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The implementation of a digital chest drainage system significantly reduces complication rates after lobectomy – a randomized clinical trial

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Abstract

Aim of the study: The aim of the study was to evaluate the impact of implementing a digital chest drainage device with regulated suction during postoperative care following a pulmonary lobectomy.

Material and methods: Sixty-four patients who underwent a lobectomy at the Department of Thoracic Surgery of the Medical University of Gdańsk between June 2011 and January 2012 were included in this study. The patients were randomly divided into two groups. During the postoperative period, the patients in the study group received thoracic drainage using digital chest drainage or a conventional glass bottle. The drain was withdrawn when the daily volume did not exceed 350 ml and there was no air leakage for at least 6 hours.

Results: The patients from the study and the control groups did not significantly differ with regard to the following parameters: mean age, physiological test results, presence of concomitant diseases, and surgical access to the chest. During the postoperative period, no significant differences in the drainage duration were found (Thopaz: 4 days, controls: 4 days, $p = 0.919$). Similarly, the period of hospitalization did not differ significantly. The general complication rate was 37%, with common complications including: atrial fibrillation (19%), atelectasis requiring bronchial aspiration (9%), and prolonged air leak (8%). The complication rate in the Thopaz group was significantly lower (25%) than in the control group (50%) ($p = 0.039$). There was no mortality in either group during the postoperative period.

Conclusions: Withdrawing the drainage device at the daily volume of 350 ml together with the implementation of a light and compact digital chest drainage kit significantly reduces the complication rates after lobectomy.

Key words: lobectomy, pleural drainage, complications.

Streszczenie

Cel pracy: Ocena przebiegu okresu pooperacyjnego po wycięciu płata płuca w zależności od zastosowanej formy drenażu: drenażu cyfrowego z regulowaną siłą ssania i tradycyjnego drenażu butlowego.

Materiał i metody: Pomiędzy czerwcem 2011 r. a styczniem 2012 r. do badania włączono 64 pacjentów poddanych lobektomii w Klinice Chirurgii Klatki Piersiowej Gdańskiego Uniwersytetu Medycznego. Pacjenci byli losowo kwalifikowani do jednej z dwóch grup. W grupie badanej pacjenci w okresie pooperacyjnym drenowani byli przy zastosowaniu drenażu cyfrowego Thopaz Medela. W grupie kontrolnej po zabiegu stosowano klasyczny drenaż dwubutlowy. Dren usuwano przy dobowej objętości nieprzekraczającej 350 ml i braku przecieku powietrza od minimum 6 godzin.

Wyniki: Pacjenci grupy badanej i kontrolnej nie różnili się istotnie pomiędzy sobą: średnim wiekiem, wynikami testów czynnościowych, częstością chorób towarzyszących i odsetkiem zabiegów wykonanych z dostępu wideotorakoskopowego. W okresie pooperacyjnym nie stwierdzono istotnych różnic w medianie długości utrzymywania drenażu (Thopaz 4 dni, kontrola 4 dni, $p = 0{,}919$). Podobnie, nie stwierdzono różnic w długości hospitalizacji (Thopaz 6 dni, kontrola 5,5 dnia, $p = 0{,}559$). Częstość występowania powikłań wynosiła 37%. Najczęstszymi stwierdzanymi powikłaniami były: migotanie przedsionków (19%), niedodma wymagająca odessania wydzieliny (9%) oraz przedłużony przeciek powietrza (8%). W okresie pooperacyjnym nie było zgonów. U pacjentów z grupy Thopaz istotnie rzadziej stwierdzano powikłania (25%) niż w grupie kontrolnej (50%) ($p = 0{,}039$).

Wnioski: Usuwanie drenażu przy dobowej objętości 350 ml wraz z zastosowaniem lekkiego, przenośnego zestawu drenażu cyfrowego pozwala znacząco obniżyć częstość występowania powikłań po lobektomii.

Słowa kluczowe: lobektomia, drenaż opłucnej, powikłania.

