Original Article

The effect of early tracheal extubation combined with physical training on pulmonary rehabilitation of patients after lung transplantation: a randomized controlled trial

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Background: This study aimed to explore the effect of early extubation combined with physical training on pulmonary rehabilitation of patients after lung transplantation.

Methods: This is an open parallel randomized controlled trial. A total of 96 lung transplant patients admitted to Wuxi People's Hospital (July 2018 to June 2019) were included. Inclusion criteria: (I) aged 18–75; (II) lung transplantation; (III) communicate normally; (IV) voluntary participation. According to the random number method, they were divided into the control group (routine nursing intervention) and the observation group (early extubation combined with a physical training program). The indwelling tracheal intubation time, discharge time, intensive care unit (ICU) stay time, lung function, 6 Minutes Walk Distance (6MWD), Modified Barthel Index (MBI) and satisfaction rate were recorded and analyzed.

Results: The observation group's first-time postoperative ambulation (t=2.10, P=0.039), indwelling tracheal intubation time (Z=2.864, P=0.004), and discharge time (t=3.111, P<0.001) were shorter than the control group, while the difference of ICU stay time was not statistically significant (Z=−1.658, P=0.097). Before treatment, there was no significant difference in the lung function, 6MWD, and MBI of the two groups (P>0.05). After treatment, the Forced Expiratory Volume In 1 s (FEV1)% (t=−2.707, P<0.001), forced vital capacity (FVC)% (t=−3.716, P<0.001), FEV1/FVC (t=−3.539, P<0.001), 6MWD (t=−5.567, P<0.001), and MBI indexes (t=−4.073, P<0.001) were better than in observation group. The satisfaction rate of the observation group was better than the control group (P<0.05).

Conclusions: For lung transplant recipients, early extubation combined with a physical training program is scientific, safe, and feasible. This approach is helpful to promote the postoperative recovery of lung transplant patients, reduce the length of hospitalization, help patients improve their lung function and ability to engage in activities of daily living, and increase the satisfaction rate of postoperative recovery. Results show that the combination of early extubation and a physical training program is worthy of clinical promotion for lung transplant recipients.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2100051954.

Keywords: Early tracheal extubation; early activity; lung transplantation; pulmonary rehabilitation

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Introduction

Lung transplantation is currently an effective method for the clinical treatment of end-stage lung disease. The incidence of postoperative complications is high. Bronchial complications, including necrosis and dehiscence are the main etiologies of death in the first two weeks after lung transplantation (1). Infection is also the main cause of morbidity and mortality. Immunosuppressive drugs could induce hypertension, diabetes, hyperlipidemia, gastrointestinal complications, cytopenia and renal dysfunctions (2). Effectively reducing the incidence of postoperative complications is the key to the success of lung transplantation (3,4). Enhanced recovery after surgery (ERAS) is a series of perioperative optimization measures based on evidence-based medicine that enable patients to achieve a rapid recovery (5). ERAS can be performed throughout the perioperative period. According to the Manual of Physical Therapy and Critical Rehabilitation Work, the main ERAS physical training includes: (I) body position change; (II) passive/active range of motion; (III) Resistance training; (IV) Neuromuscular electrical stimulation; (V) activity of daily living (6). Studies have shown that postoperative pulmonary rehabilitation can improve the activity endurance of patients after lung transplantation, improve lung function, and effectively reduce postoperative complications (7,8). Early endotracheal extubation is firstly used in 1980s in cardiac and liver surgery (9). Early endotracheal could reduce the cost and ventilation associated complications (10). Although the current lung transplantation surgery technology has continued to develop, the incidence of perioperative complications in lung transplantation patients is still higher than expected, and there is a lack of standardized perioperative procedures and a system of multidisciplinary cooperation for the study of lung transplantations. In order to further improve the perioperative survival rate of lung transplant recipients and explore a safe and effective perioperative management measures, the transplantation center of Wuxi People's Hospital formulated the early extubation combined with an early exercise program based on the relevant recommendations of the Expert Consensus on Tracheal Catheter Extubation in 2014 (11). We applied our program to patients after they received a lung transplantation and achieved satisfactory results. We present the following article in accordance with the CONSORT reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-119/rc).

