Electronic versus traditional chest tube drainage following lobectomy: a randomized trial

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Abstract

OBJECTIVES: Electronic drainage systems have shown superiority compared with traditional (water seal) drainage systems following lung resections, but the number of studies is limited. As part of a medico-technical evaluation, before change of practice to electronic drainage systems for routine thoracic surgery, we conducted a randomized controlled trial (RCT) investigating chest tube duration and length of hospitalization.

METHODS: Patients undergoing lobectomy were included in a prospective open label RCT. A strict algorithm was designed for early chest tube removal, and this decision was delegated to staff nurses. Data were analysed by Cox proportional hazard regression model adjusting for lung function, gender, age, BMI, video-assisted thoracic surgery (VATS) or open surgery and presence of incomplete fissure or pleural adhesions. Time was distinguished as possible (optimal) and actual time for chest tube removal, as well as length of hospitalization.

RESULTS: A total of 105 patients were randomized. We found no significant difference between the electronic group and traditional group in optimal chest tube duration (HR = 0.83; 95% CI: 0.55–1.25; P = 0.367), actual chest tube duration (HR = 0.84; 95% CI: 0.55–1.26; P = 0.397) or length of hospital stay (HR = 0.91; 95% CI: 0.59–1.39; P = 0.651). No chest tubes had to be reinserted. Presence of pleural adhesions or an incomplete fissure was a significant predictor of chest tube duration (HR = 1.72; 95% CI: 1.15–2.77; P = 0.014).

CONCLUSIONS: Electronic drainage systems did not reduce chest tube duration or length of hospitalization significantly compared with traditional water seal drainage when a strict algorithm for chest tube removal was used. This algorithm allowed delegation of chest tube removal to staff nurses, and in some patients chest tubes could be removed safely on the day of surgery.

Keywords: Air leak • Chest tube • Electronic pleural drainage system • Pulmonary lobectomy • Fast-track surgery • Postoperative management

INTRODUCTION

Chest tubes are used to evacuate air and fluids following lung resections, and can be used to monitor when drainage of the chest cavity is sufficient. Until recently, this field has been managed from a traditional paradigm or empirical evidence [1]. A number of factors influence the duration of treatment with chest tubes, one of these being the clinical decision per se to remove the chest tube, which has been shown to have interobserver variability [2].

Electronic drainage systems have shown increased agreement rate concerning clinical decision making regarding chest tube removal [2]. Besides adding objectivity to the clinical decision of chest tube removal, electronic drainage systems have shown superiority to traditional drainage systems in a limited number of studies. At present, there are five prospective randomized trials comparing electronic with traditional chest tube drainage [3-7]. In addition, there are observational studies [8, 9]. Most studies included various types of lung resections, and used algorithms with external suction in both groups of varied length and strength [2, 3, 6-11].

In our institution, we routinely use traditional water seal chest drainage without external suction to facilitate early mobilization postoperatively. Until the advancement of an electronic drainage system that allowed mobilization with the device, it was not possible to apply suction without immobilizing patients to the extent of the suction tube. So far, studies evaluating suction versus water seal have not collectively given clear-cut recommendations on how to manage chest tubes following lung resections [12-15]. With the advent of the electronic drainage system, we wanted to test this system versus our routine drainage system, where both study groups had equal opportunity to mobilize early postoperatively. In addition, because of ever increasing demands to reduce costs, hospital stay and document quality in patient care, we decided to conduct a randomized controlled trial as part of a medico-technical...
evaluation before adopting electronic drainage systems as a routine following thoracic surgery.

METHODS

The present study was approved by the Regional Ethics Committee and the Danish Data Protection Agency. The study was powered to detect a difference in length of hospitalization of at least 1 day because a shorter hospital stay would reduce costs. Eligible for inclusion were all patients admitted for lobectomy by thoracotomy or video-assisted thoracic surgery (VATS), age older than 18 years and who were able to read and understand the information regarding the study.

Exclusion criteria were as follows: previous history of pulmonary or cardiac surgery, expected difficulties with postoperative mobilization, patients not able to co-operate with a lung physiotherapist, participation in concomitant studies or trial in the department, where a different drainage protocol could influence results, postoperative mechanical ventilation, the insertion of more than one chest tube perioperatively and finally bilobectomy or middle lobectomy.

Patients were enrolled into the study by the thoracic surgeons 1 day prior to surgery, when being examined and evaluated for surgery. Written informed consent was obtained from all patients.

