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## Single versus double chest tube after anatomical pulmonary resections — randomized trial

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**Abstract:** Background: Pleural drainage is the standard procedure after different thoracic procedures. The drainage rules used in various centers vary considerably. Although many centers use now single chest tube instead of the classical double-tube system, high-level evidence supporting this approach is scant.

Objectives: The aim of this trial was to compare effectiveness of single chest tube versus the double-tube system and factors influencing this effectiveness.

Material and Methods: A prospective randomized trial including patients treated between 2016 and 2017. The primary endpoint was drainage time and the secondary endpoints were drainage volume and air leak time.

Results: There were 312 patients: 153 finally analyzed in the single-tube group (ST) and 145 patients in the double-tube group (DT). Both groups were comparable regarding patients' characteristics ( $p = 0.11$ – $0.60$ ). There was no significant difference in drainage time ( $p = 0.084$ ). Single chest tube was associated with significantly lower drainage volume (1515 ml vs 1998 mL,  $p = 0.001$ ), mean air leak intensity (26.5 vs 64.2 mL/min,  $p = 0.005$ ) and mean air leak time (59.9 vs 89.0 hours,  $p = 0.002$ ). On the multivariate analysis only fused fissure ( $p = 0.027$ ) was associated with total drainage time. Drainage volume was associated with double-tube ( $p = 0.039$ ) and VC ( $p = 0.049$ ), air leak intensity with double-tube ( $p = 0.032$ ) and BMI ( $p = 0.048$ ) and air leak time with double-tube ( $p = 0.008$ ) and BMI ( $p = 0.043$ ). Complications occurred more often in the DT group ( $p = 0.04$ ).

Conclusions: in patients who underwent anatomical pulmonary resections single chest tube is associated with lower chest tube output, air leak intensity and air leak time.

**Keywords:** lung cancer, chest drainage, air leak, pulmonary lobectomy.

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## Introduction

Pleural drainage is the standard procedure after different thoracic procedures. The drainage rules used in various centers vary considerably. Although many centers use now single chest tube instead of the classical double-tube system, high-level evidence supporting this approach is scant.

## Objectives

The aim of this trial was to compare effectiveness and drawbacks of both strategies. We hypothesize that single-tube chest drainage is superior to the double-tube system.

## Material and Methods

We conducted a prospective, randomized clinical trial including consecutive NSCLC patients, with 1:1 randomization using the sealed envelopes method. The study was financially supported by Jagiellonian University. The study protocol was approved by the Bioethical Committee of the Jagiellonian University, where the full protocol is available (No 122.6120.285.2015).

Sample size was determined using General Linear Model, assuming significance level equal to 0.05, power equal to 0.90 and that the Root Mean Square Standardized Effect (RMSSE) to be medium, i.e.  $\text{RMSSE} \geq 0.25$ . There were no changes to the protocol after trial commencement.

## Setting

The study was conducted at the Department of Thoracic Surgery, Jagiellonian University, John Paul II Hospital, Cracow, Poland.

## Patients

Consecutive NSCLC patients operated on between February 2016, and December 2017 were enrolled by surgeons participating in the study. Patients received detailed information about the study and expressed written consent to participate in the study.

Inclusion criteria were as follows:

- age >18 years;
- NSCLC clinical stage I-IIIa (the only IIIa subgroup allowed was single-level N2) according to the 7th edition of the TNM classification;
- general fitness adequate for the planned resection according to the ERS/ESTS Guidelines [1];
- anatomical lung resection.

Exclusion criteria included:

- pneumonectomy;
- postoperative mechanical ventilation;
- reoperation due to bleeding in the postoperative course.