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Introduction

Chest drainage duration is the most significant factor influencing the duration of postoperative hospitalization after pulmonary resection less extensive than pneumonectomy [1, 2]. In the presence of an air leak, retaining the drain is universally accepted. Moreover, withdrawing the drain while a high daily volume of fluid is produced is controversial [3]. Recently, in thoracic surgery departments, conventional water seal chest drainage devices have begun to be replaced by digital chest drainage devices. Digital drainage allows for the objective evaluation of air leakage [4, 5]. The precise regulation of intrapleural pressure enabled by the device allows for a shift from simple pleural drainage to an innovative treatment modality [6]. Thanks to the unification of this treatment, managing multicenter trials and comparing results from different centers has become more feasible.

Aim of the study

The aim of the study was to evaluate the influence of digital drainage on complication rates, drainage duration, and hospitalization time after lobectomy.

Material and methods

Patients, aged 44-79, qualified for lobectomy according to the commonly accepted ERS/ESTS protocol [7], entered this prospective trial. The patients free from significant concomitant diseases [with the exception of mild chronic obstructive pulmonary disease (COPD)], who had good or very good performance status (PS 0-1) and low risk of complications during general anesthesia [ASA (American Society of Anesthesiologists) I-II], were randomly assigned to one of the two study arms in a ratio of 1 : 1 after having provided their written informed consent.

The exclusion criteria of the study consisted of: preoperative treatment with chemo- or radiotherapy and clinical and/or radiological features of active inflammation (especially aspergillosis, lung abscess, pneumonia, or tuberculosis). Patients in whom a decision to change the extent of the resection was undertaken intraoperatively were also excluded. Finally, patients who withdrew their drains accidentally or had them withdrawn due to postoperative psychosis were excluded from the study.

Between June 2011 and January 2012, 64 patients entered the study. After providing their written informed consent, the patients were randomized using the coin-toss method and allocated to one of the two study groups. Group I was the study group (n = 32) while group II was the control group (n = 32). Patients from the study group received postoperative drainage using a digital drainage device (Thopaz, Medela AG, Switzerland). Patients from the control group received postoperative drainage using classic Sherwood glass bottles. Suction was obtained via a central wall suction system.

All patients underwent a simple lobe excision with systematic lymph node excision. After the surgery, a single 28F thoracic drain was left. During the first 2 postoperative days, drain suction was set at –15 cm H_2O. Subsequently, active suction was replaced by gravitational drainage. The decision to withdraw the drain was evaluated once a day, based on two universally accepted conditions: the daily volume of the drained fluid must not exceed 350 ml and no air leakage must be present (defined as the absence of bubbles in the water seal bottle during coughing or the application of the Valsalva maneuver). The patients from the control group were asked to cough a few times during the morning visits. The presence of air leakage was observed by a thoracic surgeon with sufficient professional experience, who decided whether to withdraw the drain. In the study group, the drain was removed when the air leak was between 0 and 20 ml/min, as determined with the digital device; the readings from the previous 6 hours of drainage were also analyzed during the morning visits. The study was designed to find the differences between the postoperative course in the two different drainage systems. The period between the cessation of air leakage and the drain withdrawal was not recorded due to unreliable data in the glass bottle system. The amount of air leakage in the digital drainage group was not recorded for the same reason.

The study was approved by the University Ethics Committee of the Medical University of Gdańsk (Approval: 400/2009).

To compare the results in an interval scale characterized by normal distribution, a Student's t-test for independent samples was applied. The data in an interval scale not characterized by normal distribution were compared using a Mann-Whitney U test. The data in the nominal scale were compared using a χ^2 or Fisher's exact test, if necessary. A significance level of $p < 0.05$ was assumed for the verification of all the hypotheses.

Results

The data acquired from all the patients were subjected to statistical analysis. Age, gender, frequency of concomitant diseases, results of spirometry and physiological tests, as well as smoking habit, were similar in both study groups (Table I).

