Regulated drainage reduces the incidence of recurrence after uniportal video-assisted thoracoscopic bullectomy for primary spontaneous pneumothorax: a propensity case-matched comparison of regulated and unregulated drainage

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Received 12 June 2015; received in revised form 22 July 2015; accepted 27 July 2015

Abstract

OBJECTIVES: To compare the recurrence rate of primary spontaneous pneumothorax (PSP) after uniportal video assisted thoracic surgery (VATS) bullectomy and mechanical pleurodesis in patients managed with a regulating pressure drainage system compared and those managed with a traditional one.

METHODS: Retrospective propensity score case-matched analysis of 174 consecutive patients submitted to uniportal VATS bullectomy and mechanical pleural abrasion (2007–13) in two centres. Definition of recurrence: Recurrent PSP requiring new treatment (i.e. aspiration, chest tube reinsertion, reoperation) within 12 months from the operation. All patients were managed with a single 24-Fr chest tube. Group 1 (106 patients): Tube connected to a traditional device (T) maintained on wall suction (−20 cmH₂O) for 48 h. Group 2 (68 patients): Tube connected to a regulating pressure device (R) set at −20 cmH₂O for 48 h. Chest tube removal criteria: No air leak (no bubbling or air flow <20 ml/min for at least 8 h) and pleural effusion <200 ml/day. Propensity score case-matching analysis was performed using the following variables: Age, gender, height, weight, side of operation, dystrophic score, length of stapled parenchyma.

RESULTS: The two groups of 68 pairs were well matched for baseline and surgical characteristics. Patients of Group 2 (R) showed a significantly lower incidence of recurrence rate compared with matched counterparts (T) (3, 4.4 vs 10, 14%, P = 0.041). There were no differences in persistent air leak incidence, chest tube duration or hospital stay between the groups. Group 2 had a higher 48-h output of pleural effusion compared with Group 1 (P < 0.0001).

CONCLUSIONS: By stabilizing the pleural pressure at the preset values, novel regulating pressure devices may enhance pleurodesis, leading to a reduced incidence of PSP recurrences after uniportal VATS bullectomy and pleural abrasion.

Keywords: Uniportal VATS • Single port • Primary spontaneous pneumothorax • Bullectomy • Pleurodesis

INTRODUCTION

The incidence of primary spontaneous pneumothorax (PSP) is 24/100 000 a year in men and 9.9/100 000 a year in women in England and Wales [1]. The surgical treatment remains a standard of choice to reduce the recurrence rate. Although current clinical guidelines do not clearly recommend the routine use of video assisted thoracic surgery (VATS) approach [2, 3], a recent paper from the Epithor Project confirms the general current practice reporting that ~87% of 7396 patients surgically treated for PSP underwent VATS procedures [4]. Although there is still equipoise in the role of VATS in reducing recurrences compared with thoracotomy [5], many authors have already shown that VATS is associated with lower postoperative morbidity, shorter hospital stay and reduced pain [6, 7]. The latter outcomes become even more evident with the use of the uniportal approach, which has been shown to have surgical costs similar to and postoperative stay costs lower than the three-port VATS [8, 9].

However, to date, no data have been published about postoperative management of chest tubes after surgical treatment of PSP. Although guidelines do not suggest the routine use of suction for
these patients, the recent publications on chest tube management after lung cancer resections and the routine introduction in our clinical setting of an electronic drainage device may help surgeons to find a standardized postoperative protocol after surgical treatment of PSP. The aim of this study is to compare the 1-year recurrence rate of PSP after uniporal VATS bullectomy and mechanical pleurodesis in patients managed with a regulating pressure drainage system compared with those managed with a traditional one.

METHODS

This is a retrospective analysis performed on prospectively collected data on 174 consecutive patients operated on for PSP in two centres (2007–13). Exclusion criteria were presence of underlying lung disease and patients older than 40 years. All patients were submitted to single-port video-assisted bullectomy and mechanical pleural abrasion. The study was approved by the local Institutional Review Boards.

Indications for operation were ipsilateral recurrent episode of PSP, bilateral simultaneous pneumothorax, complicated first episode of PSP (persistent air leak of more than 5 days) and patients operated on after their first episode for professional risk (e.g. divers or pilots).

