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Running head: Suction on chest drains after lobectomy

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Classifications. Air leak, chest drain, electronic pleural drainage system, fast-track surgery, video-assisted thoracoscopic surgery, postoperative management.

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Abstract

**Background.** Management of chest drains following thoracic surgery remains an area with little consensus. To optimize our chest drainage algorithms with electronic chest drainage systems we conducted a randomized controlled trial comparing low variable suction (-5 cm H₂O) versus high variable suction (-20 cm H₂O).

**Methods.** We did a prospective open label randomized trial in patients undergoing lobectomy. Sample size was calculated from a clinical relevant difference in chest drain duration as one full day. Endpoints were chest drain duration and length of hospitalization. Data were analyzed by Kaplan-Meier survival analysis and multivariate Cox proportional hazards regression.

**Results.** We randomized 106 patients. There was no statistical significant difference in chest drain duration and length of stay between the low suction and the high suction groups: Median chest drain duration and hospitalization were 25 hours (IQR (interquartile range) 21-55) versus 28 hours (IQR 23-77; p=0.97) and 5 days (IQR 3-6) versus 5 days (IQR 3-7; p=0.75), respectively. Multivariate analysis demonstrated that DLCO (the diffusing capacity of the lung for carbon monoxide) was the only significant predictor of chest drain duration (p=0.015) and length of hospitalization (p=0.003). Complications requiring re-insertion of the chest drain were significantly more frequent in the low suction group (p=0.03).

**Conclusions.** There was no clinical relevant difference in chest drain duration or length of hospitalization, but re-insertion of chest drains were significantly more frequent in the low suction group suggesting that low suction levels should not be used after lobectomy. Trial registry number ISRCTN10408356

(250 words)
Management of chest drains following thoracic surgery remains controversial. Air and fluid needs to be evacuated to restore a fine balance in the pleural space in such a way that it is both safe for the patient and with as little discomfort and restriction as possible. There is still no consensus whether external suction is important to reduce chest drain duration or length of hospitalization. In favor of applying external suction is that suction re-expands the remaining lung after lobectomy. In contrast, at least in some patient groups, application of suction is claimed to maintain air leaks and thus prolongs chest drain duration [1, 2]. Several studies have compared application of external suction to a simple water seal without suction and their results are conflicting. Currently, the evidence “does not offer improved clinical outcomes” regarding duration of air leak, incidence of prolonged air leakage, chest drain duration or length of hospitalization when external suction is applied [3, 4]. The majority of previous studies, however, were done with conventional chest drainage systems with or without application of suction to the water seal. One of the arguments against application of external suction to a simple water seal drainage system is that it restricts the patients from mobilizing, but over the last decade new electronic chest drainage devices have been introduced that allow mobilization while variable suction is applied. A number of studies have compared electronic chest drainage systems with traditional drainage systems, and the majority of these were in favor of the electronic chest drainage system [5-7].

In a recent study we did not find any significant difference in chest drain duration and length of stay comparing the electronic chest drainage system with a traditional water seal. However, we continued to use the electronic chest drainage system because it allowed delegation of the decision to remove the chest drain to the staff nurses in patients who had an uneventful postoperative course [8]. To get a better practical understanding of the electronic chest drainage system and its use in our daily fast-track clinical practice we decided to investigate if the level of variable suction applied with the electronic chest drainage system to the chest drain after lobectomy would influence the chest drain duration and the length of hospitalization.
Patients and Methods

This trial was approved as a quality securing and quality developing project by the Regional Ethics Committee of Southern Denmark and the trial was approved by the Danish Data Protection Agency. Trial registry number ISRCTN10408356. We conducted the study in accordance with the Declaration of Helsinki. We wanted to investigate how variable suction influenced air leakage and fluid output following lobectomy. The study was designed as a university based single center randomized trial and we hypothesized that the level of variable suction applied has no effect on chest drain duration. We powered the study to detect a clinical relevant difference of at least one full day of chest drain duration, regardless of fluid output. In addition, we wanted to study the effect of suction on the amount of pleural fluid and these results have been reported elsewhere [9].

All patients admitted for standard lobectomy, age older than 18 years and the ability to give informed consent were eligible for inclusion. Exclusion criteria were: previous history of pulmonary or cardiac surgery, expected difficulties with postoperative mobilization, participation in concomitant research studies in our department where a different chest drainage protocol could influence results, expected postoperative mechanical ventilation, insertion of more than one chest drain and finally bilobectomy or middle lobectomy. One day prior to surgery the consultant surgeon determined if the patient could be enrolled according to the protocol and written informed consent was obtained from all patients.