The procedures performed and the accessibility of the surgical site in both study groups are listed in Table II. Right lower lobectomy was more common in group II, but the small samples of the subgroups suggest that this does not influence the end results. The most common pathological status of the resected specimen was adenocarcinoma in stage pIA, which is typical for patients operated on in our center. The pathological stage and type of the disease were similar in both study groups (Table III, Table IV).

The mean drainage time was comparable in both study groups (Fig. 1). Similarly, the duration of hospital stay was comparable (Fig. 2). Significant differences were discovered when analyzing the postoperative complications. The complication rate was significantly higher in the group in which conventional glass bottle drainage was applied [group II (glass bottle): 50%; vs. group I (Thopaz): 25% p = 0.039]. Cardiovascular and pulmonary complications were most frequent (atrial fibrillation 38%, atelectasis requiring bron-

Tab. I. Comparison of the two study groups

Parameter	Group I (Thopaz) (n = 32)	Group II (glass bottle) (n = 32)	p value
age (years)	63 (52-79)	63 (44-75)	0.831
male gender	16	22	0.127
frequency of concomitant diseases	16	15	0.802
frequency of arterial hypertension	11	14	0.442
frequency of diabetes mellitus	3	4	0.689
frequency of coronary artery disease	3	3	1.000
FEV_1 (dm^3)	1.66 (1.29-3.92)	2.13 (1.48-3.94)	0.095
FEV_1%	89 (47-118)	95 (59-128)	0.337
FVC (dm^3)	3.00 (2.37-5.77)	3.26 (2.05-5.05)	0.429
FVC%	98 (60-130)	103 (84-113)	0.404
6-minute walk test distance (meters)	552	553	0.974
smoking (pack years)	29 (0-60)	30 (0-75)	0.888

FEV_1 – forced expiratory volume in 1 second; FVC – forced vital capacity

Tab. III. Histology of the resected specimens

Histological type	Group I (Thopaz) (n = 32)	Group II (glass bottle) (n = 32)	p value
adenocarcinoma	18	17	0.802
squamous cell carcinoma	11	12	0.794
large cell carcinoma	1	0	0.313
typical carcinoid	1	1	1.000
other malignancies	0	1	0.313
benign	1	1	1.000

chial aspiration 19%, prolonged air leak 15%, redrainage 3%, bronchial stump fistula 1.5%, pneumonia 1.5%). Other complications that occurred in the study groups were: hemorrhage requiring reoperation (1.5%) and cerebral stroke (1.5%). Cardiovascular and pulmonary complications were more common in the classical drainage group (47%) than in the Thopaz group (22%; p = 0.035). A comparison of the postoperative complications in both study groups is presented in Table V. The complete list of patients with complications which occurred in the postoperative period is presented in Table VI. There were no deaths during the postoperative period.

The daily amount of fluid (350 ml) at which it was acceptable to remove the drain was higher than the 200 ml traditionally accepted in our department. In spite of this, none of the patients were redrained due to the presence of fluid in the pleural cavity. Only one patient in group II was redrained due to pneumothorax.

Tab. II. Types of procedures performed in the study groups

Procedure	Group I (Thopaz) (n = 32)	Group II (glass bottle) (n = 32)	p value
right upper lobectomy	15	10	0.200
middle lobectomy	4	2	0.391
right lower lobectomy	2	8	0.039
left upper lobectomy	9	8	0.777
left lower lobectomy	2	4	0.391
VATS access	18	15	0.453

VATS – video-assisted thoracic surgery

Tab. IV. Stages of the resected non-small cell carcinomas

Stage of NSCLC	Group I (Thopaz) – patients with NSCLC (n = 31)	Group II (glass bottle) – patients with NSCLC (n = 31)	p value
pIA	11	11	1.000
pIB	10	8	0.576
pIIA	4	8	0.199
pIIB	1	1	1.000
pIIIA	5	3	0.449