Methods

Patients

This is a parallel randomized controlled trial. A total of 96 lung transplantation patients admitted to Wuxi People's Hospital from July 2018 to June 2019 were selected as the research participants. According to the random number method, the 96 cases were divided into a control group (n=48; routine nursing intervention) and an observation group (n=48; early extubation combined with physical training program). The pulmonary rehabilitation and the ability of daily living were compared between the two groups. In the control group, there were 42 male patients and 6 female patients, with an average age of (56.0±11.5) years, 32 single lung transplants, and 16 double lung transplants. In the observation group, there were 39 male patients and 9 female patients, with an average age of (58.1±10.4) years, 28 patients received a single lung transplant, and 20 patients received a double lung transplant. There was no statistical difference in general data between the two groups (P>0.05), indicating comparability (*Table 1*). Data of patients during hospitalization were collected. Data collection and follow-up after discharge were not performed.

Patients were included in the study if they fulfilled all of the following criteria: (I) aged 18–75 years old; (II) successful implementation of lung transplantation; (III) clear consciousness, normal communication, and cognitive ability, and able to complete the required questionnaire independently or with the help of researchers; and (IV) volunteered to participate in this study. Patients were excluded if they fulfilled any of the following criteria: (I) poor prognosis or short-term death; (II) serious complications; and/or (III) postoperative cognitive dysfunction. A patient's participation in the study was terminated if they had serious adverse reactions before the end of the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The patients and their families signed the informed consent form, and the study was reviewed and approved by the ethics committee of Wuxi People's Hospital (No. KY21100).

Study methods

Therapeutic method

After lung transplantation, the patients in the two groups received routine treatment, including infection control, anti-rejection treatment, and vital organ protection

Table 1 General information of the patients of two groups

Item	Group		t/χ^2	P
	Control group (n=48)	Observation group (n=48)		
Gender, n (%)			χ^2=0.334	0.194
Male	42 (87.5)	40 (83.33)		
Female	6 (12.5)	8 (16.67)		
Age, ($\bar{x}$±S)	56.0±11.5	58.1±10.4	t=−0.938	0.016
Type, n (%)				
Single-lung transplantation	32 (66.67)	28 (58.33)	χ^2=0.7111	0.118
Double-lung transplantation	16 (33.33)	20 (41.67)		
FEV1% (%)	27.8±12.6	28.9±14.1	−0.403	>0.05
FVC% (%)	41.2±11.9	39.8±12.5	0.562	>0.05
FEV1/FVC (%)	63.2±13.7	64.1±12.4	−0.337	>0.05
6MWD (m)	158.2±72.1	149.4±65.7	0.625	>0.05
MBI score	47.4±11.2	49.9±12.0	−1.055	>0.05

FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity; 6MWD, 6 Minutes Walk Distance; MBI, Modified Barthel Index.

treatment. Ventilator-assisted ventilation was performed through airway intubation, and synchronous intermittent instruction ventilation mode was adopted.

Nursing intervention

The patients were admitted to the intensive care unit (ICU) and received nursing and rehabilitation exercises according to the specialty routine (see section Early tracheal extubation scheme and Physical training. The responsible nurse assisted the patient with ankle pump exercises in bed twice a day. As well as routine nursing, the observation group underwent early tracheal extubation combined with early exercise. This plan was formulated according to the relevant recommendations of the Expert Consensus on Tracheal Catheter Extubation in 2014, combined with the broad framework of early exercise for ICU patients (11) and adjusted based on the characteristics of lung transplant patients.

Early tracheal extubation scheme

Within 24 hours after admission to the ICU and before transfer, ICU doctors should make treatment plans according to relevant recommendations in the guidelines. To determine that the patient no longer needed mechanical ventilation to maintain adequate ventilation and oxygen supply, the following criteria were used: (I) patients gradually woke up after the withdrawal of propofol, remifentanil, and muscle relaxants; (II) body temperature was >36 ℃; (III) the intraoperative blood loss was less than 100 mL/h, and the hemodynamics was stable; (IV) there was no obvious pulmonary edema (i.e., watery secretions of the transplanted lung) under fiberoptic bronchoscopy; (V) before extubation, oxygenation index >200 mmHg, $PaCO_2$ <50 mmHg, and blood lactic acid <3 mmol/L; and (VI) the chest X-ray before extubation showed no obvious exudation. Early extubation may be attempted for patients meeting the above conditions. All patients should be closely monitored after extubation, and early active oxygenation and airway clearance should be used to prevent re-intubation. This included sputum aspiration, bronchodilator therapy, diuretic, or non-invasive ventilation.

