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Impact of the learning curve in the use of a novel electronic chest drainage system after pulmonary lobectomy: a case-matched analysis on the duration of chest tube usage☆,☆☆

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Abstract

The objective of this investigation was to verify the impact of the learning curve involved after the introduction of a novel electronic chest drainage device on the duration of chest tube usage following pulmonary lobectomy. Propensity score case-matched analysis was used to compare the first consecutive 51 lobectomy patients managed with an electronic chest drainage (E) device with 51 controls managed with a traditional device (T). There was no difference in the characteristics of the two matched groups. Compared with patients managed with a traditional device, those with the electronic one had 1.9-day shorter duration of chest tube drainage (2.5 vs. 4.4 days; $P<0.0001$) and a 1.5-day shorter hospital stay (4.5 vs. 6 days; $P=0.0003$). Consequently, they had an average reduction in hospital costs of €751 (€1802 vs. €2553; $P=0.0002$). Compared with those in group T, patients in group E had a consistently shorter duration of chest tube use in relation to the very first patients treated. The learning curve sloped down for the first 40 patients before reaching a plateau, when the maximum benefit of using the electronic device was evident. Compared with traditional devices, the use of a novel electronic chest drainage system was beneficial from its initial application. The inherent learning curve was short and did not affect the efficiency of the system.

Keywords: Air leak; Chest drainage; Hospital stay; Lobectomy; Postoperative management

1. Introduction

In recent years, new electronic chest drainage systems have been produced and tested for the postoperative management of patients undergoing pulmonary resection. These novel systems have been shown to reduce interobserver variability in the decision of when to remove a chest tube [1], leading to a shorter duration of chest tube use and a shorter hospital stay [2, 3]. However, the introduction of a new device implies a learning curve, which may impact on its initial safety and efficacy.

The objective of this investigation was to verify the existence and duration of a possible learning curve after the introduction into clinical practice of a new electronic chest drainage system (Thopaz; Medela Healthcare, Baar, Switzerland). Moreover, we wanted to verify whether this initial period had any negative influence on the efficacy of this new tool compared with a case-matched population treated with traditional drainage systems.

2. Methods

This was an observational propensity score case-matched analysis performed on the first 51 consecutive patients submitted to pulmonary lobectomy and managed with a novel electronic chest drainage device (Thopaz). These patients were compared with 51 case-matched controls managed with a traditional device.

All 51 patients managed with the new electronic system (group E) were operated on in 2010 and were matched using a propensity score with a sample of patients drawn from a pool of 235 individuals undergoing lobectomy from 2008 through 2010 (group T).

The exclusion criteria were: air leak longer than seven days (after which all patients are connected to a portable chest drainage device and possibly sent home); admission to the intensive care unit and the use of assisted mechanical ventilation; chest wall/diaphragm resection; reoperation for any cause; and postoperative death. These exclusion criteria were used to select pairs of lobectomy patients in whom the role of chest tube drainage systems could be assessed, minimizing as much as possible the influence of other confounding factors on the duration of chest tube insertion or hospital stay.

All patients were operated on by qualified thoracic surgeons using a muscle-sparing, nerve-sparing lateral thoracotomy

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[4] or video-assisted thoracotomy. Perioperative pathways of care were standardized for all patients. As a rule, incomplete fissures were developed intraoperatively using staplers, and a single chest tube (24-F) was positioned in these patients at the end of the operation. None of the patients received preventative measures to reduce the risk of air leak (sealants, buttressed staple line, pleural tent, pneumoperitoneum, etc.).

Chest tubes were managed using an alternate suction regimen, which was the standard regimen at the time of this writing in our unit:

- Traditional system: external suction set at −15 cm H_2O during the night and no suction during the day [5].
- Electronic system: pump set at −15 cm H_2O during the night and at −8 cm H_2O (indicated by the manufacturer as 'water seal' mode) during the day.