NSCLC – non-small cell lung cancer

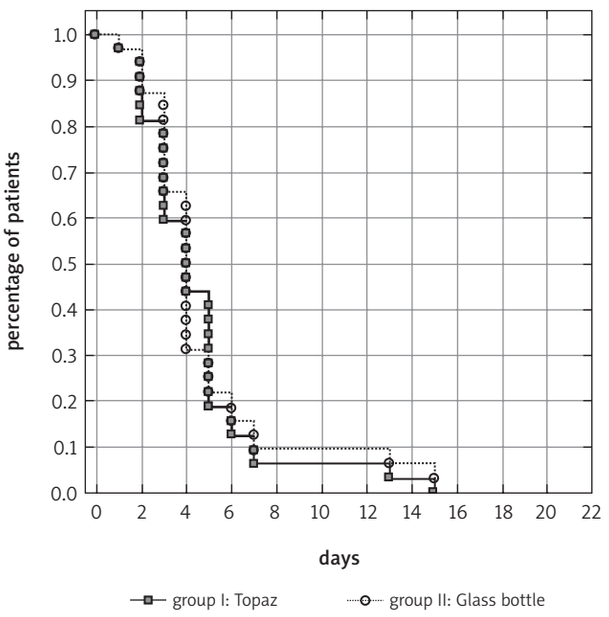

Fig. 1. Comparison of drainage times

Discussion

In 1875, Bülau introduced the underwater drainage tube for the pleural cavity. It became a simple, very efficient and safe method of evacuating air and fluid from the pleural cavity. The principles of chest drainage have not changed significantly since the 19th century. The glass bottle used for chest drainage became a trademark of thoracic surgery.

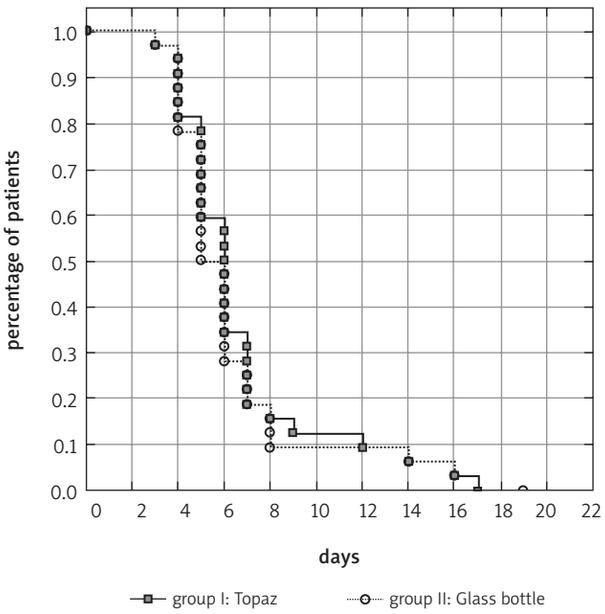

Fig. 2. Comparison of the durations of postoperative hospital stay

The ability to treat patients with chest drainage has since become a defining characteristic of the thoracic surgeon. Recently, the implementation of digital chest drainage systems has altered the attitude towards pleural drainage and made it a significant part of the postoperative treatment. Modern devices, due to repeated pressure measurements, provide constant pressure in the pleural cavity, which promotes more sufficient lung expansion. Moreover, reliable air leak monitoring enables earlier drain withdrawal, concurrently preventing premature drain pulls.

In our center, the most common indication for a pulmonary lobectomy is non-small cell lung cancer (NSCLC). All the patients are qualified for radical treatment during multidisciplinary meetings. The decisions are undertaken on the basis of universal oncological and physiological protocols. This procedure facilitates homogeneity in this group of patients. In such uniform groups of patients, even small improvements in routine postoperative care could translate into substantial benefits.