Physical training

The acute postoperative rehabilitation of lung transplant patients started in the ICU. The main problems in the acute phase after lung transplantation include ineffective airway clearance, low gas exchange rate, and rejection reactions. In order to reduce the severity of lung disease and multiple underlying disease states, a "starting exercise" scheme was required, which consisted of progressive physiotherapy. Recommended goals and indications are shown in *Table 2* (6). The target treatment frequency was 3–5 times per week for a total of 4 weeks.

Table 2 Recommended goals and indications

	0 level	1 level	2 level	3 level	4 level	5 level
Degree of coordination	Inability cooperation S5Q[1] =0	Inability or limited cooperation S5Q[1] <3	Moderate cooperation S5Q[1] =3	Nearly perfect cooperation S5Q[1] =4/5	Perfect cooperation S5Q[1] =5	Perfect cooperation S5Q[1] =5
Basic assessment	Failed the basic assessment[2]	Pass the basic assessment[3]	Pass the basic assessment[3]	Pass the basic assessment[3]	Pass the basic assessment[3]	Pass the basic assessment[3]
Basic condition	Basic assessment= • Cardiopulmonary unstable: mean arterial <60 mmHg or inhaled oxygen concentration >60% or oxygenation index <200 or respiratory frequency >30 times/min • Nervous system instability • Emergency surgery • Body temperature >40 ℃	Neurological or surgical or traumatic conditions are not suitable for bed and chair transfer	Obese or neurological or surgical or traumatic states are not suitable for active bed-chair transfer (even if MRC score >36)	MRC score =36+ BBS sit to stand =0+ BBS stand =0+ BBS sit =1	MRC score =48+ BBS sit to stand =0+ BBS stand =0+ BBS sit =2	MRC score =48+ BBS sit to stand =1+ BBS stand =2+ BBS sit =3
Body position	Body position[4]	Body position[4]	Body position[4]	Body position[4]	Body position[4]	Body position[4]
	• Turn over every 2 h	• Turn over every 2 h • Position management	• Turn over every 2 h • Sit upright in bed • Passive transfer with bed and chair	• Turn over every 2 h • Passive transfer with bed and chair • Sit by the bed • Stand with assistance (2 person)	• Positive transfer with bed and chair • Sit by the bed • Stand with assistance (1 person)	• Positive transfer with bed and chair • Sit by the bed • Stand
Treatment	No treatment	Physiotherapy[4]	Physiotherapy[4]	Physiotherapy[4]	Physiotherapy[4]	Physiotherapy[4]
		• Passive range of joint motion • Bedside passive cycling training • Neuromuscular electrical stimulation	• P/AROM Training • Resistance training of upper and lower limbs • Passive or active bedside leg cycling training • Neuromuscular electrical stimulation	• P/AROM Training • Resistance training of upper and lower limbs • Positive bedside/sit upper and lower limbs cycling training • Neuromuscular electrical stimulation • ADL Training	• P/AROM Training • Resistance training of upper and lower limbs • Positive bedside/sit upper and lower limbs cycling training • Walking (assisted) • Neuromuscular electrical stimulation • ADL Training	• P/AROM Training • Resistance training of upper and lower limbs • Positive upper and lower limbs cycling training • Walking (assisted) • Neuromuscular electrical stimulation • ADL Training

[1], S5Q: Answer 5 standardization questions for collaboration: A. open and close your eyes; B. look at me; C. open your mouth and stick out your tongue; D. shake one's head to show approval or disapproval (nodding); and E. I count to five, then frown with your eyebrows. [2], Failed the basic assessment: at least one risk factor. [3], If basic assessment is not possible, the grade is lowered to L0. [4], Safety: Each activity should be delayed in the event of serious adverse events (cardiovascular, respiratory, and systemic tolerability) during the intervention period. MRC, the medical research council; BBS, berg balance scale; P/AROM, passive/active range of motion; ADL, activity of daily living.

Observational indicators

(I) Primary endpoint: lung function; (II) secondary endpoints: indwelling tracheal intubation time, discharge time, intensive care unit (ICU) stay time, 6 Minutes Walk Distance (6MWD), Modified Barthel Index (MBI) and satisfaction rate. The perioperative conditions of patients in the two groups were compared (indwelling endotracheal intubation time, ICU stay time, time to get out of bed for the first time, and length of hospital stay).

The cardiopulmonary function and the ability to engage in daily living activities were evaluated using a pulmonary function assessment, a 6-minute walking test, and a MBI before lung transplantation and 4 weeks after rehabilitation training. Lung function assessment was performed as follows (12): a pulmonary function instrument was used to detect the pulmonary function status of patients, and the ratios of forced vital capacity (FVC) to the expected value (FVC%), forced expiratory volume in 1 second (FEV1) to the expected value (FEV1%), and FEV1/FVC were measured and recorded.

