Regulated tailored suction vs regulated seal: a prospective randomized trial on air leak duration†

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Abstract

OBJECTIVE: The objective of this study was to compare the air leak duration of two regulated chest tube modes following pulmonary lobectomy.

METHODS: This is a prospective randomized trial on 100 consecutive pulmonary lobectomies (2010–11) performed for lung cancer. A single 24-French chest tube was connected to an electronic system capable of maintaining the pleural pressure within preset values (regulated suction mode) or within a physiological range (regulated seal mode). Patients were randomized to two groups: Group 1, regulated individualized suction (range: −11 to −20 cmH2O, according to lobectomy type); Group 2, regulated seal (−2 cmH2O). The main endpoint was the duration of air leak (h) calculated from the end of the operation to a value consistently below 20 ml/min. Patients with prolonged air leak (>168 h) were connected to a portable device before discharge. Their air leak duration was considered as 192 h. The sample size was calculated to detect 1-day difference in air leak duration with a statistical power of 80%.

RESULTS: The two groups were well matched for several baseline and surgical characteristics. No crossovers occurred between groups. The average air leak duration (Group 1: 28 vs Group 2: 22.2, P = 0.6), and the number of patients with prolonged air leak (Group 1: 5 vs Group 2: 4, P = 0.7) and with other complications (Group 1: 6 patients vs Group 2: 7 patients, P = 0.9) were similar between the groups. Sixteen patients of Group 1 and 21 of Group 2 had an air leak present immediately after extubation. Among them, patients of Group 2 (regulated seal) had an air leak lasting 34.5 h less than those of Group 1 (regulated suction) (52.9 vs 87.4, P = 0.07).

CONCLUSIONS: Regulated seal is as effective and safe as regulated suction in managing chest tubes following lobectomy. This information demonstrates with objective data the non-superiority of regulated suction vs regulated seal and may assist in future investigations on regulated pleural pressure.

Keywords: Pulmonary lobectomy • Air leak • Chest tube • Regulated suction • Digital drainage

INTRODUCTION

Previous trials evaluating the effect of suction on the duration of air leak following lung resection [1–6] may have been invalidated by technical limitations. In fact, traditional chest drainage devices cannot have any control on whether the preset level of suction is indeed maintained inside the chest.

Modern collection devices are able to apply a variable level of suction to maintain the desired intrapleural pressure [7]. They represent the ideal instruments to reliably assess the effect of different levels of negative pressure on the duration of air leak.

The objective of this prospective randomized study was to compare the effect of two controlled chest tube modes on the duration of air leak following pulmonary lobectomy by using an electronic regulated suction system.

PATIENTS AND METHODS

This is a prospective randomized study on 100 consecutive patients submitted to pulmonary lobectomy (October 2010–December 2011) for lung cancer in a single centre.

The study was approved by the local Institutional Review Board, and all patients gave their consent to participate in the trial.

The following exclusion criteria were applied: chest wall resection, reoperation, completion lobectomies and need for post-operative mechanical ventilation or intensive care assistance.
All patients were operated on by qualified thoracic surgeons through a muscle-sparing and nerve-sparing lateral thoracotomy [8]. Incomplete fissures were developed by using stapling devices. The bronchus was closed by mechanical staplers. Systematic lymph node dissection was performed in all patients. At the end of the procedure, the lung was submerged in sterile saline and reinflated (with a positive pressure of 25 cmH2O) to test for intraoperative air leaks. Any attempt was made to reduce the volume of significant air leaks by applying sutures. No sealants, buttressing material, or pleural tents were used in this series. A single 24-French chest tube was used in all patients and placed at the end of the operation in a lateral mid-position up to the apex. As a rule patients were extubated in the operating room and transferred to a dedicated general thoracic surgery ward. Admission to intensive care was reserved for patients with life-threatening cardiopulmonary complications needing active life-support treatments.