All patients were operated through a single-port video-assisted approach according to the original technique described by Rocco [10]. In brief, a single incision of 2–2.5 cm was performed on the lateral chest. As a rule, a 5-mm 30° videothoracoscope was used to enhance visualization. Grasping instruments and mechanical staplers were introduced alongside the thoracoscope through the same incision. The target area bearing blebs or bullae was excised through a wedge resection by using an Endo-GIA stapling device. If no blebs were evident, a wedge resection of the apex of the lung was performed anyway, as this has been described [11, 12] as the area most frequently affected by dystrophic changes or emphysema-like changes. After the lung resection, a mechanical parietal pleural abrasion was performed and extended from the apex to the base using the diathermy scratch pad mounted on an angled grasping instrument.

At the end of the procedure, a single 24-Fr chest tube was placed laterally to the apex. All procedures were performed by the same three expert surgeons well trained in uniporal VATS.

After the procedure, the chest tubes were connected to a traditional or a digital chest drainage system (Thopaz, Medela Healthcare, Switzerland) based on the availability of the system. Both centres are well trained in digital drainage use.

The patients were therefore divided into two groups.

Group 1 (106 patients): Tube connected to a traditional device (T) maintained on wall suction (−20 cmH₂O) for at least 48 h.

Group 2 (68 patients): Tube connected to a regulating pressure device (R) set and maintained at −20 cmH₂O for at least 48 h.

Both centres shared common pathways of chest tube management after pneumothorax operation consisting of a 48-h period of continuous suction to favour lung expansion and pleura–pleura apposition enhancing pleurodesis.

Chest tube removal criteria were the following: presence of no air leak (no bubbling on the traditional device or air flow <20 ml/min for at least 8 h on the digital device) and a pleural effusion <200 ml/day.

As standard protocol, chest X-rays were not performed daily but immediately after the surgical procedure to check chest tube position and when the air leak stopped. If any concern arose about lung expansion or the presence of prolonged air leak, chest X-ray was requested. All patients had chest radiographs taken prior to discharge from hospital.

Chest pain was controlled by intravenous or oral paracetamol up to a maximum of 3 g per day. Non-steroidal anti-inflammatory drugs were not administered in order not to hinder pleurodesis.

All patients were encouraged to mobilize as early as possible.

For the purpose of this study, a pneumothorax recurrence (primary end-point of the study) was defined as a recurrent episode needing admission and invasive treatment (aspiration, chest tube or new surgical procedure) within 1 year from the index operation. All patients had a minimum of 12 months of follow-up to be included in the study, as the end-point was occurrence of PSP recurrence within 12 months.

We selected 1 year as the follow-up period to minimize the temporal bias caused by the fact that most of the patients managed with a digital drainage system were operated on in the most recent period. An unrestricted cross-sectional follow-up would have skewed the analysis theoretically favouring the digital group (with the short follow up, less risk of overall recurrence). Follow-up after surgery consisted of a clinical interview and chest radiography in our outpatient clinic at 1 month and only clinical appointments at 3 and 12 months postoperatively.

During the time of the study, another 12 patients were excluded because they were not available at follow-up.

Statistical analysis

To minimize selection bias in the context of a retrospective comparative analysis, a propensity score case-matching analysis was performed [13]. The propensity score was constructed by using the following variables: age, gender, height, weight, side of operation, dystrophic severity score [14], length of stapled parenchyma. The two matched groups were then compared in terms of baseline characteristics and incidence of postoperative major cardiopulmonary complications. Standardized difference (effect size) was used to assess the magnitude of differences in preoperative variables between the two groups. Effect size is calculated by dividing the difference of the averages of the two groups by the standard deviation for the total population. According to Cohen classification, an effect size of 0.2 indicates a small difference, 0.5 a medium difference and 0.8 a large difference [15]. Standardized difference appears more appropriate than the P-value to establish whether an adequate balance was achieved in matching, as it is less sensitive to sample size. Postoperative outcomes were compared by means of the χ²-test or the Wilcoxon rank-sum test. A P-value of 0.05 was accepted as significant. The statistical tests were performed on the statistical software Stata 12.0 (Stata Corp., College Station, TX, USA).

RESULTS

The characteristics of all patients included in the study are reported in Table 1.