The 6-minute walking test was performed as follows: each patient's 6MWD was measured. The MBI scale was used to score the ability of patients to engage in daily living activities, with a total score of 100. The higher the score, the stronger the patient's living ability.

The assessment of safety outcomes: during the intervention period, the occurrence of serious adverse events, including cardiovascular, respiratory, and systemic tolerability complications, was the indicators of unsafety. Otherwise, the intervention was safe.

The evaluation of rehabilitation nursing was compared between the two groups. A scientific survey assessment questionnaire was used, which was divided into excellent, good, general, and dissatisfied. Excellent degree = (excellent number + good number)/total number × 100%.

Statistical analysis

SPSS 20.0 statistical software (IBM Corp, Armonk, NY, USA) was used for statistical analysis, and the normal distribution of measurement data was presented as mean ± standard deviation ($\overline{x}$±S). No missing data. The efficacy was analyzed according to the results of perioperative conditions, lung function, living activities and nursing satisfaction. There were no intervention related complications during the intervention period. The two groups were compared using a student's *t* test. The measurement data of skewness distribution were expressed as median and quartile M (Q25, Q75) and analyzed by rank-sum test (Mann-Whitney U Test). Classification data were represented by the number of cases and percentile n (%) and analyzed using the Chi-square test. All statistical tests were two-sided, and P<0.05 (two-sided) was considered statistically significant.

Results

General Information

The period of recruitment was from July 2018 to June 2019. The flowchart of this study was shown in *Figure 1*. There was no statistical difference in the general data between the two groups (P>0.05), as shown in *Table 1*.

Comparison of perioperative conditions between the two groups

The time of first postoperative ambulation, endotracheal intubation, and discharge in the observation group was shorter than those in the control group, and the differences were statistically significant (P<0.05). There was no significant difference in the length of ICU stay between the two groups (P>0.05), as shown in *Table 3*.

Comparison of lung function between the two groups before and after treatment

Before treatment, there were no statistically significant differences in lung function indicators between the two groups (P>0.05). After treatment, FEV1%, FVC%, and FEV1/FVC in the observation group were better than those in the control group, with statistically significant differences (P<0.05), as shown in *Table 4*.

Comparison of daily living activities between two groups before and after treatment

Before treatment, there were no statistically significant differences in 6MWD and MBI indicators between the two groups (P>0.05). After treatment, 6MWD and MBI indicators of the observation group were better than those of the control group, with statistically significant differences (P<0.05), as shown in *Table 5*.