The criteria for chest tube removal were the following:

- Traditional system: pleural effusion lower than 400 ml/day; absence of air leak as detected by bubbles in the air leak chamber of the system after repeated expiratory efforts.
- Electronic device: pleural effusion lower than 400 ml/day; air leak flow <40 ml/min for more than 8 h (and without spikes of airflow greater than this value) as detected by the graph shown in the display of the device at the patient's bedside.

Air leakage was checked twice daily, during the morning and evening rounds, by the attending physician. The decision to remove the chest tube was always taken by the staff surgeon on duty based on the above-mentioned criteria.

The electronic system, Thopaz, is a portable pump capable of providing a regulated variable suction level according to the preset negative pressure chosen by the physician and the feedback received from the intrapleural space and detected by a pressure sensor built in the system. The device features a display showing a real-time air leak flow value estimated by an algorithm based on the activity of the pump in maintaining the preset negative value of intrapleural pressure. The machine is also able to record the airflow during the entire episode of care.

Fixed and variable costs were retrieved from the data systems of the hospital's accounting and pharmacy departments. Costs are expressed in Euros (€) and adjusted for the inflation rate as of January 2011. For reference, the average daily cost of a hospital stay in our setting is about €400 in the ward.

2.1. Statistical analysis

Several surgical and perioperative variables were used to construct the propensity score [6, 7] employed to match the 51 patients in group E with the 51 controls in group T. The variables used were age, gender, body mass index, forced expiratory volume in 1 second (FEV_1%), carbon monoxide lung diffusion capacity, ratio of FEV_1 to forced vital capacity, ratio of residual volume to total lung capacity, preoperative arterial oxygen and carbon dioxide tensions, preoperative albumin level, preoperative haemoglobin level, insulin-dependent diabetes status, smoking (pack–years), use of induction chemotherapy, side and site of lobectomy, length of stapled parenchyma, and presence of pleural adhesions.

The two matched groups were then compared in terms of chest tube duration and hospital stay. Numeric variables with a normal distribution were compared by means of the paired Student's *t*-test, and those with a non-normal distribution (assessed by the Shapiro–Wilk normality test) were compared using the Wilcoxon matched-paired signed-rank test. Categorical variables were compared by the χ^2-test or Fisher's exact test as appropriate. A curve was finally generated by plotting the duration of chest tube usage for the two matched groups, with patients ordered by date of operation. All tests were two-tailed with a significance level of 0.05.

Statistics was performed using Stata 9.0 software (StataCorp, College Station, TX, USA).

3. Results

The propensity score yielded two well-matched groups of 51 pairs each. There was no difference in the baseline and perioperative characteristics of the two matched groups (Table 1). Thirty-eight patients from group E and 41 from group T had an air leak after lobectomy. The total pleural effusion after 48 h was 406 ml in group E and 503 ml in group T (P=0.1).

Compared with patients managed with a traditional device, those with the electronic one had a shorter duration of chest tube drainage (2.5 days vs. 4.4 days; P<0.0001), a shorter hospital stay (4.5 days vs. 6 days; P=0.0003) and reduced hospital costs (€1802 vs. €2553; P=0.0002). We did not observe any complications related to chest tube management (i.e. need for chest tube re-insertion) in either of the matched groups.

Table 1. Results of the comparison of the baseline and surgical characteristics of the two matched groups

Variables	Traditional group (51 patients)	Electronic group (51 patients)	*P*-value
Age	68.5 (10.6)	66.7 (10.1)	0.3
FEV_1 (%)	89.5 (16.4)	87.7 (17.6)	0.6
DLCO (%)	80.7 (19)	81.2 (19.4)	0.8
BMI (kg/m^2)	25.4 (4.5)	26.4 (5.9)	0.3
Right side (*n*,%)	31 (61%)	32 (63%)	0.8§
Upper site (*n*,%)	36 (71%)	30 (59%)	0.2§
Pleural adhesions (*n*,%)	16 (31%)	9 (18%)	0.2[a]
Length of stapled parenchyma (mm)	168 (111)	163 (109)	0.8§[b]

Results are expressed as means±SD unless otherwise indicated. BMI, body mass index; DLCO, carbon monoxide lung diffusion capacity; FEV_1, forced expiratory volume in 1 second. [a]Fisher's exact test. [b]χ^2-test.

