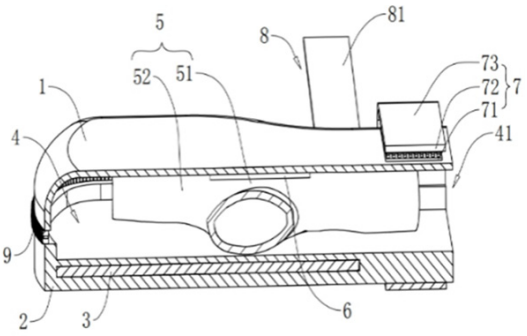

Figure 1. The structural representation of the novel medical restraint gloves. 1. Upper cloths. 2. Lower cloths. 3. Hard pad. 4. The accommodating cavity. 41. Entrance. 5. The protective gloves. 51. The protective back part. 52. The protective finger part. 6. The hook and loop fasteners. 7. The binding part. 71. The parent part. 72. The subpart. 73. The connecting belt. 81. The binding part. 9. Zipper.

are connected. The protective back part is fixed on the inner wall of the back of the hand. One end of the glove shell is not sewn to form an entrance for hand, the other end, namely the opening of the finger end, is sewn in the form of zipper. The pre-binding part is provided near the entrance. The pre-binding parts include a parent part set on the outer wall of the upper cloth, a connecting belt set on the outer wall of the upper cloth at one end, and a subpart set on the other end of the connecting belt. The parent part is provided with a hook surface of the hook and loop fasteners, and the subpart is provided with loop surface of the hook and loop fasteners. The binding part including two bands used for increasing the restraint effect is set near the entrance.

The members of the project team should be trained on the correct restraint methods to avoid operational errors. The correct restraint method was as follows: the need for restraint should be evaluated. The novel medical restraint gloves were applied following signing the informed consent. First, the zipper (No. 9) was unzipped to open the upper cloth (No. 1) and the lower cloth (No. 2), so as to observe the internal conditions. The patient's palm was put into the entrance (No. 41), and the protective gloves was put on (No. 5). Then the subpart (No. 72) on the connecting belt (No. 73) and the parent part (No. 71) on the upper cloth (No. 1) were stuck together. Next, the zipper (No. 9) was zipped to make the patient's palm toward the hard pad (No. 3). Finally, the binding band (No. 81) was tightened on the wrist circling the outside surface of the upper cloth (No. 1) and the lower cloth (No. 2). Relax the restraint for 3-5 minutes every 2 hours. During use, the zipper could be opened at any time to observe the limb end circulation, activity, and perform the glucose detection and blood oxygen saturation monitoring.

Observation indicators

In this study, the primary indicator was the comprehensive evaluation of gloves, and the secondary ones are the effectiveness and safety.

(1) The effectiveness of gloves was evaluated as follows [14]: ① Appearance and packaging: whether the packaging and structure were complete, whether the material was contaminated and soft. ② Protective performances: whether the catheter can be effectively prevented from being pulled out. It was defined that as long as the patient's fingers on either side of the upper limb can grasp the catheter, it was considered as an opportunity to pull out the catheter. ③ Treatment operations: whether it was convenient for treatment operation. ④ Whether the fixed gloves/rings slipped. ⑤ Whether the fingers were flexible. ⑥ Whether the gloves were turned over.

(2) The safety of gloves was evaluated as follows [11]: ① Whether there was local skin redness. ② Whether there was any strangulation mark. ③ Whether there was local skin damage. ④ Whether there was local skin swelling.

(3) The comprehensive evaluation of gloves was performed as follows [12]. The comprehensive evaluation consisted of 11 indicators, including effectiveness, safety, comfort level, slipping gloves, incidence of unplanned extubation, damage to skin, local swelling, blood circulation, nerve compression, joint dysfunction, satisfactory of patients and their families. ① The comprehensive evaluation was qualified if 9-11 of the 11 indicators reached the standard and the severity of adverse reactions was judged as grade 1-2. ② The comprehensive evaluation was unqualified if 3 or more of the 11 indicators did not reach the standard and the severity of adverse reactions was judged as grade 3-4.

Table 1. Comparison of general information between two groups

Group	Control group (n=32)	Observation group (n=31)	t/χ^2 value	*P* value
Age (years)	45.4±8.6	43.6±7.7	0.874	0.385
Gender (n)			0.790	0.374
Male	25	23		
Female	7	8		
APACHE II scores	14.1±1.9	13.9±1.7	0.440	0.662
Types of disease			0.858	0.836
Craniocerebral injury (n)	12	9		
Cerebral hemorrhage (n)	9	10		
COPD (n)	7	9		
Cardiac insufficiency (n)	4	3		
Type of tubes				
Nasogastric tube	17	15	0.141	0.707
Urethral catheter	20	25	2.540	0.111
PICC	8	5	0.757	0.385
CVC	27	29	1.342	0.247
Trachea cannula	9	11	0.394	0.531

Note: COPD: chronic obstructive pulmonary disease; PICC: Peripherally inserted central catheter; CVC: Central venous catheter.