## Intervention

Standard procedure used in all patients, is summarized below. All patients were operated on by Board-certified thoracic surgeons via anterior thoracotomy or VATS. Approach (VATS or open) was chosen by the operating surgeon, on the basis of his preferences. Pleural adhesions were divided using electrocautery. Interlobar fissures were separated with staplers, vessels were controlled by ligation, clipping or stapling, and bronchi were closed with a stapler. Systemic mediastinal lymphadenectomy was performed according to the ESTS guidelines [2]. The tightness of the bronchus stump and air lung parenchyma were checked using positive pressure of 30 mmHg. In case of air leakage, aerostasis was performed using surgical sutures, stapler, sealing fibrin sponge or tissue glue.

At this stage, randomization to the single tube (ST) group and the double tube (DT) group was performed by a nurse in 1:1 ratio using sealed envelopes. At the end of the procedure, one or two chest tubes were placed in the pleural cavity according to the randomization. In the ST group, 28 F chest tube was inserted in the anterior axillary line towards the top of the pleural cavity. In the DT group, one tube was placed in the same manner as in the ST group, and the second tube, 32 F, was inserted in the middle axillary line towards the costophrenic recess of the pleural cavity. An electronic suction system (Thopaz+, Medela AG, Baar, Switzerland) was used in all patients. On the day of surgery,  $-20$  cm  $H_2O$  suction was applied. In the morning on the postoperative day 1 chest X-ray was obtained. In patients with full re-expansion of the lung, suction was switched to  $-8$  cm  $H_2O$ . In case of incomplete lung expansion, suction pressure was maintained at  $-20$  cm  $H_2O$ . In case of persistent air leakage exceeding 7 days and exceeding 200 ml/min, the patient's own blood collected from the peripheral vein in the amount of 50–60 ml was administered through the drain to the free pleural cavity (autologous blood patch).

Pain control procedure included paravertebral analgesia and pain intensity monitoring every 4 hours using the Numeric Rating Scale (NRS). If pain intensity was  $\geq 4$ , additional analgetics were administered i.v.

Chest physiotherapy was introduced on the day of surgery, after patient's recovery.

Criteria for chest tube removal were as follows: re-expanded lung, no air leak in the last 24 hours, daily chest tube output  $< 250$  mL. In the DT group, minimal time interval between removal of the first and the second tube was 24 hours. Small, asymptomatic residual air space in the apex of the pleural cavity in the absence of air leakage was not a contraindication for chest tube removal. Chest X-ray was performed next day after removal of the tube and the patient was discharged home.

## Endpoints

The primary endpoint was drainage time. Secondary endpoints were: total drainage volume and air leak time.

## Variables measured

Patients' characteristics were recorded, including: age, gender, body mass index (BMI), forced expiratory volume in the first second ( $FEV_1$ ), vital capacity (VC), carbon monoxide lung diffusion capacity (DLCO), WHO performance score, tumor clinical stage, histology and grade. During

surgery and in the postoperative period, following variables were recorded: approach (open vs VATS), side and site (upper vs lower lobe) of resection, presence of pleural adhesions, length of staples line, interlobar fissure status (fully developed, partially developed or absent) and pain intensity using the Numeric Rating Scale (NRS).

### Statistical analysis

For analysis of the measured variables a univariate analysis was performed using parametric (t tests) and non-parametric tests (U Mann-Whitney). Shapiro-Wilk test was used to check if probability distribution of variable fulfils normality condition for t-tests. For variables where group sizes ratio was 2:1 or higher, U Mann-Whitney test was performed. A p value of 0.05 was considered statistically significant. For prolonged leak as dependent variable p values were calculated using multivariate regression with logit as a link function. Single versus double chest tube drainage were compared in a multivariate regression analysis using several selected factors.

All values were calculated using statistical packages included in STATISTICA 10 software and Python programming language.