Thirty-six patients were operated on for prolonged air leak, 121 for recurrent episode of PSP and 17 for other reasons (professional or willingness of the patient). The characteristics of the two unmatched groups are reported in Table 2.
| Table 1: Characteristics of the patients enrolled in the study (n=174) |
|-----------------|-----------------|-----------------|
| Variables       | Regulated pressure (68 patients) | Traditional (106 patients) |
| Age             | 24.1 (7.1)       | 23.8 (7.2)       |
| Gender male     | 131 (75%)        | 129 (76%)        |
| Dystrophic score| 2.6 (0.7)        | 2.5 (0.7)        |
| Side of operation, right | 90 (51%) | 87 (53%) |
| Body mass index (kg/m²) | 20.6 (2.6) | 20.7 (2.6) |
| Length of stapled parenchyma (cm) | 14.6 (5.6) | 14.4 (6.0) |

Results are expressed as means and standard deviations unless otherwise specified.

| Table 2: Characteristics of the patients in the regulated and traditional groups (unmatched) |
|-----------------|-----------------|-----------------|
| Variables       | Regulated pressure (68 patients) | Traditional (106 patients) | Effect size |
| Age             | 24.8 (7.7)       | 23.7 (6.9)       | 0.15        |
| Gender male     | 55 (81)          | 76 (71)          | 0.2         |
| Height (cm)     | 176 (8)          | 175 (7.5)        | 0.12        |
| Weight (kg)     | 65.0 (11)        | 63.0 (9.4)       | 0.2         |
| Dystrophic score| 2.4 (0.8)        | 2.8 (0.4)        | 0.6         |
| Side of operation, right | 33 (49) | 57 (53) |
| Length of stapled parenchyma (cm) | 13.3 (4.5) | 15.5 (6.0) | 0.4        |

Results are expressed as means and standard deviations unless otherwise specified. Effect size or standardized difference is calculated by dividing the difference of the averages of the two groups by the standard deviation in the total population. Effect size: 0.2, small difference; 0.5, medium difference; 0.8, large difference.

**DISCUSSION**

**Main findings**

The use of regulated pressure immediately after surgical treatment for PSP may promote the adhesion between two layers of pleura, reducing recurrence rate. The results of this study showed a significant reduction in the recurrence rate of pneumothorax when managed with regulated pressure compared with the management with the traditional pleural system.

**Clinical background and rationale for the study**

Several authors have tried to identify prognostic factors of failure of PSP surgical treatment: most of the trials remained focused on the comparison of different surgical approaches regarding pleurodesis. However, other reports studied the interferences of other factors in the outcomes of this treatment. One of the main findings of Gaunt et al. [16] was that the presence of a residual apical space on chest radiography after surgery increases significantly the recurrence of pneumothorax. They were able to confirm the already known hypothesis about the direct correlation of a failure to achieve early pleural symphysis and relapses. Naunhein and colleagues [11] identified the failure to identify and ablate a bleb at operation as the only independent predictor of recurrence in a series of 113 VATS procedures. For this reason, it is the practice of...
the two participating centres to wedge the apex even in case of patients with Stage I–II of Vanderschueren [17].

Current guidelines suggest the use of suction after treatment for PSP only if the lung fails to re-expand and recommend high-volume low-pressure systems [2, 3]. To our knowledge however, only one trial assessed whether suction or water seal is superior in the management of chest tubes after VATS blebectomy [18]. Ayed et al. in a randomized fashion demonstrated that placement of chest tubes on water seal after a brief period of suction resulted in a significantly shorter time of chest tube removal and hospital stay compared with suction. Although a recurrence analysis was performed, they did not make a direct comparison between the two groups.

The application of a regulated pressure inside the chest in our patients leads to a reduction of recurrence rate. We can speculate that the capability of this system to maintain the pressure stable even in the case of air leak helps the juxtaposition of the two pleural layers after abrasion in a constant and steady state. This assumption may be supported by the evidence of no differences in terms of air leak and chest tube duration between the two groups. That a regulated seal is as effective and safe as regulated suction in terms of postoperative pleural fluid may be supported by the evidence of no differences in terms of postoperative pleural fluid between groups [20]. This may be important information to warrant new investigations about the possible long-term efficacy of pleural abrasion based on the amount and type of fluid drained.

Limitations

(i) This is not a randomized trial. Propensity score analysis may not account for differences due to factors unrelated to the variables used for constructing the matching. There may still be unaccounted confounders influencing the recurrence rate in these patients.

(ii) We decided to include only patients submitted to pleural abrasion as the pleurodesis technique because that was the routine standard of care for PSP in the two centres in the period of investigation. However, we cannot rule out that including into the analysis other procedures (pleurectomy, talc, etc.) may affect these results. Independent investigations are warranted to verify the reproducibility of our findings with other pleurodesis methods.

