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Postoperative chest tube management: measuring air leak using an electronic device decreases variability in the clinical practice☆,☆☆

Gonzalo Varela *, Marcelo F. Jiménez, Nuria Maria Novoa, José Luis Aranda

Service of Thoracic Surgery, Salamanca University Hospital, 37007 Salamanca, Spain

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Abstract

Objectives: Since there are no data in the literature regarding variability in the management of postoperative pleural drainages, we have designed a prospective randomized study aimed at measuring inter-observer variability in deciding when to withdraw chest tubes after lung resection and to evaluate if the use of an electronic device to measure postoperative air leak decreases clinical practice variations. **Methods:** Sixty-one patients undergoing pulmonary resection were randomly assigned to one of the following groups: digital group (electronic measure of pleural air leak using Millicore AB DigiVent™ chest drainage system) or traditional group (standard water seal pleural chamber). Chest tube withdrawal criteria were established in advance. During morning rounds, two thoracic surgeons with comparable clinical experience and blinded to the decision of their counterpart, evaluated chest tube withdrawal criteria and noted whether the tube should be withdrawn or not. Inter-observer variability kappa index and global, positive, and negative agreement rates were calculated on 2×2 tables. Each observation episode was considered in the calculation. **Results:** Fifty-four observations were recorded in the traditional group. Kappa coefficient was 0.37 (overall agreement rate: 0.58; positive agreement rate: 0.72; and negative agreement rate: 0.64). In the digital group, 67 observations were recorded. Kappa coefficient was 0.88 (overall agreement rate: 0.94; positive agreement rate 0.94; and negative agreement rate 0.94). **Conclusions:** We have demonstrated a high rate of disagreement related to the indication to remove chest tubes after lung resection and the improvement of the agreement rate with the use of an electronic device to measure postoperative air leak and pleural pressures.

Keywords: Variations in clinical practice; Lung resection; Chest drainage

1. Introduction

Variability in clinical practice is a cause of inappropriate use of diagnostic and therapeutic procedures. Integrating individual clinical expertise with the best available external clinical evidence from systematic research has been shown to decrease variability in clinical practice [1]. Only a few surgical practices in cardiothoracic surgery are evidence-based [2]. Recent surveys have uncovered major variations in key aspects of intercostal drain management, suggesting that decisions are being made on individual preferences without resorting to sound evidence [3]. In fact, there is no agreement in the medical literature on the number of chest tubes needed and its management after lung resection [4,5], the use of suction or not [6] or the need to clamp tubes before withdrawal [7].

Currently there is not objective data quantifying variability among surgeons working in the same team on the indication to withdraw a chest tube after lung resection. We have therefore hypothesized that considerable inter-observer variability exists mainly due to the existence of air leak through the tube and that objective quantification of air leakage may decrease inter-observer variability.

The objectives of this investigation are: a) to measure inter-observer variability in deciding when to withdraw chest tubes after lung resection in clinical settings; b) to evaluate if the use of an electronic device to measure postoperative air leak decreases clinical practice variations.

2. Methods

2.1. Design and clinical settings

Prospective randomized trial was developed in a tertiary care academic general hospital. Four qualified thoracic surgeons were involved in the agreement study.

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* Corresponding author. Tel.: +34 923 291 383; fax: +34 923 291 383.
E-mail address: gvs@usal.es (G. Varela).

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2.2. Patients

Consecutive patients undergoing any kind of pulmonary resection, except pneumonectomy, have been included in the study. Patients were randomly assigned (using random numbers generated by a computer) to one of the following groups: digital group (electronic measure of pleural air leak using Millicore AB DigiVent™ chest drainage system) [8] or traditional group (standard water seal pleural chamber). The chest drainage system we have used in the digital group incorporates a single use electronic sensor with two components, one to measure air flow and the other for intrapleural pressure. Besides being presented in an LCD display (including real time pleural pressure and instantaneous and 1, 3, and 6 previous hours air flow), data can be stored for further analysis.