At the surgeon’s discretion all patients underwent standard lobectomy by video-assisted thoracoscopic surgery (VATS) or thoracotomy. Epidural catheter pain management was used in all patients because this was our standard procedure. All patients received a single dose of antibiotics preoperatively. Hilar structures were dissected anatomically and divided by mechanical staplers, and systematic lymph node dissection of the hilar and two mediastinal lymph node stations was performed in every patient. Only a single standard chest drain was placed (size Charrière 24 inner/outer diameter 5.0/8.0 mm, Silicone Drain® by ConvaTec Limited, Deeside, Flintshire, UK) at the end of the surgery. The chest drain was connected to an electronic drainage
system (Thopaz Digital Chest Drainage System® by Medela AG, Baar, Switzerland) after the system was tested to ensure proper function.

All patients were subsequently randomized (1:1) by sequentially numbered, opaque and sealed envelopes to receive either low variable suction (-5 cm H$_2$O) or high variable suction (-20 cm H$_2$O) on a digital drainage device. The study was not blinded as it was necessary to observe the graphic display on the electronic chest drainage system to determine when the chest drain could be removed according to protocol. Thus, this was an open labeled randomized study.

Patients followed a routine postoperative course including pain management: following the surgical procedure they were transferred to a recovery unit for a few hours and subsequently to the thoracic surgery ward, where they were mobilized according to department guidelines on the same day of surgery. The staff nurses checked the chest drain according to the protocol at least once in every shift (3 shifts of 8 hours each per 24 hours). The decision to remove the chest drain was delegated to the staff nurse in charge of the patient and removal followed a strict algorithm in all patients: when airflow had decreased to $\leq 20$ ml/min for 6 consecutive hours or $\leq 50$ ml/min for 12 consecutive hours without any visible spikes on the digital display in a patient, who was fully mobilized and sufficiently relieved of pain to allow for coughing with a pain score less than 3 on a visual analogue scale of 1-10 [8, 10]. Chest drains were removed regardless of fluid output providing that it was serous and not chylous or bloody without transparency [9]. In instance of complications the attending physician was contacted. By routine in our department the first postoperative chest X-ray was always postponed until 2 hours following chest drain removal unless the patient developed hemodynamic or respiratory problems during the postoperative course. The primary endpoint was chest drain duration and the secondary endpoint was length of hospitalization. Sample size was calculated from a clinical relevant difference in chest drain duration as one full day [8], from an estimated average chest drain duration of 3.0 days (SD 1.5 days) versus 2.0 days (SD 1.5 days). Alpha was set at 0.05 and power (beta) at 90%, which resulted in a sample size of 53 patients in each group.
Data were collected pre-, peri- and postoperatively and included: Age, gender, forced expiratory volume in the first second (FEV1), diffusing capacity of the lung for carbon monoxide (DLCO), surgical approach, the resected lobe, adherences and completeness of fissure. Any need for chest drain reinsertion following removal, pleurocentesis or development of pleural empyema within 30 days or postoperative pneumonia was also recorded. All patients were seen 14 days after surgery in our outpatient clinic.

Data were analyzed by Kaplan-Meier survival analysis and multivariable Cox regression analysis. In the multivariable model we included the following parameters: level of suction (low/high), gender (male/female), lobe (upper or lower), surgical approach (VATS or thoracotomy), lung function (DLCO) and peri-operative air leakage (yes/no). All statistical analyses were performed using IBM’s SPSS 24.0 statistical software, and statistical significance was determined as p<0.05.

Results
A total of 248 lobectomies for lung cancer were performed in a 13-month period (March 2015 – April 2016). The CONSORT diagram (Figure 1) demonstrates that we included 106 patients in this trial [11]. Baseline characteristics are shown in Table 1. Low variable suction was applied in 53 patients (VATS/thoracotomy 34/19) and high variable suction in the remaining 53 (VATS/thoracotomy 25/28).

A total of 7 protocol violations occurred (Figure 1): Reasons in the low suction group was increased suction from -5 cm H$_2$O to -15 cm H$_2$O because of progressing subcutaneous emphysema (n=1), technical problems from the drainage system with repeated alarms (n=1), and increased suction to -10 cm H$_2$O by mistake (n=1). In the high suction group violations were decreased suction level to -5 cm H$_2$O for unknown reasons perhaps by mistake (n=2) and a change from electronic to traditional water seal drainage system for unknown reasons perhaps by mistake (n=2). All patients that violated the study protocol were analyzed as intention-to-treat.
Six chest drains could be removed on the same day of surgery according to the protocol algorithm - all in the low suction group. One patient required re-insertion of a chest drain on the same day of removal due to pneumothorax. One patient in the low suction group developed chylothorax and the chest drain was removed on POD12 after appropriate treatment. Two patients were re-operated on the same day of surgery because of bleeding (one patient in each group) and the chest drain duration in both was calculated from the primary operation to chest drain removal. All three patients were included in our data analysis according to the intention-to-treat principle.