Statistical analysis

All data collected in this research were analyzed with statistical product and service solutions (SPSS) software (version. 20.0). Measurement data were presented as mean ± standard deviation and independent-sample t test was applied for comparison between the two groups. Enumeration data were presented as number/percentage and chi-square test was applied for comparison between the two groups. P<0.05 was indicated as statistical significances.

Results

Comparison of general information

As shown in **Table 1**, there were no significant differences in the term of age, gender, APACHE II scores, types of disease, type of catheter and confinement time between the two groups, indicating the two groups were comparable (all P>0.05).

Comparison of effectiveness indexes

As shown in **Table 2**, in control group, there were 32 patients with complete packaging and structure of gloves, 26 patients with qualified protective performances, 18 patients with qualified treatment operations, 18 patients with proper fixed gloves/rings, 8 patients with flexible fingers and 18 patients without overturned gloves. In the observation group, all 31 patients were with complete packaging and structure of gloves, qualified protective performances, qualified treatment operations, proper fixed gloves/rings, flexible fingers and without overturned gloves (all P<0.001).

Comparison of safe indexes

As shown in **Table 3**, in control group, there were 9 patients with local skin redness, 6 patients with strangulation marks, 2 patients with local skin damage and 5 patients with local skin swelling; while there was one patient with local skin redness and 2 patients with strangulation marks. In contrast to that in control group, the local skin redness incidences in the observation group were significantly lower (P<0.05).

Comparison of comprehensive evaluation results

As shown in **Table 4**, the results of comprehensive evaluation indicated that 100% of patients in observation group had qualified effects, while 50% of patients in control group had qualified effects. In contrast to the control group, observation group exhibited significantly better results of comprehensive evaluation (P<0.05).

Table 2. *Comparison of* effectiveness of gloves between two groups (Cases)

Parameters		Observation group (N=31)	Control group (N=32)	χ^2 value	*P* value
Packaging and structure	Qualified (%)	31 (100.00%)	32 (100.00%)	0.000	1.000
	Unqualified (%)	0 (0.00%)	0 (0.00%)		
protective performances	Qualified (%)	31 (100.00%)	26 (81.25%)	4.433	0.035
	Unqualified (%)	0 (0.00%)	6 (18.75%)		
Treatment operations	Qualified (%)	31 (100.00%)	18 (56.25%)	17.438	0.000
	Unqualified (%)	0 (0.00%)	14 (43.75%)		
Fixed gloves/rings	Qualified (%)	31 (100.00%)	18 (56.25%)	17.438	0.000
	Unqualified (%)	0 (0.00%)	14 (43.75%)		
Flexible fingers	Qualified (%)	31 (100.00%)	8 (25.00%)	37.558	0.000
	Unqualified (%)	0 (0.00%)	24 (75.00%)		
Overturned gloves	Qualified (%)	31 (100.00%)	18 (56.25%)	17.438	0.000
	Unqualified (%)	0 (0.00%)	14 (43.75%)		

Table 3. Comparison of safety of gloves between two groups (Cases)

Parameters		Observation group (N=31)	Control group (N=32)	χ^2 value	*P* value
Local skin redness	Yes	1 (3.23%)	9 (28.12%)	5.565	0.018
	No	30 (96.77%)	23 (71.88%)		
Strangulation marks	Yes	2 (6.45%)	6 (18.75%)	1.182	0.277
	No	29 (93.55%)	26 (81.25%)		
Local skin damage	Yes	0 (0.00%)	2 (6.25%)	0.484	0.487
	No	31 (100.00%)	30 (93.75%)		
Local skin swelling	Yes	0 (0.00%)	5 (15.62%)	3.340	0.068
	No	31 (100.00%)	27 (84.38%)		

Table 4. Comparison of comprehensive evaluation results between two groups (Cases)

Parameters		Observation group (N=31)	Control group (N=32)	χ^2 value	*P* value
Comprehensive evaluation	Qualified (%)	31 (100.00%)	16 (50.00%)	20.777	<0.001
	Unqualified (%)	0 (0.00%)	16 (50.00%)		

