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Case Report

Evaluation of the Safety of a Rehabilitation Robot for Critically Ill Patients

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Abstract

Background: Critically ill and disabled patients require a lot of manpower during their rehabilitation. Artificial intelligence technology, which has the potential to improve the quality of care for critically ill patients, has been increasingly used for these patients' rehabilitation.

Objective: To evaluate the safety of a rehabilitation robot in assisting the rehabilitation of critically ill patients.

Method: One hundred patients in the intensive care unit of our hospital were divided into an experimental group and a control group. The rehabilitation robot was used in the experimental group to assist the patients' sitting, standing, lying on the side, lying prone, limb movement, pneumatic treatment, and vibration expectoration. For the control group, these operations were carried out by medical personnel. The differences in post-treatment values for vital signs and the frequency of adverse events, including infusion tube falling off, bedsore, and trauma, during treatment were compared between the two groups.

Results: There were no differences in gender, age, body mass index, the status of complications, Barthel index, pre-treatment heart rate, pre-treatment mean arterial pressure or pre-treatment respiratory rate between the two groups. The differences in post-treatment values for vital signs and the frequency of infusion tube falling off during treatment were not significant between the two groups ($P > 0.05$). In addition, we did not observe bedsore and trauma in both groups during the treatment.

Conclusion: The robot has shown satisfactory safety in assisting the rehabilitation of critically ill patients.

Keywords: Rehabilitation; Robot; Equipment; Safety

Introduction

The diagnosis, treatment scheme, and rehabilitation plans for critically ill patients should generally be established by a multidisciplinary team involving doctors, therapists, and nurses. Early rehabilitation can prevent complications of care in the intensive care unit (ICU) and promote the recovery of critically ill patients' body functions [1]. In addition, rehabilitation can reduce muscle atrophy, preserve diaphragm function, reduce the occurrence of acquired weakness in critically ill patients, and reduce the use of mechanical ventilation [2-4]. Thus, rehabilitation has become an important part of ICU patient care. One previous study found that if ICU patients were prescribed with active exercise and physical rehabilitation in the early stage (48-72 hours) after their ICU care, their long-term quality of life would be significantly improved [5]. In addition, critically ill patients need adequate rehabilitation to be able to return to work. However, rehabilitation of critically ill patients requires a lot of manpower [6]. Therefore, some researchers tried to use robots to replace medical personnel in this process [7]. One such robot has been designed [8,9], which can assist ICU patients' sitting, standing, lying on the side, lying prone, limb exercise, barometric treatment,

and vibration expectoration during their rehabilitation. However, the safety of this rehabilitation robot remains to be investigated. Herein, we evaluated the safety of this rehabilitation robot in 100 ICU patients in our hospital.

Materials and Methods

Patients

ICU patients in the People's Hospital of Qiandongnan Miao and Dong Autonomous Prefecture, Kaili City, Guizhou Province, China were recruited from June 1, 2021 to April 1, 2022.

Inclusion criteria

ICU patients older than 18 years were included.

Exclusion criteria

Patients with spinal fractures, rib fractures, limb fractures, untreated open chest and/or abdominal injuries, limb venous thrombosis, an abdominal pressure higher than 15 mmHg, difficulty lying flat due to heart failure, limited movement of limb joints, extensive burns, and respiratory and circulatory instability were excluded. Those with incomplete clinical data or unable to cooperate were also excluded. In total, 100 patients (23-53 years old, mean age: 33.22±8.84 years) were included in the study, including 58 males and 42 females.