Eight patients required re-insertion of their chest drain because of complications and this was more frequent in the low suction group (7 patients versus 1 patient; p=0.03). The reason was progressing pneumothorax after removal of chest drain in 5 patients (one patient on day 0, two on day 2, one on day 3 and the last patient when re-admitted on postoperative day 8 with pulmonary edema and pneumothorax). Another reason was progressing subcutaneous emphysema in one patient, who was re-admitted on day 10. Lastly, a pleurocutaneous fistula in the old drain incision was the reason for re-insertion of a chest drain after re-admittance in one patient in the low suction group. In the high suction group one patient needed re-insertion of a chest drain because of pneumothorax on postoperative day 4. Only one of the eight patients that required re-insertion of the chest drain had the chest drain removed with an air flow of more than 20 ml/min according to the algorithm (spikes to 30 ml/min). Six had “No air leak” detected peri-operatively and air flow in the recovery of 0 ml/min in 4 patients, 10 ml/min in 1 patient and 130 ml/min in 1 patient. Two patients had an air leak peri-operatively and an air flow of respectively 20 ml/min and 80 ml/min (this patient was in the high variable suction group). Table 2 shows the distribution of air leaks and air flows peri-operatively and in the recovery room in the two groups.

Other complications were pneumonia in one patient, who was re-admitted shortly after discharge. Another patient developed a torqued middle lobe and was re-operated. Prolonged air leak (defined as air leak > 5 days [12]) was seen in 4 patients in the low suction group and in 7 patients in the high suction group (p=0.34).
Median chest drain duration and hospitalization were 25 hours in the low suction group (IQR 21-55) versus 28 hours in the high suction group (IQR 23-77) and 5 days (IQR 3-6) versus 5 days (IQR 3-7), respectively (Table 3). There was no statistical significant difference in chest drain duration (p=0.97) or length of stay (p=0.75) between the low suction and the high suction groups. Multivariate Cox regression analysis revealed that DLCO was the only significant predictor of chest drain duration (p=0.015) and length of hospitalization (p=0.003).

Comment

We found no significant difference in chest drain duration or length of stay in patients who were treated with low variable suction compared with high variable suction following lobectomy for lung cancer when using an electronic drainage device. We used -20 cm H$_2$O as the high variable suction level because this has been used previously in the literature [4]. We used -5 cm H$_2$O in the low variable suction group, and at the time we designed the study, we did not consider to use -8 cm H$_2$O, which the electronic drainage device company defines as equivalent to passive drainage, because we wanted to investigate as high a difference between the two levels of suction as possible and because we routinely use -5 cm H$_2$O in patients with very fragile lung parenchyma. Multivariate analysis identified DLCO as the only predictor of both chest drain duration and length of stay, which is not new to thoracic surgeons as poor lung function is known to be a risk factor of prolonged air leak [13]. It was interesting to note that perioperative air leakage was not a predictor of chest tube duration or length of stay. One would have expected that peri-operative air leakage would influence length of chest tube duration and we have no explanation except to say that thoracic surgeons often experience that air-leakage detected during the operation has ceased in the recovery-room and vice versa. In retrospect we realize that it would have been ideal to stratify patients before randomization based on presence or absence of perioperative air leakage.

It is noteworthy that there were significant more complications in the low suction group that required re-insertion of a chest drain. This suggests that a higher level of suction should
be used routinely following lobectomy in the fully mobilized patient, when working with the electronic digital drainage system that we used.

The present study has limitations: we used an open-labeled randomization because we wanted to observe the digital graphs on the electronic chest drainage system display to determine when the chest drain could be removed and consequently our study was not blinded. However, we do not suspect that this would influence the duration of chest drainage because removal followed a strict protocol. It was a problem that many eligible patients during the study period were not included for unknown reasons as seen in the CONSORT diagram (Figure 1), but since the patients were subsequently randomized we do not think that this would influence our results. We admit that stratifying for the surgical approach (VATS or thoracotomy) during the randomization process would have been ideal, but it was simply not thought of when the study was designed. Our multivariate analysis, however, did not reveal that surgical approach was a significant predictor of air leakage.

One may also argue that we used an incorrect algorithm for chest drain removal, which did not apply to a low variable suction group because so many drains had to be reinserted. Thus, although purely speculative, if one decided to use low negative variable suction it would make sense to test that the ceased air leak was true by applying a higher negative pressure variable suction to the chest drain for a brief period before removing it. We did not consider this to be a problem because the low variable suction level had been used in previous studies, although with a different chest drain removal algorithm [14].

