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A Prospective Randomized Single-Blind Control Study of Volume Threshold for Chest Tube Removal Following Lobectomy

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Abstract

Background The aim of the current study was to assess the feasibility and safety of a new volume threshold for chest tube removal following lobectomy.

Methods The prospective randomized single-blind control study included 90 consecutive patients who underwent lobectomy or bilobectomy for pathological conditions between March 2012 and September 2012. Eligible patients were randomized into two groups: early removal group (chest tube removal at the drainage volume of 300 ml/24 h or less) and traditional management group (chest tube removal when the drainage volume is less than 100 ml/24 h). Criteria for the early removal group were established and met prior to chest tube removal. The volume and characteristics of drainage, time of drainage tube extraction, and postoperative hospital stay were recorded. All patients received standard care while in the hospital and a follow-up visit was performed 7 days after discharge from hospital.

Results In accordance with the exit criteria, 20 patients were excluded from the study. The remaining 70 patients included in the final analysis were divided into two groups: early removal group ($n = 41$) and traditional management group ($n = 29$). There was no difference between the two groups in terms of age, sex, comorbidities, and pathological evaluation of resection specimens. In eligible patients ($n = 70$), the mean volume of drainage 24 h after surgery was 300 ml, while the mean volume of drainage 48 h after surgery was 250 ml. The average daily drainage 48 h after surgery was significantly different than the average daily drainage 24 h after surgery ($Z = -2.059$, $P = 0.039$). The mean duration of chest tube placement was 44 h in the early removal group and 67 h in the traditional management group ($P = 0.004$). Patients who underwent early removal management had a shorter postoperative hospital stay compared to the traditional management group (5 vs. 6 days, $P < 0.01$). No statistically significant differences were observed between the rates of pleural effusion development, thoracentesis, and postoperative complications 1 week after hospital discharge.

Conclusion Early removal of the chest tube after lobectomy is feasible and safe and may shorten patient hospital stay and reduce morbidity without the added risk of postoperative complications.

Introduction

Throughout the years, fast-track surgery, including an anesthetic technique, surgery, and quick rehabilitation, has evolved, resulting in minimal hospital stay and a fast return to normal activity for the patient. Operative procedures in the pleural space often require chest tube drainage. Often the chest tubes are kept in place until complete lung expansion and lung fluid drainage have ceased or lung fluid and drainage have decreased to a minimal amount, at which time the tubes are removed and the thoracostomy closed. Timing of the removal of the chest tubes when there is no air leak or empyema is often empirically established, with wide variations among surgeons. A main reason for the variations in timing among surgeons is the lack of evidence-based studies. Recently, studies have

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reported the safe removal of the chest tube with drainage exceeding 100 ml/24 h. Younes et al. [1] and Hessami et al. [2] have reported the safe removal of the chest tube with drainage at 200 ml/24 h. McKenna et al. [3] showed that chest tube removal was safe with drainage at 300 ml/24 h after c-VATS, and Cerfolio and Bryant [4] reported successful removal of chest tubes with drainage of up to 450 ml/24 h after thoracotomy. The aim of this prospective randomized single-blind control study was to evaluate the feasibility and safety of a new volume threshold for chest tube removal compared with traditional management after lobectomies for lung diseases. This study aimed to establish the volume per day of uninfected drainage at which removal of the chest tube is still safe and is associated with a low pleural fluid reaccumulation rate.

Materials and methods

Patients

A prospective randomized single-blind clinical study of the control method was performed with data collected from patients who had undergone lobectomies at the Beijing Chao-yang Hospital between March 2012 and September 2012. Patients who underwent elective lobectomy and bilobectomy by complete video-assisted thoracic surgery (c-VATS) or open thoracotomy were eligible for this study. Patients with non-small-cell lung cancer, who underwent pulmonary resection, had complete thoracic lymphadenectomy as previously described [5]. The exclusion criteria included lobectomies with chest wall resections; intrapericardial resections; those with heart failure, nephritic syndrome, chronic renal failure, and cirrhosis; and patients in whom the surgeon expected increased postoperative hemorrhage, such as hematological system diseases and pleural extensive adhesion. The exit criteria included prolonged air leakage (i.e., >6 days); a densely bloody, purulent, or cloudy pleural effusion; and adverse cardiovascular and cerebrovascular events. Patients who met these criteria were excluded from the study. One mortality on the sixth postoperative day occurred due to cardiac arrest. In total, 19 patients were excluded from the study due to densely bloody, purulent, or cloudy pleural effusion and prolonged air leakage, which were related to primary lung diseases.