Measurements

The patients were randomly divided into two groups (an experimental group and a control group) (Table 1), with 50 patients in each group. For the experimental group, the patients were lying on the robot, which assisted the patients with sitting, standing, lying prone, limb movement (30 minutes/time), pneumatic treatment (20 minutes/time) and vibration expectoration (8 minutes/time) three times a day, and with lying on the side every 4 hours. In the control group, the patients were lying on ordinary beds, and the same operations were performed by nursing staff with the same schedule. The treatment for both groups lasted for 72 hours, during which adverse events of bedsore, falling off of infusion pipeline, and trauma were monitored. The X10 Patient Monitor produced by Shenzhen Libang Precision Instrument Co., Ltd. was used to measure the heart rate (HR), mean arterial pressure (MAP) and respiratory rate (RR) of the two groups of patients before and after the treatment. For the post-treatment values, these indices were measured immediately after the patients' sitting, standing, lying on the side and lying prone, 20 minutes after the start of limb movement, 10 minutes after the start of pneumatic treatment, and 5 minutes after the start of vibration expectoration. All the indices were measure three times when the patient was calm (when the sedation agitation scale score was 4) to obtain the average values, which were subjected to our subsequent analyses. The differences in pre-treatment values for HR, MAP, and RR, self-care ability score (Barthel Index), body mass index, the status of complications, age and gender between the two groups were first analyzed to determine whether the two groups of patients were comparable. If so, the differences in post-treatment values for HR, MAP, and RR, and the frequency of adverse events (Table 2), including infusion tube falling off, bedsore and trauma, between the two groups were analyzed to assess the safety of the robot.

Parameters	experimental group (n=50)	Control group (n=50)	$t/u/\chi^2$	*P*
Sex, Male/Female, n	27/23	31/19	0.658	0.544
Age, y	33.82±8.48	32.62±9.24	0.677	0.500
Body mass index,Kg/m^2	25.90±3.50	24.71±3.29	1.753	0.083
Hypertension, n	5	8	0.802	0.554
coronary heart disease, n	3	5	0.549	0.715
Diabetes, n	4	6	0.447	0.741
Barthel index,poinjt	99.84±0.68	99.68±1.17	0.837	0.405
Basal HR,Times/m	77.34±12.55	72.86±11.47	1.863	0.065
Basal MAP,mmHg	92.26±11.33	89.84±8.20	1.223	0.224
Basal RR,Times/m	18.40±1.03	18.34±1.08	0.284	0.777

Table 1: Comparison of basic data between the experimental group and the control group.

Parameters		experimental group (n=50)	Control group (n=50)	$t/u/\chi^2$	*P*
Lying	HR, Times/m	76.64±15.61	74.76±110.04	0.716	0.476
	MAP, mmHg	88.22±9.94	86.26±8.27	1.072	0.286
	RR, Times/m	17.22±2.51	17.46±1.81	-0.612	0.542
sitting	HR, Times/m	78.34±13.04	74.98±11.64	1.359	0.177
	MAP, mmHg	89.50±9.30	90.9±10.80	-0.695	0.489
	RR, Times/m	18.10±2.69	17.38±1.14	.743	0.085
standing	HR, Times/m	76.98±14.50	76.74±11.98	0.090	0.928
	MAP, mmHg	88.42±10.10	86.40±8.36	1.089	0.279
	RR, Times/m	17.42±2.42	17.18±0.94	0.654	0.514
lying on one's side	HR, Times/m	76.74±11.26	75.84±9.56	0.431	0.667
	MAP, mmHg	87.56±8.75	87.74±7.83	-0.108	0.914
	RR, Times/m	21.18±1.00	20.78±1.30	1.724	0.088
Prone position	HR, Times/m	85.16±11.80	83.10±9.00	0.981	0.329
	MAP, mmHg	89.48±9.32	87.00±7.01	1.496	0.138
	RR, Times/m	21.76±1.06	21.58±1.40	0.724	0.471
limb movement	HR, Times/m	82.38±12.57	78.40±11.42	1.657	0.101
	MAP, mmHg	88.82±9.78	88.28±8.64	0.293	0.770
	RR, Times/m	20.30±3.51	19.90±2.41	0.664	0.508
Barometric treatment	HR, Times/m	76.06±14.69	76.54±11.10	-0.184	0.854
	MAP, mmHg	87.56±8.62	86.74±7.09	0.519	0.605
	RR, Times/m	18.56±1.55	18.34±1.59	0.701	0.485
vibration expectoration	HR, Times/m	88.16±11.80	86.00±8.94	1.032	0.305
	MAP, mmHg	91.20±7.79	91.58±8.59	-0.232	0.817
	RR, Times/m	26.22±2.82	25.78±4.06	0.629	0.531
infusion pipeline falling off		1	3	1.008	0.617
bedsore		0	0		
traumatic adverse events		0	0		

Table 2: Comparison of HR, map, RR and complications between the experimental group and the control group after rehabilitation.