(iii) We limited our follow-up to 1 year for all patients. This was to minimize the dropout rate and selection bias due to the fact that most of the patients managed with traditional devices were operated on in an earlier phase. Although an analysis with a longer follow-up would be of interest to confirm our findings, most of the papers with medium- to long-term follow-up showed that the majority of recurrences occurred during the first year after surgery [21, 22].

(iv) A standardized protocol of continuous (regulated or unregulated) suction for 48 h was adopted in our centres. As a recent finding [18] demonstrated that suction was associated to higher incidence of air leak and longer length of hospital stay after surgery for PSP, we cannot exclude that the comparison with ‘no-suction’ modalities would have yielded different results.

(v) Owing to the retrospective nature of the study, we were not able to quantify the time of disconnection from suction or the mobilization periods in the traditional group. This factor may have influenced the results and may have been one of the elements that could have helped to achieve a better pleurodesis in the digital group. Patients were in fact encouraged to walk around the ward and their tubes were temporarily disconnected from the wall suction while they did so. In this regard, the traditional group had a more discontinued suction regimen than the Thopaz group, as the latter patients were constantly on suction, the Thopaz pump being a portable device.

Clinical and research implications

Although the current guidelines on the treatment of pneumothorax suggest to limit the use of suction for complicated patients, there are no standardized recommendation about the postoperative management of chest drain. In lung cancer research, a thorough argumentation has been published comparing suction versus ‘water seal/no suction’ [23, 24]; however, no data have been published about the effect of the application of different protocols of chest tube management on the recurrence of PSP after surgery. A recent best evidence topic confirmed that, in clinical practice, the decision of when to remove chest drains has changed, with no documented contraindications to removing it as early as 2 days postoperatively [25]. The use of a digital device capable of recording all the information and well accepted by this electronically experienced young group of patients may facilitate the adoption of a fast-tracking policy also for the surgical treatment of PSP. Furthermore, this is a pilot study to investigate the effect of a regulated pressure on the complex mechanism of pleurodesis. We demonstrated a statistical difference between patients managed with this ‘regulated pressure device’ and traditional chest drainage system in terms of PSP recurrences, but further randomized trials with clinical–pathological models are warranted to directly correlate these findings to the effect of a stable internal pressure.

CONCLUSIONS

By stabilizing the pleural pressure at preset values, novel regulating pressure devices may enhance pleurodesis, leading to a reduced incidence of PSP recurrences after uniporal VATS bullectomy and pleural abrasion.

Conflict of interest: Dr. Brunelli has a consultancy agreement with Medela Healthcare.

REFERENCES


APPENDIX. CONFERENCE DISCUSSION

**Dr H. Batirel** (Istanbul, Turkey): How many chest tubes do you routinely place, one or two? Do you place the chest tubes via the same incision as the uniportal resection?

**Dr Pompili:** We usually place only one 24 Fr chest tube through the uniportal incision.

**Dr Batirel:** Do you think this system provides better pleurodesis?

**Dr Pompili:** Yes, we think that regulated suction may enhance or facilitate pleurodesis. However, there would be the need to explore the macroscopic and microscopic effects on the pleurodesis in these patients, because these are conclusions based on a retrospective study, and we cannot rule out that some other factor may have influenced these results. Probably the stable pressure interferes with the juxtaposition of the two pleural layers.

**Dr Batirel:** For the recurrence cases did you perform any further surgical intervention or did you just drain the patients?

**Dr Pompili:** These recurrences include not only the surgically treated but also patients treated with the reinserion of chest tube drainage.

**Dr T. Grodzki** (Szczecin, Poland): I have one additional question because this is a paper delivered by a group experienced with suction devices. Is it your policy to be limited to just pleural abrasion, which is usually considered to be an inferior method, versus pleurectomy? Maybe the rate of recurrence would be even smaller if pleural abrasion were to be followed by pleurectomy and digital drainage. It could theoretically eliminate the recurrence rate to zero.

**Dr Pompili:** Absolutely, I agree. Our study focuses only on pleural abrasion as the pleurodesis technique. So we cannot exclude that the use of other types of pleurodesis may have influenced results. Probably the effect of a regulated suction would be quite different with other types of pleurodesis like pleurectomy or talc.