The 90 included patients were randomly divided into two groups in which chest tube removal was determined on volume per day of fluid drainage. For randomization, a table of random numbers was generated and a number was drawn for each patient. After randomization, the study was not blind to the investigators. Twenty patients were dropped from the study due to the exit criteria. The remaining 70 patients were included in the final analysis and divided into the early removal group (removal of chest tube at the drainage level of 300 ml/24 h, $n = 41$) and the traditional management group (removal of chest tube when drainage was <100 ml/24 h, $n = 29$). The flow diagram of the study is presented in Fig. 1. The size of the two groups was unequal due to randomization and the exclusion or exit criteria. The investigators had no influence on the size of the two groups. The study and the electronic prospective database used for this study were approved by the Institutional Review Board of Beijing Chao-yang Hospital. Patient consent was obtained for entry into the prospective database and patients were aware that this information would be used for research purposes.

Chest tube protocol

The complete thoracoscopic lobectomy or open thoracotomy was performed as previously described by McKenna [6, 7]. The bronchus staple line was examined for leakage, and afterward all staple lines and dissection sites were sprayed with a fibrin sealant. After pneumostasis and hemostasis were confirmed, one or two 30F chest tubes were placed in the apical and posterior pleural space. Lung expansion was checked with positive airway pressure until the chest tube was set on water seal. The chest drainage system was not placed on suction after the operation. The amount of drainage from each chest tube was recorded every 24 h (in ml) by the nursing staff.

Postoperative assessment

The clinical criteria for the early chest tube removal was established as follows: (1) the volume of drainage at 300 ml/24 h in early removal group and 100 ml/24 h in traditional management group; if there were two chest tubes, the volume criterion (<300 ml/day) applied to the total from the two chest tubes; (2) absence of a densely bloody, purulent, or cloudy pleural effusion; (3) absence of atelectasis on postoperative chest radiograph; and (4) absence of an air leak. Patients who met these criteria underwent early removal of the 30F chest tube on the day after surgery. A follow-up chest X-ray was conducted 24 h after the removal of the 30F chest tube to evaluate the radiologic reaccumulation rate and chest expansion.

All patients had similar discharge from the hospital and a 1-week follow-up, which consisted of daily evaluation of the volume of uninfected pleural fluid drained (in the morning), no air leakage, and evaluation by chest X-ray confirming expansion of the lung. Drainage time (from the day of the operation until the chest tubes were removed) and postoperative hospital stay (from the day of the operation until the patient was discharged from the hospital) were recorded. The time course of fluid characteristics (e.g., blood, chyle, or CSF) and pleural effusion investigation (e.g., pleural liquid/

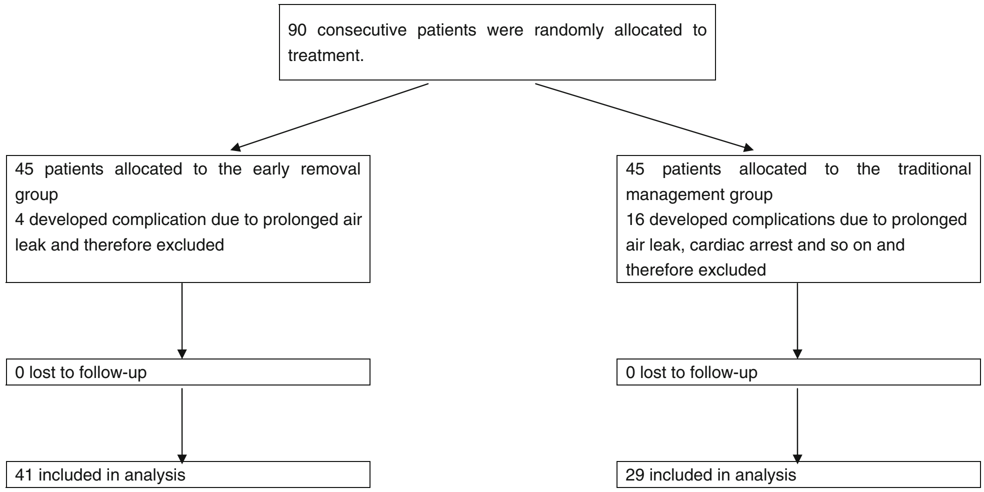

Fig. 1 Flow diagram of a trial of the removal of the chest tube on the basis of volume drainage