In the present study, an attempt was made to define the influence of the implementation of a digital chest drainage device on the postoperative hospital stay. Based on reported observations, there is no significant difference in clinical parameters between the classical and the modern drainage systems during the postoperative period, if the assumed volume of daily drainage that allows safe drain removal does not exceed 200 ml [8]. We decided to increase the acceptable daily fluid drainage volume. There is no unequivocal consensus on the acceptable amount of drainage flow for safely withdrawing the drain from the pleural cavity. Traditionally, the limit was established at 150-200 ml/24 hours. Encouraging results of studies that removed the drain at the daily volume of 450 ml [3], or did not even take the daily volume of drainage into considera-

Tab. V. Complication rates in the study groups

Complications	Group I (Thopaz) (n = 32)	Group II (glass bottle) (n = 32)	p value
complication rate	25%	50%	0.039
cardiovascular and pulmonary complication rate	22%	47%	0.035
atrial fibrillation	16%	22%	0.522
prolonged air leak	6%	9%	0.641
atelectasis requiring bronchial aspiration	3%	16%	0.086
redrainage	0%	3%	0.313

Tab. VI. Detailed analysis of complications

Patient, age, operation	Complication
Patients with complications (n = 8) from group I (Thopaz) (n = 32)	
PC, 60, right upper lobectomy VATS	atelectasis requiring aspiration
BE, 60, right upper lobectomy	atrial fibrillation
DI, 75, right upper lobectomy	atrial fibrillation
SW, 64, right upper lobectomy	atrial fibrillation
KJ, 79, middle lobectomy	atrial fibrillation, persistent air leak
BR, 76, left upper lobectomy	atrial fibrillation, persistent air leak
KK, 57, right lower lobectomy	pneumonia
SL, 67, right upper lobectomy	cerebral stroke
Patients with complications (n = 16) from group II (glass bottle) (n = 32)	
SJ, 65, left lower lobectomy VATS	atelectasis requiring aspiration
MW, 74, middle lobectomy	atelectasis requiring aspiration
CM, 53, right upper lobectomy	atelectasis requiring aspiration
GW, 57, right upper lobectomy	atelectasis requiring aspiration
WE, 54, left lower lobectomy	atrial fibrillation
UK, 70, left upper lobectomy VATS	atrial fibrillation
CS, 71, left upper lobectomy VATS	atrial fibrillation
PR, 64, left lower lobectomy	atrial fibrillation
BT, 55, right lower lobectomy VATS	atrial fibrillation, atelectasis requiring aspiration
BR, 75, left upper lobectomy VATS	atrial fibrillation, persistent air leak
KA, 53, right lower lobectomy	atrial fibrillation, persistent air leak
BW, 58, right upper lobectomy VATS	recurrent pneumothorax
BU, 67, right upper lobectomy VATS	hematoma, redrainage
SG, 44, right lower lobectomy	hematoma, reoperation
KM, 75, left lower lobectomy	persistent air leak, bronchial stump fistula, chronic empyema
WM, 69, left lower lobectomy	redrainage due to pneumothorax

VATS – video-assisted thoracic surgery

tion [9], led us to set the acceptable daily drainage volume level at 350 ml. This volume represents the physiological daily production of fluid by the pleural cavity [1]. Despite the more liberal acceptable daily fluid volume, none of the 64 patients who entered the present study had to be redrained due to the presence of fluid in the pleural cavity.

In the present study, we did not discover any differences between the patients in the study and control groups pertaining to the drainage time or the duration of hospital stay. These two parameters usually strictly correlate [1, 2]. The results of this study do not confirm the results of previous studies, which reported a reduction of 1 day in postoperative stay [5, 10]. It should be emphasized that the differences between the modern and classical drainage systems may be observed when the daily fluid limit is relatively large. When the daily volume does not exceed 200 ml, the two types of drainage tend to be similar. Digital drainage devices, in contrast to classical drainage, enable the objective evaluation of residual air leakage, which allows the drain to be withdrawn within up to 2 days postoperatively in 85% of patients [11]. This benefit of gathering objective information about air leakage could be especially useful if the acceptable daily drainage volume is sufficiently high. It seems that the limit defined in this study (a daily fluid volume of 350 ml) could be still too low to demonstrate the clinical difference resulting from the implementation of digital chest drainage. The drainage period could be shortened, in comparison to classical drainage, if the acceptable daily fluid volume was equal to or exceeded 400 ml [10, 11].