### Results

Enrolment was stopped after inclusion of the pre-specified number of patients. Finally, 312 patients were randomized. As 20 of them were excluded from final analysis (Fig. 1), the study group included 292 patients (143 men), the mean age was 66 years (range: 24–85). Final analysis included data of 153 patients in the single-tube group, including 57 VATS resections and 96 open resections (144 lobectomies and 9 segmentectomies) and 145 patients in the double-tube group, including 46 VATS and 99 open resections (139 lobectomies and 6 (segmentectomies). Data of all patients were analyzed by the originally assigned groups. As presented in Table 1, both groups were comparable regarding age, sex, BMI, pulmonary function tests, performance score and tumor histology ( $p = 0.111$ – $0.602$ ). Intraoperative measurements are summarized in Table 2. There was no significant difference regarding type of resection, pathological stage, approach (VATS or open), adhesions and presence of interlobar fissure ( $p = 0.378$ – $0.658$ ).

On the univariate analysis there was no significant difference in drainage time between ST and DT group (110 vs 122 hours, 95% CI: 45–187;  $p = 0.084$ ). Single chest tube was associated with significantly lower total drainage volume (1515 mL vs 1998 mL, 95% CI: 1239.58–2192.12;  $p = 0.001$ ), mean air leak intensity (26.5 vs 64.2 mL/min, 95% CI: 11.25–115.63;  $p = 0.005$ ) and mean air leak time (59.9 vs 89.0 hours, 95% CI: 10.8–120.5;  $p = 0.002$ ).

On the multivariate analysis the only factor associated with total drainage time was fused fissure ( $p = 0.027$ ). Drainage volume was associated with the use of two tubes ( $p = 0.039$ ) and VC ( $p = 0.049$ ), air leak intensity was associated with the use of two tubes ( $p = 0.032$ ) and BMI ( $p = 0.048$ ), air leak time was associated with the use of two tubes ( $p = 0.008$ ) and BMI ( $p = 0.043$ ).

Complications occurred in 57 patients (Table 3): in 23 patients in the ST group and in 34 patients in the DT group ( $p = 0.044$ ). 6 patients (4 in DT group and 2 in SD group) required re-operation due to bleeding and hematoma in the pleural cavity; they were excluded from further analysis. The most frequent complication was prolonged air leakage, which required intervention in 14 patients (10 in the DT group and 4 in the ST group). Autologous blood patch was successfully used in 7 of them (all in the DT group). One patient was discharged home with persistent air