Fig. 1 shows that, compared with patients in group T, those in group E had a consistently shorter duration of chest tube drainage with respect to the initial cases. The learning curve sloped down for the first 40 patients before reaching a plateau, when the maximum benefit of the electronic device was evident.

4. Discussion

The duration of chest tube usage following pulmonary resection, which is mainly dictated by the volume of pleural effusion and the presence of air leak, has been shown to be one of the major factors influencing postoperative stay and costs [8–10]. When a traditional chest drainage system is used, the decision of when to remove a chest tube is usually complicated by a high interobserver variability [1]. This is due to the absence of objective measures that can be quantified and replicated among the different observers.

Most recently, in the attempt to solve this problem, several medical companies have produced electronic devices that are able to objectify and record the duration of air leak. These novel instruments have already been shown to markedly reduce interobserver variability in chest tube management [1], as well as the duration of chest tube insertion and hospital stay [2, 3]. In a previous randomized trial, we showed that the use of an electronic chest drainage device (different from the one used in this study) was associated with a cost saving of approximately €500 per patient [3].

However, the introduction of every new device can be associated with a learning phase, the duration of which may be variable owing to the complexity and nature of the device and the previous experience of the users. This learning period may affect the initial efficacy of the device, impacting on both clinical outcome and costs.

The objective of this investigation was to verify the existence of a learning period associated with the introduction of a new electronic chest drainage system to our unit's clinical practice, and to determine whether this learning phase had an impact on the efficacy of this device (evaluated in terms of duration of chest tube usage compared with a traditional device). We found that patients managed with the Thopaz system had an approximately two days' shorter duration of chest tube usage, and a 1.5-day shorter hospital stay, with a consequent saving of approximately €750 per patient.

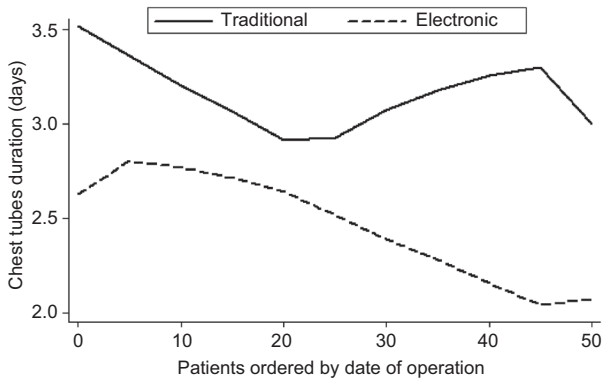

Fig. 1. Plots of the duration of chest tube usage in the two matched groups, with the patients ordered by date of operation.

When the matched groups were plotted on a graph, the curve representing the duration of chest tube usage in patients managed with the new electronic system showed that the introduction of this new system was associated with a short learning phase; this did not, however, greatly detract from its beneficial effects in terms of chest tube duration. This may have economic implications for deciding whether and how much to invest in this new system, which indeed appeared even from its first use to be cost-effective.

This study may have potential limitations. First, the results from this analysis were generated in a unit already experienced with digital chest drainage devices. Although the systems were different in their way of functioning and in their measurement scales, the concept of electronic chest tube management was not totally new for our team. This may have influenced the results, which therefore need independent confirmation to verify therir reproducibility in other settings.

Second, the analysis was limited to pulmonary lobectomies. This was done with the intention of selecting a homogeneous population in which the occurrence of air leak and the volume of the post-resectional residual pleural space (which may determine equivocal interpretations when using traditional devices) were more frequent compared with those undergoing minor resections. The generalizability of the present results to minor resections therefore needs specific investigation.

Finally, the learning curve period presented in this investigation refers to a general thoracic surgery division with a surgical volume of approximately 100 pulmonary lobectomies per year. The reproducibility of this curve to other settings with larger or smaller volumes needs to be verified.