Revealing the significant decrease in complication rates in the digital drainage group was the most important result of this study. Despite the equal drainage time in both study groups, a clear 50% reduction in general complications and a 54% reduction in cardiovascular and pulmonary complications were found. It is difficult to find a precise explanation for the demonstrated reduction in complications. The benefit constituted by this reduction of complications is not discussed widely in the literature. It is surprising that such a slight intervention as changing the drainage type would result in so significant a reduction in complication rates. The general complication rate in group II was mainly affected by atelectasis, atrial fibrillation and persistent air leaks. The decision to perform bronchial aspiration is undertaken subjectively by a physician and is based on the results of a clinical examination and chest X-ray. The study was not blinded, and in this case this could cause some bias. However, sufficient constant negative pressure in the pleural cavity acquired by digital drainage definitely helps to expand the lung. The slightly higher number of atrial arrhythmias in group II is the most difficult result to interpret. The importance of early postoperative recovery and patient mobilization after pulmonary resections is well documented [12, 13]. In our opinion, the compact dimensions of the device together with its light weight facilitate mobility and efficient rehabilitation starting from the first postoperative day, which definitely reduces perioperative risk. The third complication affecting the results is the less common persistent air leak in group I. Due to regulated suction, the draining period is shorter with a tendency towards lower incidence of persistent air leaks [10].

A rarely discussed aspect of the new drainage devices is the noise reduction. Silence in the patient's room during the early postoperative days reduces problems with night sleep [14]. This could be particularly important in hospital rooms without a central suction system, which require the use of loud installations that provide suction.

During the study period, a universal protocol of negative pressure applied to the pleural drain was implemented. For the first 2 days following the surgery, the drains were under a negative pressure of –15 cm H_2O; on subsequent days, the drainage was in gravitational mode. Studies that investigate the variation of pressures in the pleural cavity occurring when employing classical drainage have often revealed uncontrolled increases of pressure in the cavity, even to positive values. The reason for significant increases in pleural cavity pressure is the fluid retained in the connecting tube – the tube between the chest and the drainage device. If the fluid remains in the connecting tube, the external suction is reduced to zero. Moreover, in the case of even minimal air leakage, the fluid retained in the chest tube blocks the outflow of air, causing positive pressure and possibly resulting in pneumothorax. The Thopaz drainage device repeatedly measures the pleural pressure at the level of the patient and constantly clears the connecting tube, significantly enhancing lung expansion in the very early postoperative period – that is when active patient rehabilitation has not yet commenced.

Despite the fact that this observation involves only one patient in the control group, it is worth mentioning that none of the patients in the Thopaz group had to be redrained due to pneumothorax after drain removal (in contrast to the traditional drainage group). This observation is consistent with the experience of our department with using modern drainage devices since 2010. This dependable system provides an objective air leakage history for the last 24 hours, enabling optimal and safe decision making regarding drain removal.

The main bias concerning this study, as well as others involving digital drainage devices, is the lack of blinding. This challenge seems difficult to overcome in the daily routine of the clinical department with a high number of daily procedures. Secondly, the analysis of relatively small groups of patients established a very significant reduction of the complication rate. As in every study with a small number of involved patients, there is a chance that the results are incidental. However, the proper recruitment, strict inclusion criteria resulting in patient group homogeneity, and randomization entail that the results of this study must not be neglected.

Conclusions

Removing the chest drain at an elevated rate of 350 ml of daily fluid drainage is safe. The use of the Thopaz digital drainage device during the postoperative period significantly reduces the rate of postoperative complications.

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