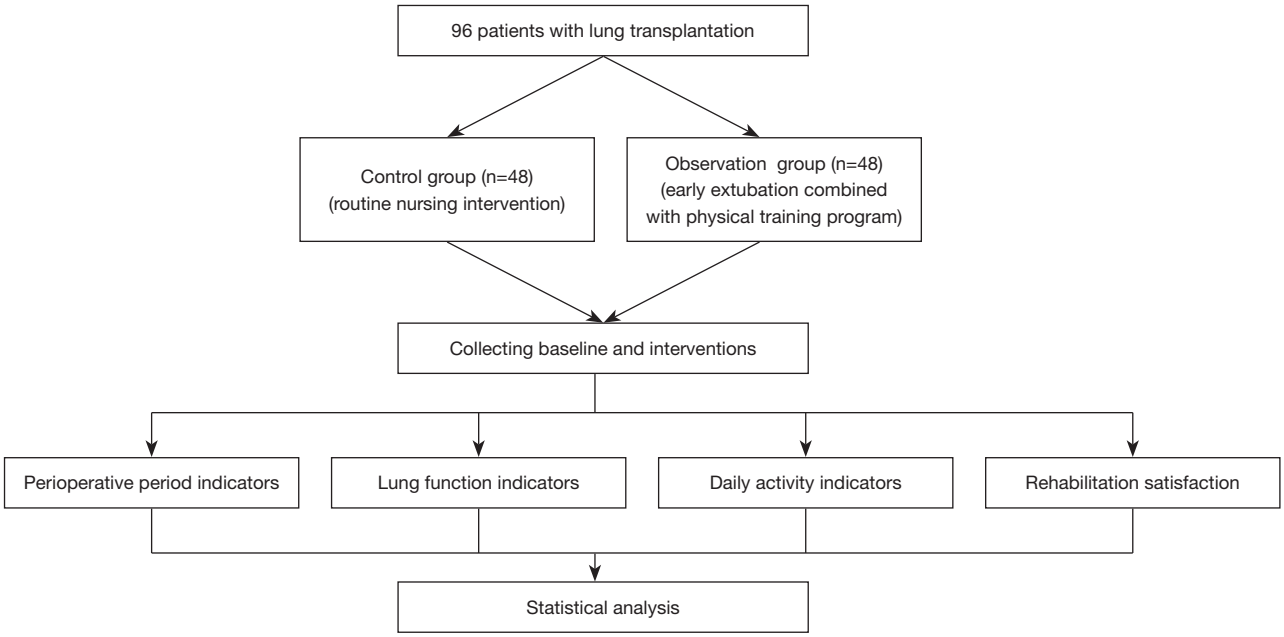

Figure 1 Flowchart of this study.

Table 3 Comparison of perioperative conditions between the two groups

Item	Group		t/Z	P
	Control group (n=48)	Control group (n=48)		
Time of first postoperative ambulation (h)	18.4±10.4	13.8±10.7	t=2.10	0.039
ICU stay time (h), M (Q_{25}, Q_{75})	4 (3, 5.5)	5 (3, 7)	Z=−1.658	0.097
Indwelling endotracheal intubation time (d), M (Q_{25}, Q_{75})	3 (2, 5.5)	2 (1, 3)	Z=2.864	0.004
Discharge time (d)	42.6±18.3	31.2±17.6	T=3.111	<0.001

ICU, intensive care unit.

Table 4 Comparison of lung function between the two groups before and after treatment ($\bar{x}$±S)

Item	Group		t	P
	Control group (n=48)	Control group (n=48)		
FEV1% (%)				
Before treatment	27.8±12.6	28.9±14.1	−0.403	>0.05
After treatment	54.3±16.5*	63.2±15.7*	−2.707	<0.001
FVC% (%)				
Before treatment	41.2±11.9	39.8±12.5	0.562	>0.05
After treatment	58.3±14.2*	70.1±16.8*	−3.716	<0.001
FEV1/FVC (%)				
Before treatment	63.2±13.7	64.1±12.4	−0.337	>0.05
After treatment	74.6±16.5*	87.3±18.6*	−3.539	<0.001

*, compared with before treatment; P<0.05. FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity.

Table 5 Comparison of daily living activities between the two groups before and after treatment

Item	Group		t	P
	Control group (n=48)	Control group (n=48)		
6MWD (m)				
Before treatment	158.2±72.1	149.4±65.7	0.625	>0.05
After treatment	312.6±66.5*	393.2±75.1*	–5.567	<0.001
MBI score				
Before treatment	47.4±11.2	49.9±12.0	–1.055	>0.05
After treatment	73.2±16.8*	86.8±15.9*	–4.073	<0.001

*, compared with before treatment; P<0.05. 6MWD, 6 minutes walk distance; MBI, Modified Barthel Index.

Table 6 Comparison of nursing satisfaction between the two groups

Group	n	Excellent	Good	General	Dissatisfied	Excellent and good rate, n (%)
Control group	48	21	15	11	1	36 (75.00)
Observation group	48	12	14	18	4	26 (54.17)
χ^2						4.554
P						0.018

Comparison of satisfactory rate of rehabilitation nursing between the two groups of patients

The excellent and good rate of patient satisfaction with rehabilitation nursing in the observation group was 75%, which was significantly better than the 54.17% in the control group, with a statistically significant difference (P<0.05), as shown in *Table 6*.

Discussion

Rapid pulmonary rehabilitation can shorten the length of hospital stay

Lung transplantation patients have a long course of disease, and most of them have a poor basic physical condition, and their autonomous motor ability and living activity ability are decreased. Even after lung transplantation, these basic physical conditions will continue to impair patients' motor ability due to surgical trauma and recovery times (13,14). During lung transplantation, the innervation of the transplanted lung needs to be removed, resulting in phrenic nerve injury and weakened auxiliary muscle strength. There are also many complications after lung transplantation, which endanger the patient's health and affect the patient's recovery. After surgery, patients need to take immunosuppressive drugs for life, insert various tubes to assist breathing, and other ongoing actions, which seriously affects the normal life of patients. Due to various factors, the body function and self-rehabilitation ability of patients are weakened after surgery, and pulmonary rehabilitation intervention is required both perioperatively and postoperatively (15,16). A large number of studies at home and abroad have shown that rapid perioperative pulmonary rehabilitation can reduce postoperative complications and shorten patient hospital stay times (17). With the extensive clinical application of the concept of rapid rehabilitation surgery, the concept of rapid rehabilitation surgery has become an important means of perioperative adjuvant therapy for patients after lung transplantation (18). Some scholars also argue that rapid rehabilitation surgery can optimize the perioperative process, improve the treatment effect of multidisciplinary collaboration, reduce medical overtreatment, and promote patients' functional recovery as soon as possible (19). Our study supports this by showing that the length of hospitalization in the observation group was shorter than that in the control group, with statistical significance (P<0.05).