Discussion

Due to the demands to leave in multiple catheters during the process of treatment, these patients with consciousness disorder have become a high-risk group of unplanned extubation. The incidence of unplanned extubation is considered as one of the sensitive and effective indicators for evaluating the implementation of risk prevention and control in clinical practice. It was reported that the protective restraint measures for consciousness disorder patients with catheters became a common auxiliary method to ensure the smooth progress of treatment [15, 16]. According to a previous report, the incidence of unplanned extubation was 0.3%-14% and critical patients accounted for 73% of unplanned extubation patients, including 78% of the elderly and children [17, 18]. The risk of adverse events during hospitalization was relatively high in these patients, who also were considered as a high-risk group of unplanned extubation. Moreover, the risk of unplanned extubation in unconscious patients with restlessness was increased, accounting for 57.1% [19, 20]. Therefore, restraint devices are important measures to ensure the safety of these patients. Exploring ideal protective restraint measures to effectively prevent the occurrence of unplanned

extubation in these patients has become an important topic in clinical practices.

In order to achieve safe and effective restraint, it is particularly necessary to improve the protective restraint tool. The new protective restraint device should possess simple structure, scientific and reasonable design and convenient use [21, 22]. It also should reduce the risk of unplanned extubation in patients and related limb injuries caused by improper restraint, and at the same time improve the clinical quality level. These novel medical restraint gloves applied in this study have obtained the National Utility Model Patent (ZL 2021 2 0394582.1). The materials were a low value consumable product commonly used in hospitals. In clinical practice, it has been confirmed that these novel medical restraint gloves have practicality, safety, progressiveness and a wide coverage.

Comparing with the traditional restraint gloves, these novel medical restraint gloves can prevent the patient's palm from overturning and dislocation along with the medical restraint gloves, thus reducing the risk of unplanned extubation in patients and the friction damage to the wrist, back of hand and finger skin of patients, facilitating the treatment operation. The palms of patients in the observation group were in the natural state, presenting the arc shape, which make the patients' hand more comfortable and flexible. In addition, patients in observation group could perform the palmar opposition of thumb and grasp motion at will, which was conducive to the maintenance of the patient's hand function. During the use of traditional restraint gloves, the finger rings of some patients were prone to slip, and the gloves were easily turn over, so that the patient's palm was facing the surface without containing the hard pad. When treating patients with traditional constraint gloves, such as glucose measurement and blood oxygen saturation monitoring, it was not easy to fix the finger, resulting in the inconvenience of treatment operation, and the glove turnover were prone to cause the incidence of unplanned extubation and skin friction damage at the restraint part [23, 24]. For some patients who had not slipped the finger rings, the fingers were straightened and fixed in the ring with poor flexibility [25]. The back of the fingers and the rings were easy to rub and cause skin redness. The results of this study showed that there were the statistical differences between the observation group and the control group in terms of the protective performance, treatment operation, the glove fixation or ring slipping, finger flexibility, glove turnover and local skin redness. This indicates that the novel medical gloves have better outcomes of effectiveness and safety. Moreover, the results of comprehensive evaluation for gloves in observation group were significantly better than that in control group. In addition, the new type of medical restraint gloves can be used without being tied to the bed rail. The patient's upper limbs can be flexibly moved to increase the patient's comfort and prevent the patient from aggravating the skin damage of the restraint part due to non-cooperation.

However, this research has several limitations that should be recognized. First, this is a retrospective study and there were no long-term follow-up results. Second, the sample size was small, which may affect its findings. Third, the data were collected from single center, which may affect its generalization to other hospitals.

In conclusion, the novel medical restraint gloves provided better outcomes of effectiveness and safety compared with traditional restraint gloves and can be used in these unconscious patients to restrain the upper limbs. In addition, the comprehensive evaluation results of this novel medical restraint gloves are significantly superior to the traditional constraint gloves. It can meet the clinical requirements and are worthy of being promoted in clinical practice.

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Disclosure of conflict of interest

None.

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References

[1] Li P, Sun Z and Xu J. Unplanned extubation among critically ill adults: a systematic review and meta-analysis. Intensive Crit Care Nurs 2022; 70: 103219.

[2] Klugman D, Melton K, Maynord PO, Dawson A, Madhavan G, Montgomery VL, Nock M, Lee A and Lyren A. Assessment of an unplanned extubation bundle to reduce unplanned extubations in critically ill neonates, infants, and children. JAMA Pediatr 2020; 174: e200268.

[3] Ai ZP, Gao XL and Zhao XL. Factors associated with unplanned extubation in the intensive care unit for adult patients: a systematic review and meta-analysis. Intensive Crit Care Nurs 2018; 47: 62-68.