Statistical analysis

The SPSS 24.0 statistical software was used for data analysis. The Kolmogorov-Smirnov test was used to examine the normality of data. Normally distributed data were expressed as mean ± standard deviation. Then, independent-sample t test was carried out for group comparison, while $\chi 2$ test was performed for comparison of count data. The significance level was set at $P < 0.05$.

Results

Comparison of baseline data between the two groups

The two groups had no statistically significant difference in gender, age, body mass index, hypertension status, coronary heart disease status, diabetes status, Barthel index, pre-treatment HR, pre-treatment MAP or pre-treatment RR ($P > 0.05$), indicating that the two groups of patients were comparable.

Comparison of post-treatment values for HR, MAP, and RR and the incidence of adverse events during treatment between the two groups

There was no difference in post-treatment values for HR, MAP, and RR or the frequency of infusion tube falling off during treatment between the two groups. In addition, there were no bedsore and trauma in both groups during the treatment ($P > 0.05$). These results demonstrate that the robot is safe in assisting the rehabilitation of critically ill patients.

Discussion

Critically ill patients in ICU are prone to acquired weakness, thromboembolism and other complications due to long-time bed rest and reduced muscle strength of limbs and diaphragm, which have a negative impact on their prognosis [1]. Timely rehabilitation can reduce complications and improve organ function and prognosis [10,11]. Many studies have shown that individualized rehabilitation treatment is beneficial for critically ill patients [12,13]. Most critically ill patients need an adequate rehabilitation treatment [14]. However, many parts of China still lack medical resources for rehabilitation. Generally, critically ill patients need more assistance during their rehabilitation [15,16] and it takes a lot of manpower to help them sit, stand, lie on the side, lie prone, perform limb movement and carry out sputum excretion, which are the common procedures in routine nursing care of these patients. In the era of artificial intelligence, a large number of robots have been developed to replace human labor [17]. Robots can complete tasks more accurately, save manpower [18], and reduce the burden on medical institutions and families. The application of rehabilitation robots in patient care is a good solution to the shortage of manpower. Therefore, we designed and patented a rehabilitation robot. In this study, we evaluated the safety of this rehabilitation robot in assisting the rehabilitation of critically ill patients. One hundred critically ill patients from the ICU of our hospital were divided into two groups. For the experimental group, we applied the rehabilitation robot to assist the patients with sitting, standing, lying on the side, lying prone, limb movement and sputum excretion; while for the control group, these procedures were carried out by professional medical personnel. There were no differences in baseline data between the two groups, demonstrating that these two groups of patients were comparable. We then determined the differences in post-treatment values for vital signs and the incidence of adverse events during treatment to evaluate the safety of this robot. The results showed that the assessed indices were not significantly different between the two groups, demonstrating that the performance of the robot in terms of safety was satisfactory during the nursing care and rehabilitation of the critically ill patients. We believe that the reasons for the satisfactory safety of the robot are as follows: The design of the robot adopts ergonomic theories to make patients feel comfortable during the treatment. The patient's tolerance was fully considered when setting the operating parameters for the robot during the treatment. The safe operation specifications were strictly followed during the treatment. The robot worked under a voltage less than or equal to 24 V, which is less than the safety voltage for the human body (30 V). The robot is equipped with many safety sensors. If a safety risk is detected during operation, the system will automatically stop running (Figures 1-4).

Figure 1: Semi reclining demonstration.

Figure 2: Lying on one's side demonstration.

Figure 3: Station demonstration.

Figure 4: Prone demonstration.

This study has some limitations: Only vital signs and adverse events were evaluated as safety indicators. This may have omitted some possible risk factors. The long-term safety, operation system safety, nosocomial infection control, and heat preservation, etc., which are also critical aspects of the robot's safety performance, were not evaluated. We will conduct more comprehensive and in-depth research to address these issues in the future to bring more benefits to critically ill patients.

Conclusion

The rehabilitation robot shows satisfactory safety in assisting the rehabilitation of critically ill patients.

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Ethical Approval and Consent to participate

The research was approved by the medical ethics committee of the people's Hospital of Qiandongnan Miao and Dong Autonomous Prefecture. The use of the rehabilitation robot was approved by the patient or guardian

Data sharing policy

Data available from 463082910@qq.com

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