## CONSORT Flow Diagram

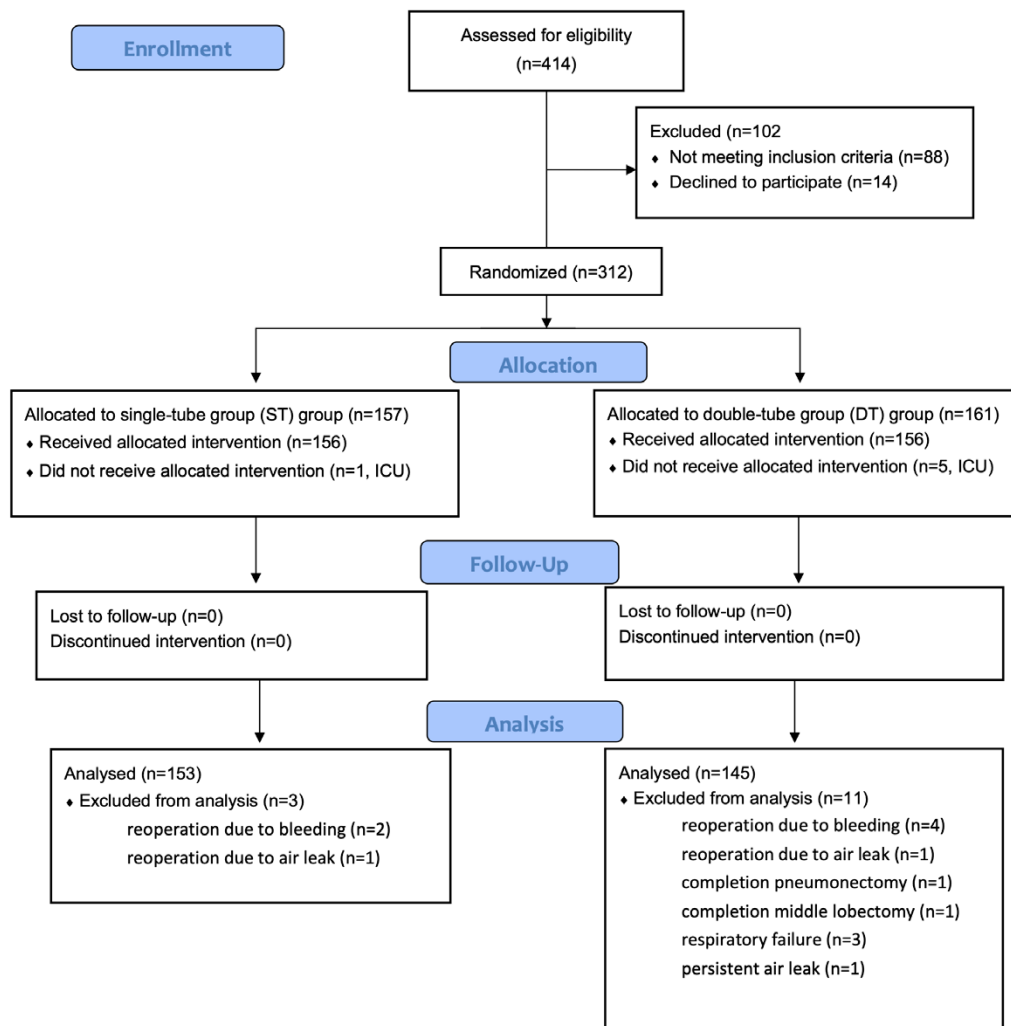


Fig. 1. Study Flow Chart.

leakage with a chest tube connected to the Heimlich valve set (Pneumostat). In 3 patients, (2 in ST group and 1 in DT group) chylous drainage occurred, which was successfully treated conservatively. In 3 patients (2 in ST group and 1 in DT group) bronchofiberscopy was performed due to atelectasis. One patient in the ST group developed renal failure treated with dialysis.

There were no postoperative deaths.

**Table 1.** Patients' demographics.

Variable		ST group	DT group	p value	Test
Number of patients n		153 (51.3)	145 (48.7)		t-student
Sex n (%)	Male	95 (62.1)	48 (33.1)	0.4563	
	Female	58 (37.9)	97 (66.9)		
Mean age (range)		65.33 (24–82)	66.33 (39–85)	0.7368	
D <sub>LCO</sub> (mmol/min/kPa)		5.69	5.82	0.1115	
VC (ml)		3254	3142	0.2425	
FEV <sub>1</sub> (ml)		2469	2388	0.4887	
BMI (kg/m <sup>2</sup> )		26.55	26.52	0.5586	
WHO Performance Score		0.37	0.34	0.4922	
Tumour types n (%)	AC	76 (49.7)	68 (46.9)		U Mann-Whitney
	SCC	53 (34.6)	57 (39.3)		
	AC/SCC	1 (0.7)	3 (2.1)	0.6021	
	LCC	11 (7.2)	10 (6.9)		
	Carcinoid	12 (7.8)	7 (4.8)		

BMI — Body Mass Index; D<sub>LCO</sub> — carbon monoxide diffusion capacity; VC — vital capacity; FEV<sub>1</sub> — forced expiratory volume in 1s, AC — adenocarcinoma; SCC — squamous-cell carcinoma; LCC — large-cell carcinoma.