Only cases with standard postoperative course were considered in the study. Exclusion criteria included: need of mechanical ventilation after completing the procedure, early reoperation (within 7 days) due to hemorrhage or any other cause, and patient hospital discharge with maintained chest drainage due to prolonged air leak over 5 days. These cases were excluded since the decision to discharge patients with a chest tube was made during morning rounds and therefore were unblinded and results could not be compared to the study cases.

2.3. Variables

The following variables were recorded: age of the patient, diagnosis (lung cancer or not), type of lung resection (wedge, segmentectomy, lobectomy), intraoperative finding of fibrous pleural adhesions and/or macroscopic emphysema in the remaining lobe/s, pneumothorax after chest tube removal requiring drainage, and postoperative hospital stay (days from surgery to discharge).

2.4. Intra and perioperative management

All patients were operated on under general anesthesia and mechanical ventilation was performed in most cases through a double lumen tube. In some patients a single lumen tube was used and bronchial occlusion was achieved by a balloon catheter.

Sealants were not routinely used and the surgeon decided the indication according to the intraoperative findings.

After completing the procedure, pleural space was drained with a single chest tube, which was connected to the chest drain without suction. Patients were extubated in the operating theatre and temporarily transferred to an intermediate care unit. All patients received postoperative analgesia using epidural anesthetics and narcotics for the first three postoperative days and intensive chest physiotherapy was started after the admission of the patients in the intermediate care unit.

Chest tube withdrawal criteria were established in advance and, for the traditional group consisted of: absence of air leak through the chest tube at the time of the evaluation, pleural fluid drainage under 400 ml/24 h and postoperative chest X-ray showing no pneumothorax over 1/3 of the hemithorax or lobar atelectasis. Similar criteria were followed in the digital series, except that absence of air leak was required in the last 6 h as could be read in the digital display. Chest tube was not clamped in any case. The morning after chest tube withdrawal a chest X-ray was performed to rule out the occurrence of pneumothorax.

2.5. Estimation of the inter-observer variability

During morning rounds, two thoracic surgeons with comparable clinical experience and blinded to the decision of their counterpart, evaluated chest tube withdrawal criteria and noted whether the tube should be withdrawn or not. When the decision was to keep the chest tube in place, the reason (air leak, excess of fluid, or abnormal chest X-ray) was also annotated. The opinion of each surgeon was blinded to the other. In all cases, nurses acted under the orders of the surgeon in charge of the ward and chest tube was withdrawn according to his decision.

2.6. Statistics

A pilot study was performed to calculate the inter-observer variability using standard pleural drainage chambers without electronic devices. Then, sample size was calculated supposing 50% improvement in the overall agreement rate in the digital group for $\alpha < 0.05$ and $\beta = 0.85$.

Differences of recorded categorical variables between groups were estimated using the chi-square test. Non-parametric tests were used to evaluate differences between continuous variables in both groups.

Inter-observer variability kappa index and global, positive, and negative agreement rates were calculated on 2×2 tables. Each observation episode was considered in the calculation.

For statistics, Stata10.0 software was used.

2.7. Ethics

Patients were informed of the purpose of the study and were invited to sign an informed consent document. Local research ethics committee approved the study protocol.

3. Results

Sixty-one cases (35 in the digital and 26 in the traditional group) were finally included in the study and 121 observations regarding chest tube withdrawal were done (67 in digital and 54 in traditional patients).

Both series of cases were comparable in age, rate of lung cancer diagnosis, type of procedure performed, and intraoperative findings (Table 1).

After chest tube withdrawal, one patient in the traditional series required reinsertion of chest tube due to a symptomatic pneumothorax. Two additional cases in the traditional and one in the digital series had apical pneumothoraces, which were asymptomatic and therefore not drained.