5. Conclusions

In conclusion, we were able to demonstrate that the introduction to clinical practice of a novel electronic system to manage chest tubes following pulmonary lobectomy had a short learning curve. However, compared with the use of a traditional system, the benefits in terms of the duration of chest tube usage were evident from the initial cases.

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Conference discussion

Dr. H. Jessen Hansen (*Copenhagen, Denmark*): Were there any patients in either of the groups where you had to reinsert a tube due to subcutaneous emphysema or pneumothorax after tube removal?

Dr. Pompili: No. In this series we had no cases with pneumothorax or other complications after removal of the chest drain.

Dr. H. Jessen Hansen (*Copenhagen, Denmark*): That's great. I think it is an interesting option, and you are now giving a fixed rate for when the tube can be removed, but is it still the doctor's single decision or is it actually so fixed and so secure that you would even allow the OR medical staff to make the decision on when the tube can be removed?

Dr. Pompili: This is a good point, because in this case, unlike a surgical procedure where you have to learn a technical skill, the learning curve is more like a confidence curve. The staff have to have confidence in the safety of the criteria for removing the chest tube. Chest tube removal criteria were decided a priori based on the consensus opinion of major centers with experience in using these digital devices. We think that it is safe to remove a chest tube when the airflow is >40 ml/min. It should be even safer with Thopaz since it shows the graph of airflow in the last 24 h, allowing the detection of higher spikes of air leak.

Dr. H. Jessen Hansen (*Copenhagen, Denmark*): But it is still the surgeon who looks at the graph and who does the decision-making?

Dr. Pompili: The medical staff are in charge of making this decision in our setting.

Dr. J. Kuzdzal (*Krakow, Poland*): You said that there was a difference in the overall cost of treatment in favor of the Thopaz device. Did you also include in this calculation the price of the Thopaz unit itself, which is quite considerable?

Dr. Pompili: The calculation is based on the entire hospital stay costs. We found no differences between the costs of the devices. Thopaz is a reuseable pump, and the cost of consumables for one patient is the same as with traditional devices. Therefore, our cost differences are due mainly to the differences in hospital stay influenced by the duration of chest tube usage.

Dr. J. Kuzdzal (*Krakow, Poland*): But was the cost of the pump itself, which is very high, included in the calculation?

Dr. Pompili: Yes, but the cost of the pump depends on the type of purchasing model, whether it is a sales model or a consignment model. We chose the consignment model in which the pump is usually given for free and only the consumable costs are charged. The consumable costs for one patient are the same as with a traditional device.

eComment: The Six Sigma approach: from mobile phones to chest tubes

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We read with interest the manuscript of Pompili et al. [1] about the learning curve after introduction into clinical practice of a new electronic chest drainage system. In recent times, several devices able to measure air leaks (AL) continuously and digitally have been introduced into clinical practice. According to the authors, the results of their study may be biased by their familiarity with other electronic devices. Consequently, these results need independent confirmation.

Chest tube management has a limited number of steps and is performed many times per year by thoracic surgeons; it is thus ideal for root-case analysis and evaluation of modifications. In a previous paper [2], we applied the Six Sigma concept to improve the process of AL evaluation; in particular to design and assess a protocol for postoperative AL evaluation, to reduce the time to rate AL at bedside, and to minimize the degree of variability of AL score. This translated into improved efficiency and effectiveness.

The Six Sigma quality improvement methodology is a data-driven approach developed by the Motorola Corporation that seeks to improve outcomes by eliminating the variation within a process [3]. To date, clinical use of Six Sigma methodology has focused on efficiency outcomes, such as reducing the length of hospital stay in stroke patients, but application of the Six Sigma method has been used successfully to improve clinical outcomes and also to reduce surgical complications in repetitive procedures [4].

In conclusion, we agree with the authors that electronic devices are cost-saving. However, we suggest the use of an objective method such as Six Sigma to evaluate the effectiveness of a new device.

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