Matters needing attention in early tracheal extubation

For lung transplantation, early removal of endotracheal intubation is one of the main measures to accelerate the application of rehabilitation surgery. Our results showed that the average extubation time in the observation group was lower than that in the control group, with statistical significance (P<0.05). At present, the common practice for an extubation plan is intraoperative extubation or early extubation within a few hours after surgery, instead of prolonged intubation and controlled ventilation (20). In some transplant centers, about two-thirds of lung transplant patients can be extubated early (21). Complications after early extubation are usually mild, such as hypoxemia or surgical complications, but these require a second surgical exploration within 36 hours. However, not all lung transplant recipients are suitable for early extubation, for example, patients with serious preoperative co-existing diseases, intraoperative complications, or poor graft quality (22). Therefore, early postoperative tracheal extubation should be carried out on the premise that patients will not be directly harmed. In terms of the selection of extubation timing, it is not necessary to perform extubation after the patient is conscious. If the patient's vital signs are stable, the cough reflex is little, sputum volume is reduced, and the patient can independently and effectively clean the respiratory tract, the extubation can be performed after the evaluation meets the requirements and even when the patient is still unconscious (23). The results of this study showed that the mechanical ventilation time in the observation group was significantly shorter than that in the control group (P<0.05).

Early physical training can improve lung function and motor performance

Exercise training is the core component of a rapid pulmonary rehabilitation program. Early postoperative pulmonary rehabilitation training can improve the respiratory function, physical function, and quality of life of lung transplant patients. The results of this study showed that the postoperative ambulation time of patients in the observation group was significantly shorter than that in the control group, with statistical significance (P<0.001). The study has shown that pulmonary rehabilitation is an effective treatment plan, and an early exercise training can improve the activity endurance of patients after receiving a lung transplantation and can effectively reduce the impact of postoperative complications on patients (24). However, early lung rehabilitation training did not provide targeted guidance according to the individual differences of lung transplantation patients, which may lead to some patients being unable to master effective sputum removal skills after surgery, resulting in pulmonary infection and other complications, and seriously reducing the survival rate (25). Therefore, the formulation of a pulmonary rehabilitation program should pay attention to the individual and specific needs according to the actual situation of patients. In this study, before treatment, there were no statistically significant differences in lung function indicators, 6MWD, and MBI between the two groups (P>0.05). After treatment, FEV1%, FVC%, FEV1/FVC, 6MWD, and MBI indicators in the observation group were better than those in the control group, with statistically significant differences (P<0.05). This shows that the patients in the observation group who did the physical rehabilitation training had significantly improved postoperative functions, and the rehabilitation effect was very good. This is consistent with the research results of Ulvestad *et al.* (26). In addition, 75% of patients in the observation group were satisfied with rehabilitation nursing, which was significantly better than the 54.17% of the control group, and the difference was statistically significant (P<0.05). The postoperative rehabilitation effect of patients was improved, and their quality of life was improved, which also helped to improve the doctor-patient relationship.

Conclusions

It is very important to develop standardized strategies and methods for tracheal extubation and early exercise programs for lung transplantation patients. However, this study has the following limitations: (I) a lack of indicators of postoperative complications of lung transplantation were included; and (II) this study was a single-center trial with potential bias, and a high-quality, multi-center study is needed to verify the results. Early tracheal extubation after lung transplantation is an effective guarantee to improve postoperative the quality of life of patients. It is safe and feasible to carry out early activities at the same time as early extubation, and this can promote the postoperative rehabilitation of lung transplant patients, reduce the length of hospital stay, help patients improve their lung function and ability to engage in daily living activities, and improve their satisfaction rate of postoperative rehabilitation. The

conclusions in this study are worthy of clinical application.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-119/rc

Trial Protocol: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-119/tp

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-119/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-119/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The patients and their families signed the informed consent form, and the study was reviewed and approved by the ethics committee of Wuxi People's Hospital (No. KY21100).

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