**Design of the study**

Immediately after closure of the chest, chest tubes were connected to an electronic drainage system (Thopaz, Medela Healthcare, Switzerland) featuring a pressure sensor placed near the chest and with the capability of varying the suction level according to the feedback received from the pleural cavity. The system is able to record pressure and airflow through the chest tube and works to maintain the pleural pressure within a preset value with a minimal variability in the range of 0.1 cmH2O. Furthermore, when the preset pressure is at or below −8 cmH2O and there is no air leak, the device works passively, as a one-way valve, only monitoring and recording the pleural pressure driven by the patient himself.

Patients of both groups with an air leak lasting longer than 7 days were disconnected from the electronic device and placed on a portable chest drainage system before discharge [9]. For the purpose of this investigation, their air leak duration was considered as 192 h (8 days).

Simple unrestricted randomization was performed following the Consolidated Standards of Reporting Trials (CONSORT) criteria and guidelines [10] (Fig. 1).

Patients were randomized to receive two different types of chest drainage management:

- **Group 1**, regulated individualized suction mode, with a preset level chosen according to the type of lobectomy and ranging from −11 cmH2O to −20 cmH2O according to a previous study [11] (Table I).
- **Group 2**, regulated seal mode (−2 cmH2O). At this level of suction, the system works only to compensate the occurrence of values more positive than −2 cmH2O. Otherwise, the device works passively as a one-way valve without exerting any active suction.

This was an-intention-to-treat analysis. No crossover between groups occurred.

**Primary endpoint** was the duration of air leak expressed in hours and calculated from the end of the operation to a value...
Continuous variables of the two groups were compared by the Wilcoxon rank test (non-parametric distribution) or by the Student’s t-test (normal distribution). Categorical variables were compared by the $\chi^2$ or the Fisher’s exact tests as appropriate. The following preoperative variables were considered: the patient’s age and gender, forced expiratory volume in 1 s (FEV1), forced expiratory capacity (FVC), FEV1/FVC ratio, predicted postoperative FEV1 (ppoFEV1), carbon monoxide diffusion lung capacity (DLCO), ppoDLCO and smoking history (pack-years). The FEV1, FVC, ppoFEV1, DLCO and ppoDLCO values were expressed as a percentage of predicted values for age, sex and height. The ppoFEV1 and ppoDLCO were calculated on the basis of the functioning segments removed during operation and was estimated by computed tomography scan and bronchoscopy [12].

The DLCO was measured by the single-breath method. We computed the number of pack-years of smoking as the total number of years smoked multiplied by the average number of cigarettes smoked per day, divided by 20. Operative variables included the side (right and left) and site (upper and lower) of resection, the presence of pleural adhesions and the length of the stapled parenchyma (mm). For the purpose of this study, the following procedures were classified as upper resections: right and left upper lobectomies, right upper bilobectomy and middle lobectomy. Lower resections included right and left lower lobectomies, and right lower bilobectomy. Only dense pleural adhesions occupying more than 30% of a lobe or more than one lobe were taken into consideration for the analysis. All the statistical tests were two-tailed, with a significance level of 0.05, and were performed on the statistical software Stata 9.0 (Stata Corp, College Station, TX, USA).

### RESULTS

The two groups were well matched for baseline and surgical characteristics (Tables 2 and 3) with the exception of more males and lower FEV1/FVC ratio in the regulated seal group. There was no dropout from, or crossover between the groups. During the period of the study, 10 patients were excluded for legitimate exclusion criteria. No mortality was observed in this series.

The average air leak duration (Group 1: 28 h vs Group 2: 22.2 h, $P = 0.6$), incidence of air leak lasting longer than 7 days (Group 1: 5 patients vs Group 2: 4 patients, $P = 0.7$) and incidence of other cardiopulmonary complications (Group 1: 6 patients vs Group 2: 7 patients, $P = 0.9$) were similar between the groups (Table 3).

The duration of air leak in those patients with an air leak lasting longer than 7 days was also similar between the two groups (Group 1: 14.2 vs Group 2: 17.2, $P = 0.6$).