plasma protein ratio) were recorded. Postoperative complications (including subcutaneous emphysema, clinically relevant pneumothorax, prolonged air leak, pneumonia, or empyema) were also recorded. Physical examination was performed and chest X-rays were taken at 1 week after surgery. The presence of fluid in the pleural space (identified by X-rays, physical examination, and patient symptoms) was determined. In symptomatic patients with notable reaccumulation of pleural fluid (more than 10 % of the pleural cavity filled with effusion), needle thoracentesis was performed to empty the accumulated fluid. An additional chest X-ray was taken of patients with recurrent effusion and pneumothorax who did or did not undergo thoracentesis to confirm resolution of the effusion and pneumothorax. The 1-week ipsilateral radiologic reaccumulation rate and thoracentesis rate were recorded. The hospital readmission rate was recorded for both groups.

Statistical analysis

Sample size was calculated using the optimal effectiveness test sample size calculation formulas. Type I error was 0.05 with a two-tailed test and type II error or power was 80 %, μ_T was the experimental group mean, μ_c was the control mean, and σ was the combined standard deviation (SD). In accordance with previous findings [1, 8], chest tube removal at 100 ml/24 h occurred at 84 ± 20 h, while removal of the chest tube at 200 ml/24 h occurred at 48 ± 20 h. After the above calculations were conducted, the sample size of each group was 18 patients. The subjects were randomized into two groups in which the chest tube was removed depending on the volume of fluid drained per day. The baseline and perioperative variables, including complications, were compared between the two groups. Continuous variables were expressed as the mean ± standard deviation (SD), or medians compared by analysis of Student's *t*-test or Wilcoxon test. Categorical variables were compared by either the χ^2 test or Fisher's exact test. All statistical analyses were carried out with SPSS for Windows (Statistical Package for Social Sciences; SPSS, Inc., Chicago, IL, USA). The null hypothesis was rejected for $P < 0.05$.

Results

Baseline data

Between March 2012 and September 2012, a total of 90 consecutive patients underwent elective lobectomies and bilobectomies by complete video-assisted thoracic surgery (c-VATS) or open thoracotomy. Owing to the exit criteria, 20 patients were excluded from the study. The remaining 70 patients were included in the final analysis. The mean patient age at the time of surgery was 56 ± 14 years for the early removal group and 55 ± 12 years for the traditional management group ($P = 0.537$). The pathologic analysis included squamous carcinoma, adenocarcinoma, other types of non-small-cell lung cancer, and benign tumor. Non-small-cell lung cancer was the most common pathology and constituted 63 % of all patients in the two groups. In the 44 patients with primary lung cancer, the postoperative stages in the early removal group were 5 patients in each of the stages (IA, IB, IIA, IIB, and IIIA). The postoperative stages in the traditional management group were 5 patients in IA, 4 in IB, 6 in IIA, 1 in IIB, and 3 in IIIA. The two groups were comparable in terms of mean age, sex, comorbidities, and pathologic evaluation of resection specimens ($P > 0.05$). Baseline data for both groups are presented in Table 1.

Perioperative data

In the study, 65 patients (93 %) underwent a lobectomy and 5 (7 %) underwent a bilobectomy. The operative

Table 1 Baseline data

Variable	Early removal group ($n = 41$)	Traditional management group ($n = 29$)	t value/Z value/χ^2 value	P value
Sex			0.059	0.808
Male	21 (51.2 %)	14 (48.3 %)		
Female	20 (48.8 %)	15 (51.7 %)		
Age (years) (mean ± SD)	56±14	55±12	0.537	0.593
Smoking index (median)	300	550	−1.246	0.213
Past medical history				
Hypertension	15 (36.6 %)	6 (20.7 %)	2.044	0.153
COPD	3 (7.3 %)	0	0.792	0.373
Asthma	2 (4.9 %)	0		0.508*
Diabetes	5 (12.2 %)	5 (17.2 %)	0.353	0.552
Pathology			1.16	0.829*
Benign	16 (39 %)	10 (34.5 %)		
Squamous carcinoma	8 (19.5 %)	4 (13.8 %)		
Adenocarcinoma	15 (36.6 %)	14 (48.3 %)		
Other types	2 (4.9 %)	1 (2.4 %)		
Postoperative stages			2.595	0.67*
IA	5 (20 %)	5 (26.3 %)		
IB	5 (20 %)	4 (21.1 %)		
IIA	5 (20 %)	6 (31.6 %)		
IIB	5 (20 %)	1 (5.3 %)		
IIIA	5 (20 %)	3 (15.8 %)		
IIIB	0	0		
IV	0	0		