[4] Liu K, Liu Z, Li LQ, Zhang M, Deng XX and Zhu H. Predictive value of the unplanned extubation risk assessment scale in hospitalized patients with tubes. World J Clin Cases 2022; 10: 13274-13283.

[5] Chang LY, Wang KW and Chao YF. Influence of physical restraint on unplanned extubation of adult intensive care patients: a case-control study. Am J Crit Care 2008; 17: 408-415; quiz 416.

[6] Cui N, Qiu R, Zhang Y, Chen D, Zhang H, Rao H and Jin J. Why are physical restraints still in use? A qualitative descriptive study from Chinese critical care clinicians' perspectives. BMJ Open 2021; 11: e055073.

[7] Chao CM, Sung MI, Cheng KC, Lai CC, Chan KS, Cheng AC, Hsing SC and Chen CM. Prognostic factors and outcomes of unplanned extubation. Sci Rep 2017; 7: 8636.

[8] Chiba Y, Yamamoto-Mitani N and Kawasaki M. A national survey of the use of physical restraint in long-term care hospitals in Japan. J Clin Nurs 2012; 21: 1314-1326.

[9] Eliasson AC, Krumlinde-sundholm L, Shaw K and Wang C. Effects of constraint-induced movement therapy in young children with hemiplegic cerebral palsy: an adapted model. Dev Med Child Neurol 2005; 47: 266-275.

[10] Huang G, Ma M and Zhang B. The application of new type of medical glove restraint appliance in the prevention of non planned extubation in patients with severe strengthening treatment. Zhonghua Wei Zhong Bing Ji Jiu Yi Xue 2015; 27: 700-701.

[11] Heinze C, Dassen T and Grittner U. Use of physical restraints in nursing homes and hospitals and related factors: a cross-sectional study. J Clin Nurs 2012; 21: 1033-1040.

[12] Wang WW and Moyle W. Physical restraint use on people with dementia: a review of the literature. Aust J Adv Nurs 2005; 22: 46-52.

[13] Cosentino C, Fama M, Foa C, Bromuri G, Giannini S, Saraceno M, Spagnoletta A, Tenkue M, Trevisi E and Sarli L. Unplanned extubations in intensive care unit: evidences for risk factors. A literature review. Acta Biomed 2017; 88: 55-65.

[14] Suzuki M, Yoshimura H, Mimuro S, Sawaki K, Naito T, Inagaki K, Kanamori T, Matsushita K, Sasaki N, Ishihara T and Sakai I. Effectiveness of programs developed for nurses to improve dementia nursing intervention ability in an acute care setting. Nihon Ronen Igakkai Zasshi 2022; 59: 67-78.

[15] Vedana KGG, da Silva DM, Ventura CAA, Giacon BCC, Zanetti ACG, Miasso AI and Borges TL. Physical and mechanical restraint in psychiatric units: perceptions and experiences of nursing staff. Arch Psychiatr Nurs 2018; 32: 367-372.

[16] Kong EH, Choi H and Evans LK. Staff perceptions of barriers to physical restraint-reduction in long-term care: a meta-synthesis. J Clin Nurs 2017; 26: 49-60.

[17] Lucas da Silva PS and de Carvalho WB. Unplanned extubation in pediatric critically ill patients: a systematic review and best practice recommendations. Pediatr Crit Care Med 2010; 11: 287-294.

[18] Menon K, Dundon B, Twolan BL and AlShammari S. Approach to unplanned extubations in a pediatric intensive care unit. Can J Crit Care Nurs 2015; 26: 25-29.

[19] Silva PS, Reis ME, Aguiar VE and Fonseca MC. Unplanned extubation in the neonatal ICU: a systematic review, critical appraisal, and evidence-based recommendations. Respir Care 2013; 58: 1237-1245.

[20] da Silva PSL, Reis ME, Farah D, Andrade TRM and Fonseca MCM. Care bundles to reduce unplanned extubation in critically ill children: a systematic review, critical appraisal and meta-analysis. Arch Dis Child 2022; 107: 271-276.

[21] Kong EH, Song E and Evans LK. Effects of a multicomponent restraint reduction program for Korean nursing home staff. J Nurs Scholarsh 2017; 49: 325-335.

[22] Pu L and Moyle W. Restraint use in residents with dementia living in residential aged care facilities: a scoping review. J Clin Nurs 2022; 31: 2008-2023.

[23] Delgado SA. Physical restraints: protecting patients or devices? Am J Crit Care 2020; 29: 103.

[24] Dunn DA. Unplanned extubation study leaves questions unanswered. Am J Crit Care 2009; 18: 9; author reply 9.

[25] Bryan M. Use of physical restraints from a bedside practice perspective. Am J Crit Care 2009; 18: 101-102.