Sixteen patients of Group 1 (32%) and 21 of Group 2 (42%) had an air leak detectable immediately after extubation in the operating room. Among them, patients of Group 2 (regulated seal) had an air leak lasting 34.5 h less than those of Group 1 ($P = 0.07$).

### DISCUSSION

Physiological background and definitions

Passive drainage occurs whenever the intrapleural pressure rises above the atmospheric pressure and no form of suction is applied to the chest drainage system [7]. Active drainage occurs when a subatmospheric pressure is applied to the pleural space either by a suction device or by creating a column of liquid in within the chest tube that extends below the level of the pleural space [7, 13]. As a consequence, even without applying any external source of suction, pleural pressure may vary depending...
on multiple factors. For instance, the presence of a column of fluid advancing downward along the chest tube may transmit a subatmospheric pressure inside the chest corresponding to the distance reached by the fluid within the tube. If the fluid stops moving it may actually increase resistance and in turn increase pleural pressure.

To date, no formal study has been performed in humans that can provide reference measures of intrapleural pressure under physiological conditions.

Clinical background and rationale for the study

Several randomized clinical trials have been published comparing the management of chest tubes with external suction vs that without external suction applied [1–5]. The results from these studies were not univocal, some of them reporting an advantage in not applying external suction [1, 2], and some finding no difference between the two modalities [3–5]. Besides different study designs and case-mixes, it is likely that the discrepant results were due to the uncontrolled nature of the two chest tube modalities. In fact, all the studies mentioned above used traditional chest drainage devices. When connected to an external source of suction, traditional systems deliver a fixed level of suction independent from the actual level of intrapleural pressure, which cannot be measured or regulated. When disconnected from the external source of suction, traditional devices are again incapable of controlling the great fluctuations in pleural pressure due to siphoning or increased resistance within the tube.

A recent study [11] has shown that the average pleural pressure recorded before removing the last chest tube in a series of uncomplicated pulmonary lobectomies (managed without external suction) showed great variations between different patients, different types of resections and even different recordings in the same patient, with values as high as +20 cmH₂O and as low as −50 cm H₂O maintained for several minutes.

Due to these extremely variable conditions, previous results generated from studies using traditional devices appear therefore unreliable and should be reconsidered.

For this reason, we chose to use an electronic chest drainage system (Thopaz, Medela Healthcare, Switzerland) capable of varying the suction level according to the feedback received from the pleural cavity (variable suction) in order to maintain a stable pressure corresponding to the preset value. This device appears ideal to study the effect of different levels of pressure on the duration of air leak.

For the purpose of this investigation, we chose two modalities of treatment: regulated suction mode individualized per type of lobectomy according to recently published data [11] (Table 1); regulated seal mode, with the suction value set at −2 cmH₂O. With this latter level, the device works only if the pleural pressure becomes more positive than −2 cmH₂O; otherwise it acts passively as a one-way valve allowing the patient to drive his own pleural pressure within physiological ranges.

Main findings

We found that the regulated seal mode had the same effect as the regulated suction one. This finding confirms, under controlled conditions, previous observations about the substantial equivalence between suction and no suction [3–5].

Interestingly, among the patients with an air leak present at the end of the operation, those managed with regulated seal showed a trend towards a shorter duration of air leak. Future studies focusing on these patients would be needed to clarify this observation.

Limitations

We included in the study patients submitted to lobectomy only since their incidence of air leak had been reported to be much higher than in those submitted to lesser procedures (ESTS database report—http://www.ests.org/documents/PDF/Database_ESTS_Report_2012.pdf). Generalization of our results to patients submitted to other types of resections therefore needs independent confirmation.

In the regulated suction group, we applied an individualized suction regimen tailored to the type of lobectomy. The level of suction was based on the data reported in the study by Refai et al. [11], who measured values of pleural pressure 1 h before the removal of the chest tube. This approach may have two limitations. First, pressure measurements in that study [11] were taken using a pressure sensor located at the canister level. Therefore, those measurements may have been influenced by several confounding factors such as siphoning effect, position of the patient or increased resistance due to tube clogging. Second, values recorded at the time of chest tube removal may not be the most appropriate to be taken as the target pressure to set in the immediate postoperative period.

