Randomized trial of digital versus analog pleural drainage in patients with or without a pulmonary air leak after lung resection

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ABSTRACT

Objective: An unclear aspect of digital pleural drainage technology is whether it can benefit all lung resection patients or only those who have a postoperative air leak. The aim of this study was to evaluate the impact of digital pleural drainage on time to chest tube removal and length of hospitalization, taking into consideration postoperative air leak status.

Methods: A single-center, randomized, controlled, open-label, parallel-group trial was conducted. On postoperative day 1, stratification according to air leak status was performed by 2 independent, blinded observers. Patients were randomized to a water-sealed, pleural drainage device (analog) or to a digital device (digital).

Results: In both air leak groups (no air leak = 87; air leak = 85), patient factors and operative details were comparable. In the no air leak group, the difference in median chest tube drainage between analog and digital randomization arms was not statistically significant (3 days vs 2.9 days; $P = .05$). Median length of stay was also comparable in that group (analog = 4.3 days; digital = 4 days; $P = .09$). In patients with an air leak, similar findings were observed for chest tube duration (analog = 5.6 days; digital = 4.9 days; $P = .11$) and length of stay (analog = 6.2 days; digital = 6.2 days; $P = .36$). Chest tube clamping trials were significantly reduced in the digital arm of the air leak absent (0% vs 16%; $P = .01$) and air leak present groups (23% vs 50%; $P = .01$).

Conclusions: Although digital devices decreased tube clamping trials, the impact on duration of chest tube drainage and hospital stay was not statistically significant, even after stratifying by postoperative air leak status. (J Thorac Cardiovasc Surg 2015;150:1243-51)

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Central Message

Although digital devices decreased clamping trials, their impact on chest tube duration or length of stay was not statistically significant.

Perspective

In contrast to previous literature, this trial evaluated the impact of digital pleural drainage technology while taking into account postoperative air leak status after lung surgery. Based on the results, we cannot recommend its use as an intervention aimed solely at reducing length of stay. We acknowledge that this technological advance presents other opportunities to improve patient care.

See Editorial Commentary page 1252.

Digital pleural drainage devices make use of electronic sensors to measure and record air leak flow from chest tubes, and they can provide a graphical display of air leak trend over time. Trials comparing digital systems to conventional, water-sealed, analog systems have shown an association among use of digital drainage devices, decreased duration of chest tube drainage, and shorter duration of hospitalization.[1-4] This association is presumably related to chest tube management being more efficient as a result of technologic advances in pleural pressure regulation, air leak measurement accuracy, and air leak trend monitoring.

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Abbreviations and Acronyms
CI = confidence interval
CONSORT = Consolidated Standards of Reporting Trials

Given that previous trials have not defined a participant's air leak status before randomization, the impact of this postoperative factor on the apparent benefits of the technology is largely unknown. The objective of this study was to examine the relationships among digital pleural drainage, time to chest tube removal, and length of hospital stay, taking into consideration postoperative air leak status. The hypothesis was that clinical outcomes associated with the use of digital drainage devices would improve, irrespective of air leak status after lung resection.

METHODS

Patient Enrollment and Selection

Prior to initiation of the trial, approval was obtained from the institutional research ethics board. The trial was designed and implemented according to the 2010 Consolidated Standards of Reporting Trials.[5] This is a single-institution, randomized, controlled, open-label, parallel-group trial involving 6 participating thoracic surgeons. A preliminary study was conducted, comparing interobserver agreement in the assessment of pulmonary air leaks using analog versus digital systems.[6] As a result, the thoracic surgery team was introduced to the new technology prior to initiation of the trial.

Patients scheduled to undergo elective, sublobar, or lobar pulmonary resection for benign or neoplastic disease were potential candidates for inclusion in the trial. Exclusion criteria were as follows: development of tension pneumothorax; pneumonectomy; previous randomization at the time of an earlier operation; elapsed randomization window; treatment plan to remove, or removal of, all chest drains within 36 hours after surgery; transfer to the intensive care unit prior to randomization; inability to provide informed consent; and age <18 years. Eligible patients who had their chest tubes removed promptly after surgery (at ≤36 hours) were excluded from the trial because they would have remained in the study for a very short period of time (≤12 hours), and contributed data of limited clinical relevance to outcomes.