The values are presented as a number (percentage of variables) or the mean ± standard deviation

COPD chronic obstructive pulmonary disease

* P values are derived from Fisher's exact test

procedures were performed by c-VATS in 52 patients and open thoracotomy in 18 patients. There was no significant difference between the two groups in terms of the resected lung lobes and the number of chest tubes used ($P > 0.05$). The median volume of drainage was 300 ml within 24 h after surgery and 250 ml within 48 h. The average daily drainage after 48 h was significantly different than the average daily drainage after 24 h ($Z = -2.059$, $P = 0.039$). The early removal group had the chest tube in place for a considerably shorter duration than did the traditional management group. The median duration of chest tube placement was 44 h in the early removal group and 67 h in the traditional management group ($P = 0.004$). The median postoperative hospital stay was 5 days in the early removal group and 6 days in the traditional management group. Patients who underwent early removal management had a significantly shorter postoperative hospital stay ($P < 0.01$).

There were no major postoperative complications in 64 patients (91.4 %). Subcutaneous emphysema developed in one patient (3.4 %) in the traditional management group while the chest tube was still in place. The chest tube was removed and the subcutaneous emphysema resolved within a couple of days. It was not necessary to reinsert the chest tube. All four patients with late effusion were in the early removal group; however, only one of them required thoracentesis. A pneumothorax was observed in one patient (2.4 %) in the early removal group after removal of the chest tube at 24 h. This patient underwent thoracentesis resulting in a quick recovery. No other interventions were performed. An additional chest X-ray was obtained in the five patients with recurrent effusion and pneumothorax who did or did not undergo thoracentesis to confirm resolution of the effusion and pneumothorax. Analysis of the data showed no statistically significant differences between the rate of pleural effusion development, thoracentesis, or complications 1 week after discharge from the hospital. The hospital readmission rate was zero for both groups. Perioperative data for both groups are presented in Table 2.

Pleural effusion investigation

Pleural effusion was investigated 24 h after surgery and at the time of chest tube removal in both groups. Unusual fluid characteristics were not observed (e.g., blood, chyle, or CSF). The median pleural liquid/plasma protein ratio was 0.51 one day after surgery and 0.53 at the time of chest tube removal in the early removal group compared with

Table 2 Perioperative data

Variable	Early removal group ($n = 41$)	Traditional management group ($n = 29$)	t value/ Z value/χ^2 value	P value
Operative time (h) (mean ± SD)	2.69±0.67	2.65±0.64	0.248	0.805
Operative site			0.984	0.321
Left	19 (46.3 %)	10 (34.5 %)		
Right	22 (53.7 %)	19 (65.5 %)		
Operative procedures			0.734	0.392
Open thoracotomy	9 (22 %)	9 (31 %)		
c-VATS	32 (78 %)	20 (69 %)		
Type of resection			0.29	0.59
Lobectomy	37 (90.2 %)	28 (96.6 %)		
Bilobectomy	4 (9.8 %)	1 (3.4 %)		
Lung lobes			9.331	0.129*
Left upper	3 (7.3 %)	5 (17.2 %)		
Left lower	16 (39 %)	5 (17.2 %)		
Right upper	9 (22 %)	5 (17.2 %)		
Middle	2 (4.9 %)	6 (14.6 %)		
Right lower	7 (17.1 %)	7 (17.1 %)		
Right upper + middle	1 (2.4 %)	0		
Right lower + middle	3 (7.3 %)	1 (2.4 %)		
Number of chest tubes			0.004	0.952
One	28 (68.3 %)	20 (69 %)		
Two	13 (31.7 %)	9 (31 %)		
Volume of drainage within				
24 h after surgery (ml) (mean ± SD)	296 ± 153	332 ± 149	−0.977	0.332
48 h after surgery (ml) (mean ± SD)	285 ± 103	252 ± 109	1.298	0.199
Drainage time (h)	44 (44–68)	67 (66–90)	−2.914	0.004
Postoperative hospital stay (day)	5 (5–6)	6(6–8)	−3.882	<0.01
Postoperative complications				0.313*
Subcutaneous emphysema	0	1 (3.4 %)		
Pneumothorax	1 (2.4 %)	0		
Reaccumulation of pleural fluid	4 (9.8 %)	0		0.136*
Thoracentesis	2 (4.9 %)	0		0.508*

The values are presented as a number (percentage of variables) or the mean ± standard deviation

c-VATS complete video-assisted thoracic surgery

* P values are derived from Fisher's exact test

0.53 and 0.57, respectively, in the traditional management group. These differences were significant. In addition, there no significant differences between the two groups in other biochemical analyses of the fluid such as pleural glucose levels, pleural liquid/plasma glucose ratio, and pleural liquid/plasma hematocrit ratio (Table 3).