**Table 2.** Intraoperative measurements.

Parameter name		ST value	DT value	p value
Type of resection n (%)	RUL	40 (13.4)	35 (11.7)	0.658
	RML	7 (2.3)	9 (3.0)	
	UB	7 (2.3)	2 (0.7)	
	RLL	24 (8.1)	24 (8.1)	
	LB	8 (2.7)	6 (2.0)	
	LUL	39 (13.1)	39 (13.1)	
	LLL	19 (6.4)	24 (8.1)	
	Segmentectomy	9 (3.0)	6 (2.0)	
Pathological stage	IA	56	50	0.385
	IB	28	32	
	IIA	23	25	
	IIB	14	11	
	IIIA	22	24	
	IIIB	3	0	
	IV	7	3	

**Table 2.** Cont.

Parameter name		ST value	DT value	p value
Approach n (%)	VATS	57 (37.3)	46 (31.7)	0.378
	Open lobectomy	96 (62.7)	99 (68.3)	
Pulmonary fissure n (%)	Absent	24 (15.7)	23 (15.9)	1.000
	Partially developed	93 (60.8)	100 (68.9)	0.531
	Fully developed	36 (23.5)	22 (15.2)	<0.001
Adhesions n (%)	Absent	116 (75.8)	100 (68.9)	0.381
	Present	37 (24.2)	45 (31.1)	

**Table 3.** Complications.

Complication		Single-tube group	Double-tube group
Prolonged air leak (>5 days)		4	10
Autologous Blood patch	1×	—	4
	2×	—	3
Persistent air leak (discharge on Heimlich valve)		—	1
Pneumothorax after tube removal requiring re-drainage		1	—
Subcutaneous emphysema after tube removal requiring re-drainage		—	1
Residual apical air space after tube removal (discharged home)		3	1
Respiratory failure		—	3
Chylothorax		2	1
Bleeding requiring reoperation		1	3
Hematoma requiring reoperation		1	3
Air leak requiring reoperation		1	1
Middle lobe torsion requiring lobectomy		—	1
Bronchial stenosis requiring pneumonectomy		—	1
Sudden cardiac arrest		1	—
Recurrent AF		6	2
Atelectasis (requires the FOB)		2	1
Kidney failure		1	—

AF — atrial fibrillation; FOB — fiberoptic bronchoscopy.

## Discussion

Although the effectiveness and drawbacks of one chest tube versus two chest tubes pleural drainage in patients after anatomical lung resection were investigated in several randomized, prospective studies, the results are not consistent [3–10]. Impact of different factors on drainage results have

been evaluated in recently published studies, with different results [3–6, 9, 11–14]. Using multivariate analysis, we tested effect of several factors identified in previous studies on clinically important postoperative measurements, including drainage time, drainage volume and air leakage.

In the univariate analysis, the drainage time did not show statistical significance between the ST and DT groups. In the multivariate analysis, the drainage time was significantly influenced by the fused interlobular fissure.

A single tube drainage was associated with significantly lower total drainage volume.

Our results are similar to the results presented by the authors of a meta-analysis of 5 randomized controlled trials including 502 patients [9]. This meta-analysis shown significant difference in the total volume of drainage ( $p = 0.03$ ) and its duration ( $p = 0.02$ ) in favor of the single tube drainage.

Similarly, the authors of meta-analysis of lobectomy patients treated with 1 versus 2 chest tubes, which included 5 studies (630 patients, 314 with one chest tubes and 316 with two tubes) confirmed that single-tube drainage reduces drainage time [7].

Similar results were reported in a study by Okur *et al.*, where the drainage volume in the single tube group was lower than in the two tubes group (600 mL vs 896 mL,  $p < 0.001$ ) and by Gayer and Baciewicz, who confirmed that the use of one chest tube reduces the volume of drainage and shortens the time of drainage and hospital stay [6, 10].

The difference in the total volume of drained fluid can be related to the shorter drainage time with a single chest tube as well as limited irritation of the pleura by the chest tube. The threshold of 250 mL/day, used in our study is moderate. The concept of safe removal of a chest tube with higher daily chest tube output is supported by the results presented by Cerfolio, Pompili, Bjerregaard, and Hristova, who have shown safety of removal the chest tube with drainage up to 400–500 mL/day without accumulation of fluid in the pleural cavity [13, 15–17]. This has been also confirmed in a metaanalysis of clinical studies comparing the efficacy of chest tube removal with a volume threshold 300 mL/day versus 100 mL/day included data of 615 patients. The volume threshold of 300 mL/day was associated with reduction of drainage time and hospital stay. No significant difference was observed in postoperative complications, such as pleural fluid reaccumulation [18]. In our study we did not confirm accumulation of fluid in the pleural cavity in the follow-up radiographs after chest tube removal in the single-drain group.