In the regulated seal group, the suction level was set at −2 cmH₂O. This level represents the minimum value able to safely prevent the development of positive intrapleural pressure in case of air leak. At this level, in case of the absence of air leak, the device works passively allowing the patients to drive their own negative pressure within physiological ranges. In fact in this group, the values recorded by the system in patients without air...
leak are always in the range of −8 to 12 cmH2O, representing the physiological pressure developed by the patient (Fig. 2).

On the other hand, in case of air leak, the pressure values are always maintained around the preset level of −2 cmH2O (Fig. 2). Additional research is needed to verify whether selecting more negative values (always within physiological ranges) in the regulated seal group (i.e. −8 cmH2O) could change the present results.

We were not able to analyse the effect of the regulated suction on patients with prolonged air leak. In fact, all patients with an air leak lasting longer than 7 days were connected to a portable device and discharged. Mere for the purpose of this investigation, their air leak duration was calculated as lasting 192 h (since the effect of the regulated seal or suction modes was lost anyway). No patient was discharged home with this device owing to regulatory reasons.

Clinical and research implications

The use of a chest drainage system capable of precisely regulating the intrapleural pressure to preset values made it possible to reliably investigate the relationship between the pressure and air leak. Future research is needed to verify the influence of different pressure levels on the postoperative recovery of the lung. Certainly, aggressive suction has not been indicated as a favourable condition from a physiological point of view and may predispose to overdistension and interstitial oedema [13]. In this regard, the use of a regulated seal would allow for a more natural parenchymal recovery showing a positive trend in the duration of air leak and preventing the occurrence of detrimental positive pleural pressures.

CONCLUSION

A regulated seal is at least as effective and safe as a regulated suction level tailored to the type of lobectomy in managing air leak. This information may set the basis for future investigation on active pleural management based on regulated pleural pressure.

Conflict of interest: A. Brunelli: Consultancy agreement, Medela Healthcare, Switzerland.

REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr P.-E. Falcao (Strasbourg, France): This work follows numerous other work that you have published previously in this field, and we have seen at the beginning of your presentation that there are currently some new issues in chest tube drainage. By creating and designing this study, you tried to give some more information.

As you have nicely shown, the aim of this new study was to compare the air leak duration of two regulated chest tube modes following pulmonary lobectomy. For this purpose, you designed an innovative study. The flow chart you have in the paper is very informative. Thanks to it, we understand immediately that it is a randomized controlled trial with, importantly, an intention-to-treat analysis. It is the perfect design to try to show a difference between groups. You have included 100 pulmonary lobectomies for lung cancer, where all patients were connected by a single 24F chest tube to a digital electronic system able to maintain the pleural pressure within either preset values, that would be group 1, or within a physiological range, and that would be your group 2. Then you created and randomized the two groups of patients that you have individualized in your study. The end point is a classical one, duration of air leaks in hours.

Now, turning to your results and conclusion. Unfortunately, you were not able to prove a significant statistical difference between your two groups. The air leak duration as well as the number of patients with prolonged air leak were similar. However, there was a small trend, which you did not mention in your presentation, that in the case of an air leak present immediately after exubation in the operating room, group 2 patients had an air leak lasting less than those in group 1. Your conclusion was totally in accordance with your finding that a regulated seal is as effective and safe as regulated suction in managing a chest tube lobectomy.

I have only one single question, but a burning question! Where do we go next in the field of digital drainage? You have a huge experience in this could you please give us your thoughts?

Dr Brunelli: I think that is a good question. We didn't expect any advantage of one over the other. What we wanted to test for the first time was the effect of a different level of suction or pressure under controlled conditions. We finally know that by setting a certain level of pressure in the machine, this is what you get inside the chest. So the fact that we didn't find any difference in duration of air leak is still an interesting result. It is not a negative result. We at least demonstrated that a regulated seal, which I think is impossible to compare with the traditional term water seal, is safe. So you can use even a very low level of pressure setting in the device, allowing you to maintain a negative pressure as long as there is an air leak, but then as soon as the air leak stops, the device just works as a one-way valve. Whilst recording what happens in the pleural cavity, it helps the patient to stabilize his own pressure. So we were not dissatisfied or disappointed by the results.

