Digital measurements of air leak flow and intrapleural pressures in the immediate postoperative period predict risk of prolonged air leak after pulmonary lobectomy

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Abstract

Background: The objective of this prospective observational study was to evaluate the association between the airflow and intrapleural pressures digitally recorded during the immediate postoperative period after lobectomy and their ability to predict the risk of subsequent prolonged air leak (PAL). Methods: A total of 145 consecutive patients underwent pulmonary lobectomy in two centers. All patients were managed with the chest tube placed on suction (–20 cm H2O) until the morning of the first postoperative day. Measurement of airflow and maximum and minimum intrapleural pressures were recorded during the 6th postoperative hour using a digital chest drainage device. Logistic regression analysis validated by bootstrap was used to test independent association of variables with PAL (air leak > 72 h). Results: The mean air leak flow at the 6th postoperative hour was 86 ml min−1 (0–1100 ml min−1). The mean maximum and minimum pleural pressures at the 6th postoperative hour were –11.4 cm H2O and –21.9 cm H2O, respectively. Logistic regression and bootstrap showed that the mean air leak flow (p = 0.007) and the mean differential pleural pressure (ΔP: maximum – minimum intrapleural pressure) (p = 0.02) at the 6th postoperative hour were reliably associated with PAL, independent of the effect of age, forced expiratory volume 1 (FEV1), chronic obstructive pulmonary disease (COPD) status, diffusing capacity of the lung for carbon monoxide (DLCO), side, and site of lobectomy. According to best cutoffs derived by receiver operating characteristic (ROC) analysis the following combinations showed incremental risk of PAL: ΔP < 10 + Flow < 50: 15% (5/33); ΔP < 10 + Flow > 50: 26% (5/14); ΔP > 10 + Flow < 50: 52% (13/25). Conclusions: The levels of both air leak flow and pleural pressure measured at the 6th postoperative hour are associated to a different extent with the duration of air leak. Interpretation of the data measured at an early time point by digital chest drainage systems allows estimation of the risk of subsequent PAL. In this way, digital devices may help to plan postoperative management to allow both safe and more accurate implementation of fast-tracking strategies.

Keywords: Air leak; Pulmonary lobectomy; Digital measurements; Chest drains; Pleural pressure

1. Introduction

New digital chest drainage systems allow quantifying of real-time and continuous monitoring and recording of air leak flow rate and intrapleural pressure from the immediate postoperative period through to the time of chest tube removal [1–6]. The potential exists to take advantage of this new technology not only to objectively identify the presence of air leak but also to, through the interpretation of its measured parameters, estimate the risk of prolonged air leak (PAL). It would thus be possible to plan the necessary treatments and safely implement fast-tracking policies. The objective of this prospective observational study was to evaluate the association between the airflow and intrapleural pressures digitally recorded during the immediate postoperative period after lobectomy and the risk of subsequent PAL.

2. Patients and methods

This is a prospective observational analysis of 145 consecutive patients undergoing pulmonary lobectomy for neoplastic disease in two centers (2008). For the purpose of this analysis, patients undergoing lung resection associated
with chest wall or diaphragm resections or needing post-operative ventilator assistance were not included. Overall operative mortality rate was 1% and these patients were also excluded from the analysis for this study.

All patients were operated on by six different board-certified general thoracic surgeons through a muscle-sparing lateral thoracotomy or video assisted thoracoscopic surgery (VATS) mini-thoracotomy. Inoperability criteria were a ppo forced expiratory volume 1 (FEV1) and ppo diffusing capacity of the lung for carbon monoxide (DLCO) < 30% in association with a \( V_{O_2} \) peak < 10 ml kg \(^{-1}\) min \(^{-1}\).

Partially complete or fused fissures were completed by means of mechanical staplers. The bronchus was stapled in most cases. At completion of the operation, the presence of an air leak was tested by submerging the lung parenchyma in sterile saline and reinflating the lung up to a sustained pressure of 25–30 cm \( H_2O \). If any significant air leak was detected, an attempt was made to eliminate or reduce it by applying sutures. No pleural tent, buttressed staple lines, or sealants were used in this series.

As a rule, one or two chest tubes (24–28 Fr), depending on surgeon preference, were placed at the conclusion of the surgical procedure. Chest tubes were maintained on suction (–20 cm \( H_2O \)) until the morning of the first postoperative day and then switched to no suction (‘under water seal’) and managed according to institutional policies; alternate suction regimen comprised of passive suction during the day and active suction during the night [7] versus simple passive suction.

As a rule, patients were extubated in the operating room and transferred to a dedicated thoracic surgical ward. Admission to an intensive care unit occurred only in cases of severe cardiopulmonary complications needing invasive ventilatory support, invasive cardiac monitoring, and inotropic support.

Multiple measurements (every 2 min) of the airflow and maximum and minimum intrapleural pressures through the chest tubes were digitally monitored and recorded (with all patients on active suction) using a micro electronic mechanical sensor technology (Medela, Switzerland). During the 6th postoperative hour, these measurements were recorded and averaged for the analysis. The data stored in the drainage system were subsequently downloaded to a computer by using the appropriate software and analyzed.