Discussion

Minimally invasive surgical techniques, particularly thoracoscopic surgery, have been performed since 1990. During that time, many advances have been made in the field of anesthesia, pain control, and perioperative support. In turn, numerous models of major outpatient surgery and "fast track" surgery have been developed. The concept of fast track surgery combines various techniques used in the care of patients undergoing elective surgery. The methods include epidural or regional anesthesia, minimally invasive techniques, optimal pain control, and aggressive postoperative rehabilitation, including early enteral (oral) nutrition and ambulation. The combination of these approaches reduces stress response and organ dysfunction, therefore greatly shortening the time required for full recovery. Recent advances in understanding perioperative pathophysiology have shown that multiple factors contribute to

Table 3 Pleural effusion investigation

Variable	Early removal group ($n = 41$)	Traditional management group ($n = 29$)	t value/ Z value/ χ^2 value	P value
Pleural liquid/plasma protein ratio (median)				
Within 24 h after surgery	0.51	0.53	−1.425	0.154
Time of chest tube removal	0.53	0.57	−1.616	0.106
Pleural glucose levels (mmol/L) (mean ± SD)				
Within 24 h after surgery	4.8 ± 2	5.4 ± 1.9	−1.174	0.244
Time of chest tube removal	4.7 ± 2.3	4.7 ± 3	−0.285	0.776
Pleural liquid/plasma glucose ratio (median)				
Within 24 h after surgery	0.77	0.75	−0.554	0.579
Time of chest tube removal	0.68	0.61	−0.924	0.355
Pleural liquid/plasma Hct (median)				
Within 24 h after surgery	0.02 ± 0.004	0.02 ± 0.003	0.807	0.442
Time of chest tube removal	0.02 ± 0.003	0.02 ± 0.002	1.212	0.23

* P values are derived from Fisher's exact test

postoperative morbidity, length of hospital stay, and length of convalescence. The introduction of minimally invasive surgery (MIS) in thoracic surgery is most likely one of the main reasons for the increased interest in chest tube management.

After lung resection, placement of chest tubes is routine. While the procedure is performed under optimal conditions which minimizes risks, the morbidity rate is not low due to prolonged air leakage, empyema, and other conditions. At the same time, chest tubes usually require specialized care in the hospital, with its consequent costs. Any reduction in the duration of chest tube drainage may decrease the likelihood of complications and decrease the necessity of hospitalization.

Based on postoperative pleural dynamics, the use of two pleural tubes (one placed in the apex of the pleural cavity and the other over the diaphragm) after upper lobectomy and only one pleural tube placed over the diaphragm after lower lobectomy is frequently recommended in the medical literature and textbooks [9]. According to clinical studies [10–13], the use of one chest tube after lobectomy appears to offer the same clinical results as the conventional practice of two tubes, one apical and one basal.

The management of chest tubes and the drainage threshold for their removal remain controversial and are based primarily on tradition rather than data. In general, the decision to remove the tube is based on the lack of air leakage, the absence of a hemothorax, and fluid drainage of less than 100 ml for the least 24 h after lobectomy done either through an open thoracotomy or video-assisted thoracic surgery [13]. Recently, several authors have suggested that the removal of a chest tube with 400–450 cm^3 of fluid drainage per day or less is safe [4, 14, 15]. Younes et al. [1] and Hessami et al. [2] reported safe removal at 200 ml/24 h; however, the populations studied in the two management protocols differed. In the study by Younes et al. [1], all patients underwent open thoracotomy and the operative procedures included exploratory thoracotomy, wedge resection, and lobectomy. In the study by Hessami et al. [2], the study population included patients of any age who had sustained blunt or penetrating chest trauma as well as those with noninfected pleural effusion due to any malignancy or other benign causes who required chest tube insertion. The primary disease may determine the total volume of drainage and drainage time. McKenna et al. [3] have reported that early removal of the chest tube is feasible with minimal complications when drainage is less than 300 ml for 24 h. Cerfolio and Bryant [4] reported successful removal of chest tubes with drainage up to 450 ml/24 h after thoracotomy. These figures appear reasonable as they are in the range of physiological daily pleural fluid filtration (an estimated value of 350 ml/day [16]). The pleural fluid originates from the parietal pleura and is resorbed by the visceral pleura. Pleural effusion develops when the amount of fluid that enters the pleural space exceeds the amount that can be removed [17]. With the re-expansion of the remaining lung after surgery, the pleural space is usually obliterated within several days to a week. In most instances, the fluid that remains is resorbed or becomes organized.