Data collection included the following: age, gender, BMI, forced expiratory volume in 1 second (FEV1), type of surgery, state of the inter-lobar fissure, pleural adhesions, postoperative pain score (VAS) with regard to chest tube removal and air leakage three times every day until chest tube removal. Study endpoints were as follows: time of optimal chest tube removal — meaning when it was possible according to the criteria of removal, time of actual chest tube removal — meaning when it was actually removed and length of stay (LOS) in hospital, which was the primary outcome. Complications such as need for chest tube reinsertion, need of pleurocentesis within 30 days, development of pleural empyema within 30 days and any need of antibiotic treatment for postoperative pneumonia were also registered.

A standard chest tube (Ch. 24) was placed routinely at the end of the lobectomy procedures. Following surgery, while still on the operating table, patients were randomized to receive intervention with either an electronic drainage system, Thopaz® (Medela AG, Baar, Switzerland) or a traditional drainage system, Thora-Seal® (Covidien, Mansfield, MA, USA) (Fig. 1). Randomization was done by use of sequentially numbered, opaque, sealed envelopes managed by the research unit of the department. Once the surgeon determined that there were no intraoperative exclusion criteria present (i.e. need of two chest tubes or bilobectomy), the sealed envelope was opened by the research unit, and read to the surgeon at the end of surgery.

Intervention by electronic drainage also included continuous suction effect of ≈15 cm H2O whereas traditional drainage by a single chamber 370 ml water seal used simple gravity without a possibility of applying external suction. The large water seal is used routinely in the department to prevent reverse air flow [16].

All the patients subsequently followed our routine postoperative observation regimen and pain management, and they were mobilized on the same day of surgery. Chest tubes were removed using the following strict algorithm: In the electronic group, the chest tube was considered eligible for removal when air leakage had ceased to ≤20 ml/min for 6 consecutive hours or ≤50 ml/min for 12 consecutive hours without any visible spikes on the digital display [17], and always in a fully mobilized patient with no or just minor pain (VAS-level 2–3 on a 10-point scale).

In the traditional group, the chest tube was considered eligible for removal when no air bubble was visible in the water seal during coughing on a fully mobilized patient with no or just minor pain (VAS-level 2–3 on a 10-point scale).

In both groups, the earliest time allowed for removal was 6 h postoperatively, and for this it was also required that fluid production was serous with a total volume of <200 ml on the day of surgery or <400 ml on the following day, as this is our routine management.

Figure 1: The two drainage systems used. The Thopaz system by Medela to the left and the Thora-Seal system by Covidien to the right.
The study was open labelled as blinding was impossible with two different drainage systems (Fig. 1). Once the chest tubes were removed, surgeons and staff nurses were typically unaware of which chest tube drainage system had been used. This information was not blinded, but our staff would have to actively seek this information going back in the electronic medical charts.

Chest tubes were observed at least once in every work shift by the staff nurses (three shifts of 8 h each per 24 h), and the decision of chest tube removal was delegated to the clinical staff nurse in charge of the patient. Chest X-rays were routinely obtained 2 hours after removal of the chest tube and again 10–14 days following surgery in our outpatient clinic.

Statistical analysis consisted of Cox proportional hazard regression analysis adjusting for FEV1 (categorized as <70, 70–90, >90%), gender, age (categorized as <60, 60–70, >70 years), BMI (categorized as <25, 25–30, >30), surgical approach (VATS or open surgery) and presence of pleural adhesions and/or incomplete inter-lobar fissures. Time was distinguished as possible (optimal) and actual time for chest tube removal, as well as length of hospitalization. Statistical significance was determined as \( P < 0.05 \). A \( \chi^2 \) test, Shapiro–Wilks test for normality and Student’s \( t \)-test for baseline variables were also used to compare the two groups. IBM’s SPSS 21.0 was used to perform statistical analysis. Nomenclature used in this paper is in accordance with the consensus definitions [1].

**RESULTS**

A total of 338 lobectomies were performed between January 2012 and August 2013. Of these, 86 patients participated in other research studies, and were consequently excluded. Another 147 were either not assessed for inclusion because of oversight or did not meet the inclusion criteria. No patient that was asked to participate refused, and this left 105 patients for randomization. A flow diagram of the study is illustrated in Fig. 2. Baseline variables were similar between the two groups with no significant differences as given in Table 1.

We found no significant difference between the electronic group and traditional group in optimal chest tube duration on intention-to-treat basis (HR = 0.83; 95% CI: 0.55–1.25; \( P = 0.367 \) (Fig. 3), actual chest tube duration (HR = 0.84; 95% CI: 0.55–1.26; \( P = 0.397 \)) (Fig. 4) or length of hospital stay (HR = 0.91; 95% CI: 0.59–1.39; \( P = 0.651 \)).