After randomization, patients who were transferred to the intensive care unit were excluded from the analysis, because critical illness and the need for mechanical ventilation usually lead to more-conservative chest tube management than that outlined in the study protocol. Patients for whom the intervention was discontinued because of reoperation for complications were analyzed in their respective randomization arms.

Clinical Outcomes

The primary study outcome was length of hospitalization, as defined by the interval between the end of surgery and the time of discharge from inpatient thoracic surgical care. The secondary outcome was duration of chest tube drainage, defined as the interval between the end of surgery and the removal of the last chest drain, or the end of surgery and discharge from the hospital with an indwelling drain. Length of stay was tabulated in discrete units of days; duration of chest tube drainage was calculated in hours and converted into days.

Ancillary outcomes included the following: complications related to chest tube removal (eg, new or worsening pneumothorax and/or increasing subcutaneous emphysema requiring chest tube reinsertion); number of pleural drain clamping trials; pleural drain fluid output; discharge from the hospital with an indwelling pleural drain; and number of postoperative chest radiographs after randomization. Other complications were compiled using our prospective, thoracic morbidity and mortality tracking system (ottawa.tmm.org).[7]

A chest tube management guideline was agreed on for the trial (Figure 1). In general, suction is applied to chest tubes immediately after surgery and discontinued on the first postoperative day, providing that subcutaneous emphysema is either absent or mild, and that the ipsilateral pneumothorax is determined to be ≤30% on chest radiograph. Suction would be resumed in the event of clinical deterioration after discontinuation. For this trial, subcutaneous emphysema was defined as mild when it was not readily visible and could be detected only by chest wall palpation or chest radiograph. Each posterior rib interspace occupied by a pneumothorax on chest radiograph accounted for a 10% volume estimate.

Serous or serosanguinous drainage of ≤250 mL in a 24-hour period was considered an acceptable fluid output threshold for chest tube removal. The fluid output criterion is an estimate of 24-hour pleural fluid turnover (0.15 mL/kg/hour) in a 70-kg patient.[8] For patients randomized to the digital device, the air leak flow parameters that indicated a resolved air leak and were considered safe for chest tube removal were as follows: air leak ≤40 mL/minute, with negative pressure applied (>8 mm Hg) or ≤20 mL/minute, while on gravity mode (≤8 mm Hg) for a minimum of 12 hours.

The air leak status of each participant was evaluated at least once daily at the time of morning inpatient rounds, and was documented in the trial database. For the analog system, an air leak was considered absent or resolved when bubbling was no longer seen in the water seal chamber on bedside assessment by the surgical team. With the digital device, a target intrapleural pressure was set and maintained by a feedback loop between electronic pressure sensors monitoring the pleural space and the unit's self-contained pump. When suction was applied using analog devices, a connection was made to an external suction source, and a target suction pressure was selected.

Air Leak Group Assignment and Randomization

Our clinical experience has been that the presence or absence of a postoperative air leak after lung resection can have a significant impact on duration of chest tube drainage and length of stay. Prerandomization stratification according to postoperative air leak status was implemented to minimize the impact of air leak duration as a confounding factor in the relationship between the intervention and the primary outcome. On postoperative day 1, independent assessments by 2 members of the surgical team were performed to determine air leak status. Participants were divided into 2 groups: those with an air leak (air leak present) and those without (air leak absent).

The air leak assessment was performed using an analog drainage system (Pleur Evac A-6002-08; Teleflex, Inc, Research Triangle Park, NC) set to −20 cm of water suction while patients purposely coughed 3 separate times. An air leak was considered to be present when air bubbles were seen in the water seal chamber from ≥2 of 3 coughs. If disagreement occurred, a third surgeon provided the decisive assessment. This air leak classification process was carried out only once, immediately prior to randomization.

The randomization window was defined as 24 to 48 hours after the end of surgery, to ensure that patients with a self-limited pulmonary air leak lasting <24 hours would be assigned to the more clinically appropriate group (ie, air leak absent). Within each air leak group, patients were randomized to either continued pleural drainage with the analog system, or pleural drainage with the digital system (Thopaz; Medela, Inc, Baar, Switzerland).