On the contrary, Tanaka in a prospective randomized study involving 108 patients did not show significant difference in the volume of drainage and its duration in the group of patients with 1 vs 2 chest tubes. He confirmed the correct expansion of the remaining lung parenchyma and the absence of residual fluid in the pleural cavities in both groups [8].

Also, Alex and Gomez-Caro in randomized trials have shown no difference in drainage time and volume between the two groups of patients with 1 vs 2 tubes [3, 5].

Air leak is one of the most important factors determining prolonged hospital stay after lung resections. In our study, single chest tube drainage was associated with significantly lower mean air leakage (26.5 vs 64.2 mL/min,  $p = 0.005$ ) and its significantly shorter duration (59.9 vs 89.0 hours,  $p = 0.002$ ), shown in the univariate analysis.

In the multivariate analysis, the duration of air leakage depended significantly on the presence of two chest tubes ( $p = 0.008$ ) and on BMI ( $p = 0.04$ ). Also, intensity of air leakage was significantly influenced by the presence of two chest tubes ( $p = 0.032$ ) and BMI ( $p = 0.047$ ). Brunelli in a recent study shown that the amount of air leakage was independently related to the duration of the air leak [19].

Chest tube may be also associated with pain. We confirmed less pain as measured using the NRS scale on the first postoperative day in the single-tube group. This is consistent with results of



other authors. Okur, in a prospective, randomized study involving 100 patients after lobectomy with 1 versus 2 chest tubes, confirmed less pain with one chest tube ( $p = 0.014$ ), and similar effect was shown in a metaanalysis published by Zhang *et al.* [6, 9]. Gayer and Baciewicz, in a study comparing drainage using 1 versus 2 chest tubes after lobectomy, confirmed less pain in the VAS scale when using one chest tube with significance on the 3rd and 4th day after surgery ( $p = 0.009$  and  $0.013$ , respectively) [10]. Gómez-Caro in a randomized study confirmed that patients with one chest tube required less pain relief medication than with two chest tubes ( $p = 0.0003$ ) [5].

Similar results were shown in a retrospective study including 183 patients by Pawelczyk, who found that one chest tube after lobectomy is associated with pain reduction [20].

Unlike the abovementioned authors, Tanaka, in a randomized study involving 108 patients after lobectomies with one versus two chest tubes, did not show a statistical difference in pain between the two groups [8].

We found significant difference in favor of single tube drainage regarding complications. As such difference was not confirmed in several previously published studies [3, 5, 8, 20], this is an important new contribution to the knowledge regarding postoperative chest drainage.

### Limitations of the study

Limitations of our study include its single-institutional setting and rather conservative rules regarding chest tube removal:  $<250$  mL of output/day and no air leak in the last 24 hours. These institutional rules were established considering results of previous randomized study [21].

Its strengths are: relatively large number of patients, short period of enrolment and precise measurements using the digital drainage system. We believe that the results are important in the discussion regarding optimal drainage strategy after lung resections and that they may contribute to change this strategy to an evidence-based one.

### Conclusions

In patients who underwent anatomical pulmonary resections for NSCLC single chest tube is associated with lower chest tube output, air leak intensity and air leak time. As there is no advantage from the use of two chest tubes regarding any postoperative parameter, it should not be routinely utilized.

### Funding

The study was supported by the Jagiellonian University statute grant.

### Conflict interest

None declared.

### Ethical approval

The study protocol was approved of the Bioethical Committee of the Jagiellonian University (No. 122.6120.285.2015).

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