Your question is very important, where do we go now? We now know that at least what we set in the machine is what we get inside the chest. I think this may set the stage for future investigation, not just about the duration of air leak, which I think is probably a marker of something else, or lung healing maybe. Maybe we can test with sophisticated analysis how the intrapleural pressure may affect the healing of the lung. In fact, there are reports, both experimental and clinical, that pleural pressure has an effect on, for example, interstitial edema. So a different level of pleural pressure, especially after lung resection, may or may not determine interstitial edema, which is probably the base of other pulmonary complications.

I think the device used in this investigation will certainly help us to better understand the management, not just of the pleural space, but of the pleural space seen as a whole with the lung and the recovery of the lung after operation.

Dr E. Lim (London, UK): Can you maybe elaborate on the fluid criteria you used for drain removal in this study?

Dr Brunelli: We used 400 ml/day. We pull the chest tube when it is less than 400.

Dr Lim: Can I just follow on with that. Increasingly in the UK, there is emphasis on multidisciplinary management. If your chest drain management is entirely protocolized apart from the surgeons, would the nurses be able to manage?

Dr Brunelli: No. At least in our centre, the surgeons and trainees manage the chest tubes. But I agree with you that using objective criteria and devices like the one used in this study may help in standardizing protocols of chest tube management by the entire team.

Dr. A. Martin-Ucar (Nottingham, UK): I think it's no surprise to show that in a controlled environment it doesn't make any difference what you do with the drain. We are not just spending too much time and money, and should we go back to what you basically said: put the patient on a Heimlich valve in the morning and leave them be, because any pressure you are applying under a controlled environment doesn't make any difference.

Dr Brunelli: Well, I think it doesn't make any difference in the duration of air leak but, of course, we didn't compare a traditional device with an electronic device. It has already been demonstrated that the use of an electronic device reduces chest tube duration and hospital costs compared to a traditional device. This is because of a more objective definition of air leak. So the fact that the comparison between two regulated pressure levels didn't yield any difference doesn't mean that there is no difference between the use of an electronic device, a regulating pressure device, and a traditional device in terms of clinical impact and, of course, chest tube duration.

Dr J. Kuzdal (Krakow, Poland): I have two questions. From a practical point of view, the most interesting is the group of patients with a prolonged air leak. In your study, the observation of this group was truncated on the seventh postoperative day. My first question is, do you think that it might have had some effect if the observation were prolonged, and that this is also an area for further investigation?

You applied preset suction pressure according to the type of lobectomy. My second question is, did you try to adjust the suction pressure to the amount of the air leak in order to decrease it or to enhance lung healing, because it can also be important from a practical point of view?

Dr Brunelli: Regarding the first question, I agree with you that the subset of patients with prolonged air leak would be interesting to study; however, we were not able to do it because we were not allowed to use this machine outside the hospital for regulatory reasons. So we had to truncate the study at the seventh postoperative day. But in the future this is probably the subset of patients that we most need to study and test different forms of management to shorten the duration of air leak.

Your second question regarding the adjustment of the suction pressure, we didn't do it for this study. I totally agree that the next step could be to study the effect of regulating pressure, just on the patients with an air leak first of all, and adjust the pressure according to different amounts of air flow, because this may have importance. I agree.

Dr Kuzdal: As we know that the amount of air leak is driven by the difference between the intrapleural and the airway pressure, having the opportunity, thanks to the new electronic machine, to adjust the pressure to reduce the suction could be important.

Dr Brunelli: But, surprisingly, what we observed in clinical practice is that there are again variable situations. In some patients when you increase the pressure level, their air flow remains stable; in others, their air flow increases steeply. So probably these are different patients with different conditions in their lungs. So this may be another field for research.