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**Figure 2: Flow diagram of the trial according to CONSORT [18].**
The presence of pleural adhesions or an incomplete fissure was a significant predictor of chest tube duration (HR = 1.72; 95% CI: 1.12–2.65; P = 0.014), but surgical approach was not (HR = 0.95; 95% CI: 0.61–1.48; P = 0.826).

The protocol was violated in four instances in the electronic group by switching drainage system. Another patient was an outlier with a 35-day hospitalization resulting from a complicated postoperative course following resection of a large completely necrotic tumour occupying the entire lobe, which was removed in a contaminated chest cavity. We decided to perform the analysis per-protocol without the 5 patients mentioned, and found no significant difference between the electronic group and traditional group in optimal chest tube duration (HR = 0.80; 95% CI: 0.52–1.22; P = 0.297), actual chest tube duration (HR = 0.80; 95% CI: 0.52–1.22; P = 0.301) or length of hospital stay (HR = 0.71; 95% CI: 0.46–1.11; P = 0.137). FEV₁ (HR = 0.41; 95% CI: 0.20–0.84, P = 0.049) and the presence of pleural adhesions or an incomplete fissure (HR = 1.60; 95% CI: 1.03–2.46, P = 0.036) were both significant predictors of chest tube duration. Medians and IQR’s for the groups are given in Table 2.

Removal of six chest tubes was postponed on the basis of fluid production >400 ml.

Six chest tubes (five in the electronic group and one in the traditional group) were removed safely on the same day of surgery, with no need for reinsertion of chest tubes. According to our algorithm, 15 chest tubes could have been removed on Day 0. However, most chest tubes were removed in close proximity to the morning rounds as shown graphically in Fig. 6. All chest tubes were removed prior to discharge, and all patients discharged to their homes.

**DISCUSSION**

This study found no significant difference on the overall chest tube duration and LOS between the electronic drainage system and the traditional water seal drainage, and therefore our results
The time when the algorithm for chest tube removal was fulfilled.

Table 2: Descriptive numeral comparison of endpoints between the two groups

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Intention-to-treat</th>
<th>Per-protocol</th>
</tr>
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<tbody>
<tr>
<td>Chest tube duration</td>
<td>Electronic (n = 55)</td>
<td>Traditional (n = 50)</td>
</tr>
<tr>
<td>Chest tube duration</td>
<td>27 (18-57)</td>
<td>43.5 (21-66)</td>
</tr>
<tr>
<td>Chest tube duration</td>
<td>41 (22-68)</td>
<td>46.5 (24-70)</td>
</tr>
<tr>
<td>Length of stay</td>
<td>4 (3-6)</td>
<td>5 (3-6)</td>
</tr>
<tr>
<td>Length of stay</td>
<td>2.2 in the traditional group</td>
<td>4.4 in the traditional group</td>
</tr>
<tr>
<td>Duration (FEV1) were all signi</td>
<td>2.5 days in the electronic group vs 4.4 in the traditional group</td>
<td></td>
</tr>
<tr>
<td>Length of stay</td>
<td>4 (3-5)</td>
<td>5 (3-6)</td>
</tr>
</tbody>
</table>

Results are shown descriptively as median in hours (chest tube duration) with IQR in parenthesis and median in days (length of stay).

The time when the algorithm for chest tube removal was fulfilled.

Figure 6: Illustration of chest tube removal in close proximity to morning rounds (Fig. 6), which could reflect that staff nurses were not comfortable making the decision to remove a chest tube despite our algorithm or that it was simply daytime when most staff were present.

One of our contraindications for chest tube removal was fluid production of more than 400 ml, which postponed chest tube removal in 6 patients. The clinical significance of higher serous fluid production was recently studied by Bjerregaard et al. [22] who demonstrated that even with a serous fluid production of 500 ml, chest tubes could be removed safely following VATS lobectomies, but this information was not available to us at the time we designed the protocol.

The present study has limitations. Most apparent is the fact that the intervention was not blinded to the patients and staff in the ward. Also, the intervention in the electronic drainage system group did in fact consist of two simultaneous interventions compared with the control group with a traditional drainage system, namely that it was electronic and at the same time applied suction. As emphasized in the introduction, our routine is to facilitate early mobilization in all patients, and this would not have been possible if we applied external suction to our traditional drainage system. On the basis of this, there could be statistical interactions that we cannot account for. It may also be argued that because of the limited sample size, we may have overlooked a difference between the two drainage systems, which was less than 1 day, but the study was powered to detect a difference in length of hospitalization of at least 1 day because this was considered to be a clinically relevant difference for the patient or a shorter hospital stay would reduce costs.