Twelve observations were recorded for the pilot study (Table 2). The global rate of agreement was 0.58 (positive agreement rate: 0.54; negative agreement rate: 0.61; and kappa index: 0.17). Supposing 50% improvement in the rate

Table 1
Characteristics of the patients included in both series

	Traditional (n = 26)	Digital (n = 35)
Median age (range)	64.1 (35–82)	58.8 (17–79)
Lung cancer	13 (50%)	16 (47.7%)
Lobectomy	14 (53.8%)	17 (48.5%)
Macroscopic emphysema in the remaining lung	6 (23.1%)	10 (28.6%)
Pleural adhesions requiring cautery	12 (46.1%)	14 (40%)

No statistical differences between groups.

of overall agreement rate, estimated sample size was 54 observations per group (α = 0.05 and β = 0.85).

Fifty-four observations were recorded in the traditional group. In 17 occasions, both observers disagreed on the indication for chest tube withdrawal (in 12 cases due to air leak and in 5 cases due to other reasons: pneumothorax in 2, and amount of drained fluid in 3). Kappa coefficient was 0.37 (overall agreement rate: 0.58; positive agreement rate: 0.72; and negative agreement rate: 0.64).

In the digital group, 67 observations were recorded. Observers disagreed only four times (three times due to discrepancies regarding air leak and one due to the amount of fluid). Kappa coefficient was 0.88 (overall agreement rate: 0.94; positive agreement rate 0.94; and negative agreement rate 0.94).

Data on agreement in both groups are shown in Table 3.

4. Discussion

Worldwide concerns on efficient patient care and health care cost-containment have encouraged surgeons to develop fast-track lung resection programs [9] and patient care pathways with proven cost-savings while preserving quality of care [10,11]. Length of hospitalization after elective thoracic surgery may be prolonged for several medical and non-medical reasons but it has been shown that variations in clinical practice among team members is one of the most important determinants of hospital length of stay after pulmonary lobectomy [12].

In this investigation we have quantified the rate of agreement between two observers with comparable experience, with regard to the decision of chest tube withdrawal. Using a conventional water seal system, the agreement rate has been found to be lower than expected and considerable improvement has been reached using a digital air flow meter. Digital systems have been found to be useful in the clinical practice to quantify air leaks though the chest tubes [8,13], but its specific usefulness in clinical decision making has never been quantified.

Table 2
Results in the pilot study

Observer 2 decision Withdraw tube	Observer 1 decision Withdraw tube	
	Yes	No
Yes	3	2
No	3	4

Kappa coefficient: 0.17; overall agreement rate: 0.58; positive agreement rate: 0.54; and negative agreement rate: 0.61.

Table 3
Inter-observer agreement in both digital and traditional groups

Observer 2 decision Withdraw tube	Observer 1 decision Withdraw tube	
	Yes	No
Traditional group (water seal drainage) [a]		
Yes	22	12
No	5	15
Digital group (electronic flow measurement) [b]		
Yes	32	3
No	1	31

[a] Kappa coefficient: 0.37; overall agreement rate: 0.58; positive agreement rate: 0.72; and negative agreement rate: 0.64.
[b] Kappa coefficient: 0.88; overall agreement rate: 0.94; positive agreement rate: 0.94; and negative agreement rate: 0.94.

In our study, the observed increased agreement rate with the digital device was probably due to the fact that an objective quantitative measure of the air leak in the last 6 h was available and increased surgeon's confidence in the security of the procedure. Tentative clamping before chest tube withdrawal is a usual practice after lung resection and other procedures [14] to rule out the existence of occult small air leaks leading to delayed pneumothorax after tube removal. This practice is controversial [15] and, in cases in which the tube is finally withdrawn, clamping time could have been avoided and the patients discharged home. One of the reported advantages of digital air meters is the avoidance of tentative clamping [13] since it eliminates subjective estimation, offers reproducible data, and facilitates the standardization of clinical practice by implementing decision making algorithms [16].

Due to the widespread policy of using two chest tubes and postoperative pleural suction, our results should be confirmed in a different setting. Besides, we have to acknowledge a possible bias due to the subjective macroscopic evaluation of pulmonary emphysema in our cases.

In conclusion, we have demonstrated a high rate of disagreement related to the indication to remove chest tubes after lung resection and the improvement of the agreement rate with the use of an electronic device to measure postoperative air leak and pleural pressures.

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