In the present study, removing the chest tube after reaching a drainage rate of 300 ml/day resulted in a median duration of chest tube placement of 44 h and a median hospital stay of 5 days, with no notable increase in thoracentesis rates. The hospital readmission rate was zero for both groups. In general, earlier chest tube removal resulted in decreased hospital stay. However, in comparison to Western countries, hospital stay cannot be used as an important indicator to assess the outcome of clinical medical treatment due to the current medical system and medical insurance policy in China. Many patients in China do not accept hospital discharge until complete recovery due to minimal hospital expenses and the significant distance from their home. Overall, it appears that defining a higher safe threshold of fluid drainage for chest tube removal may determine the hospital stay of the patient. Increasing the threshold of daily drainage to 300 ml before removing the chest tube did not notably increase the likelihood of major pleural fluid reaccumulation or the hospital readmission rate. This daily volume (300 ml) could be established as the standard for chest tube withdrawal for patients with uninfected pleural fluid and no evidence of air leaks.

In the current study, fibrin sealant (FS) was applied to staple lines and dissection sites. This decreases chest tube output and decreases air leaks. Lung volume reduction surgery (LVRS) and lung transplant surgery are featured procedures in the authors' department. Based on experience and other studies [18, 19], FS is safe and effective in preventing air leaks after lung resection and in shortening the duration of postoperative air leaks.

Fluid accumulation in the pleural space indicates disease. The accumulation is associated with many medical conditions that predispose the patient to fluid accumulation via various mechanisms, including increased pulmonary capillary pressure, decreased oncotic pressure, increased pleural membrane permeability, and obstruction of lymphatic flow. Fluid analysis yields important diagnostic information. Therefore, the time course of the pleural liquid/plasma protein ratio after closure of the chest indicates the permeability of the pleural membranes and has been recommended in previous clinical papers [20–22]. Pleural effusion has classically been divided into transudative and exudative. The leading causes of exudative pleural effusion are pneumonia, malignancy, and pulmonary embolization. Transudative pleural effusion can be differentiated from exudative pleural effusion by measurement of the pleural fluid protein levels. In exudative effusion, pleural glucose levels less than 28.8 mg/dl may indicate empyema. In biochemical analysis of the fluid, no unusual fluid characteristics (e.g., blood, chyle, or CSF) were found in either group, and the median pleural liquid/plasma protein ratio, pleural glucose levels, pleural liquid/plasma glucose ratio, and pleural liquid/plasma hematocrit ratio did not differ between the two groups 24 h after surgery and at the time of chest tube removal.

The early removal group had four patients (almost 10 %) with late effusion compared to zero in the traditional management group; however, this difference was not significant. It is possible that significance was not reached due to the small sample size, the primary limitation of this study. The results of the present study may be difficult to accept by surgeons who engage in traditional tube management. A future large, well-designed, randomized controlled trial (RCT) would therefore be useful in addressing this clinical issue. All complications were included in the analyses of the current study because of the small number of complications traditionally used to define complications related to pleural effusion. Further investigation of complications, limited to those specifically related to the accumulation of pleural effusion, is required. Regardless, early removal of the chest tube is a novel treatment protocol that may improve the postoperative quality of life of patients. Further studies may eventually establish an even higher volume per day threshold, providing clear support for early removal of chest tubes after some minor intrathoracic surgical procedures.

In conclusion, compared to the traditional management group (drainage $\leq$100 ml/24 h), early removal of a chest tube after lobectomy (drainage $\leq$300 ml/24 h) is feasible and safe. Early removal of the chest tube may result in a shorter hospital stay and, importantly, reduce patient morbidity without the added risk of postoperative complications.

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