In striving to minimize hospital stay and reduce costs, our experience with a strict algorithm for chest tube removal could be valuable way forward for others regardless of choice of drainage system. However, the fact that there was no difference in LOS between the electronic drainage system used and traditional drainage by water seal suggests that factors besides chest tube duration need attention as well to facilitate fast-track thoracic surgery.

In conclusion, this study found no significant difference in chest tube duration or length of hospitalization, but the electronic device facilitated delegation of chest tube removal to the staff nurses, because it could be evaluated objectively, and because clear algorithms for removal were defined.

Conflict of interest: none declared.
REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr M. Ibrahim (Rome, Italy): Even though this study arrives after the publication of a meaningful multicentre international clinical trial evaluating the outcomes of electronic and traditional chest drainage systems, it seems to bring new insight into the topic. I have a few questions for you in order to clarify some aspects.

First of all, you removed the chest tube when no bubbles were visible in the analogue chest drainage system and when the air leaks were less than 20 ml/min for 6 consecutive hours or less than 50 ml/min for 12 h in the digital group. There is a clear discrepancy between the two groups in terms of the air leak management. This could represent an important bias. What is your opinion on this?

Dr Lijkendijk: I agree that it could represent a bias. Maybe if we had looked at the analogue chest drainage system and allowed tiny bubbles before removing chest tubes, it could have been fairer to the Thora-Seal chest drainage group.

We know that there is a lot of inter-observer variability when removing chest tubes postoperatively, and so we needed to have clear criteria as to how we have to remove the chest tubes. Actually, the Thora-Seal group was managed, and the analogue chest tube drainage system was managed as we used to do in our department. We used to remove the chest tubes when there was no air leakage. So there was nothing different in how we managed these patients and this drainage type system.

As for the criteria that we used in the digital group, we looked to the literature and found a study by Dr Cerfolio, who used the 20 ml/min criterion when removing the digital chest tube device. The 50 ml/min is a criterion that was used in another thoracic centre in Denmark for quite some time successfully. So these are the reasons we chose to have this algorithm.

Dr Ibrahim: Secondly, you claim to have planned chest tube removal if the fluid production was less than 400 cc, but you don’t clarify if you have considered the characteristics of the fluid.

Moreover, the average time of chest tube duration was very short, as you have shown. For that reason, it could be interesting to know the duration in the subset of patients who had undergone VATS lobectomy and how it might have influenced the results. Do you have the hard data about this? Alternatively, are you planning on obtaining them and using them for further studies?

Dr Lijkendijk: As regards the fluid, how was the fluid?

Dr Ibrahim: Yes.

Dr Lijkendijk: We did observe the patients for signs of ongoing bleeding. Obviously, we didn’t remove the chest tubes if this was the case.

And as for the data on the VATS subgroup, I do have some data with me concerning the length of hospital stay, but unfortunately, we didn’t extract the data on chest tube duration yet. It is something that we will use further. The data on the length of hospital stay in the VATS subgroup is in actual numbers very similar to the thoracotomy subgroup.

Dr Ibrahim: Okay. And the last question, I seem to have understood that the digital group received 15 mmHg suction. Otherwise, the analogue group did not receive suction; is that correct? And I think this aspect could have influenced the results. What do you think?

Dr Lijkendijk: Yes. We are not convinced that applying suction would benefit or facilitate an early chest tube removal. We used suction in the digital device because it’s recommended by the company, and if we don’t use suction, it works with a one-way valve only, the Thopaz system.

We believe that essentially, it’s a study comparing two different drainage systems and way of handling the postoperative chest tube management, and we choose to focus on the mobilization of the patient and wanted to not put suction on our traditional device as it would make the patient stay near a suction line. So this is why we did this.

Dr T. Treasure (London, UK): In electronics, there is a clear distinction between digital and analogue signals but in your very nice study, you are replacing visual inspection with an electronic device.

Dr Lijkendijk: Yes.

Dr Treasure: It is the detection device which is digital. There is an implied dichotomy, that if it isn’t digital must be analogue, which doesn’t apply to chest tubes. Do you want to defend the use of the word ‘analogue chest tube’? Otherwise, I would suggest we don’t perpetuate it because what you are talking about is visually inspected conventional chest drain.

Dr Lijkendijk: Yes. Well, we could have used conventional chest drainage.

Dr Treasure: As Dr Ibrahim did.

Dr Lijkendijk: Yes, yes, exactly. Well, I don’t have a long explanation of why we used that word instead of conventional.