In conclusion, we found no significant difference in chest drain duration and length of stay between the two groups. The only predictor of chest drain duration and length of hospitalization in this study was DLCO. Our study demonstrates that more complications occur following chest drain removal when low suction is applied, which suggests that suction should be used routinely following lobectomy.
References


### Table 1. Comparison of Baseline Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>- 5 cm H$_2$O (n=53)</th>
<th>- 20 cm H$_2$O (n=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), years</td>
<td>69 (42-81)</td>
<td>69 (46-88)</td>
</tr>
<tr>
<td>Male / female</td>
<td>23 / 30</td>
<td>27 / 26</td>
</tr>
<tr>
<td>VATS / thoracotomy</td>
<td>34 / 19</td>
<td>25 / 28</td>
</tr>
<tr>
<td>Upper / Lower lobectomy</td>
<td>25 / 28</td>
<td>25 / 28</td>
</tr>
<tr>
<td>FEV$_1$, mean ± SD, %</td>
<td>88.4 (20.6)</td>
<td>83.6 (19.7)</td>
</tr>
<tr>
<td>DLCO, mean ± SD, %</td>
<td>77.4 (20.1)</td>
<td>73.7 (17)</td>
</tr>
<tr>
<td>Incomplete fissure or adhesions, %</td>
<td>36</td>
<td>47</td>
</tr>
</tbody>
</table>

DLCO = diffusing capacity of the lung for carbon monoxide; FEV$_1$ = forced expiratory volume in 1 second; VATS = video-assisted thoracoscopic surgery.

$^a$ Reproduced from Lijkendijk and colleagues [9] with permission from The Society of Thoracic Surgeons.
Table 2. Air leak

<table>
<thead>
<tr>
<th>Air leak</th>
<th>- 5 cm H₂O</th>
<th>- 20 cm H₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peri-operative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No air leak</td>
<td>38 (71.7%)</td>
<td>27 (50.9%)</td>
</tr>
<tr>
<td>Air leak</td>
<td>15 (28.3%)</td>
<td>26 (49.1%)</td>
</tr>
<tr>
<td><strong>Post-op recovery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No air flow</td>
<td>22 (41.5%)</td>
<td>16 (30.2%)</td>
</tr>
<tr>
<td>&lt; 100 ml/min</td>
<td>23 (43.4%)</td>
<td>28 (52.8%)</td>
</tr>
<tr>
<td>100-1000 ml/min</td>
<td>7 (13.2%)</td>
<td>4 (7.5%)</td>
</tr>
<tr>
<td>&gt; 1000 ml/min</td>
<td>1 (1.9%)</td>
<td>5 (9.4%)</td>
</tr>
</tbody>
</table>
Table 3. Median and IQR

<table>
<thead>
<tr>
<th>Outcome</th>
<th>- 5 cm H₂O</th>
<th>- 20 cm H₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest drain duration* / hours</td>
<td>25 (21-55)</td>
<td>28 (23-77)</td>
</tr>
<tr>
<td>Length of stay** / days</td>
<td>5 (3-6)</td>
<td>5 (3-7)</td>
</tr>
</tbody>
</table>

*chest drain duration median and IQR (interquartile range) 1st and 3rd quartile in parenthesis.**length of stay in median and IQR.
Figure legend

Figure 1: Flow diagram according to Consolidated Standards of Reporting Trials (CONSORT).
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Enrollment

Assessed for eligibility (n=248)

- Excluded (n=142)
  - Not meeting inclusion criteria (n=35)
  - Participation in other studies (n=27)
  - Bi-lobectomy (n=3)
  - Pneumonecctomy (n=2)
  - Sublobar resection (n=1)
  - Exploratory thoracotomy (n=1)
  - Unavailable electronic drainages system (n=1)
  - Declined to participate (n=6)
  - Outright exclusion / unknown reason (n=101)

Randomized (n=106)

Allocation

Allocated to external suction -5 cm H$_2$O (n=53)
- Received allocated intervention (n=53)

Allocated to external suction -20 cm H$_2$O (n=53)
- Received allocated intervention (n=53)

Follow-Up

Lost to follow-up (n=0)
- Discontinued intervention/violated study protocol (n=3)
  - Subcutaneous emphysema (n=1)
  - Technical problems (n=1)
  - Increase in suction by mistake (n=1)

Lost to follow-up (n=0)
- Discontinued intervention/violated study protocol (n=4)
  - Change in suction (n=2)
  - Change of drainage system (n=2)

Analysis

Analysed (n=53)
- Excluded from analysis (n=0)

Analysed (n=53)
- Excluded from analysis (n=0)