For the purpose of this study, a PAL was defined as an air leak lasting longer than 72 h from the conclusion of the surgical procedure. Cessation of air leak was defined as an airflow lasting longer than 72 h (18%). The mean air leak flow, maximum and minimum pleural pressures measured during the 6th postoperative hour for possible association with PAL. Significant factors were then used as independent predictors in a stepwise logistic regression analysis (dependent variable: presence of PAL), which was, in turn, validated by bootstrap resampling technique using 1000 samples [9–11].

In the bootstrap procedure, repeated samples of the same number of observations as the original database were selected with replacement from the original set of observations. For each sample, stepwise logistic regression was performed. The stability of the final stepwise model can be assessed by identifying the variables that enter most frequently in the repeated bootstrap models and comparing those variables with the variables in the final stepwise model. If the final stepwise model variables occur in a majority (>50%) of the bootstrap models, the original final stepwise regression model can be judged to be stable. Only reliable (bootstrap frequency > 50% in 1000 simulated samples) predictors were retained in the final model. Receiver operating characteristic (ROC) analysis was used to find the best cutoff values of significant and reliable predictors and patients were then grouped accordingly. Statistical analysis was performed on the Stata 9.0 statistical software.

The study was approved by the Institutional Review Boards at both of the participating sites.

3. Results

The descriptive characteristics of the patients included in the study are displayed in Table 1. Twenty-six patients had an air leak lasting longer than 72 h (18%). The mean air leak flow, maximum and minimum pleural pressures measured during

### Table 1. Patient characteristics (145 lobectomies).

| Characteristic | Mean ± SD |
|---------------|-----------|
| Age           | 67.3 (11.7) |
| FEV1%         | 83.9 (19)   |
| FEV1/FVC ratio| 0.69 (0.1)  |
| DLCO%         | 77.4 (19.6) |
| COPD (n, %)   | 39 (27%)    |
| Side (right, %)| 77 (53%)  |
| Site (upper, %)| 91 (63%)   |
| Air leak duration (h) | 40.8 (40) |
| Air leak flow (ml min \(^{-1}\)) | 86.1 (201) |
| Maximum pleural pressure (cm \( H_2O \)) | –11.4 (7.6) |
| Minimum pleural pressure (cm \( H_2O \)) | –21.9 (7.6) |

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

COPD: moderate to severe chronic obstructive pulmonary disease (FEV1 < 80% × FEV1/FVC ratio < 0.7).

\( ^a \) Mean values recorded during the 6th postoperative hour; all patients on –20 cm \( H_2O \) suction.
Differential pressure: maximum pleural pressure – minimum pleural pressure.
Bootstrap%: frequency of significance (p < 0.05) in 1000 bootstrap samples.
Parsimonious model: only significant variables are displayed.

| Predictors          | Coefficient | SE  | p-value | Bootstrap% |
|---------------------|-------------|-----|---------|------------|
| Intercept           | -2.44       |     |         |            |
| Air leak flow       | 0.003       | 0.001 | 0.007 | 82%        |
| Differential Pressure| 0.05       | 0.02 | 0.02   | 66%        |

Table 2. Results of the logistic regression analysis (dependent variable: PAL > 72 h).

According to these cutoffs, the following four combinations to find the best cutoffs for these two variables: air leak flow (ml min⁻¹) and differential pleural pressure (10 cm H₂O) were generated and showed incremental risk of PAL (Fig. 1):

- a. ∆P < 10 + Flow < 50: 4% (3/73).
- b. ∆P > 10 + Flow < 50: 15% (5/33).
- c. ∆P < 10 + Flow > 50: 36% (5/14).
- d. ∆P > 10 + Flow > 50: 52% (13/25).

Of the patients with flow <50 ml min⁻¹, those that had a ∆P > 10 cm H₂O had close to a fourfold higher risk of PAL. For patients with a flow >50 ml min⁻¹ and a ∆P > 10 cm H₂O (group d), the risk of air leak was 13-fold higher than for patients in group a.

4. Discussion

PAL remains a frequent complication after pulmonary resection. Ten to fifteen percent of patients after pulmonary lobectomy are at risk of developing this problem [12] usually resulting in a prolonged hospital stay and increased costs [13–15].

The production and commercialization of new chest drainage devices capable of objectively measuring and recording the amount of airflow through the chest tube have already been shown to decrease inter-observer variability in the timing of chest tube removal, permitting a more streamlined and increasingly standardized management [5]. This was shown to result in shortened chest tube duration and hospital stay with reductions in hospital costs that might potentially offset the increased costs of these devices in selected patients [3,4].

Along with providing objective and reproducible information on the presence and volume of air leak, these new systems have the potential to measure a series of data that can be used to gain insight on the complex relationship between pleural pressure, lung mechanics and airflow [16] in the postoperative phase. The objective of this investigation was to assess whether the amount of airflow and the level of intrapleural pressure, as detected by digital chest drainage units and measured in the immediate postoperative period, could be used as reliable predictors of the duration of air leak after lobectomy.

We found that both the airflow (ml min⁻¹) and the differential between maximum and minimum pleural pressure measured during the 6th postoperative hour were predictive of a PAL lasting longer than 72 h, independent of other potential confounding variables such as age, pulmonary function, DLCO, and side and site of resection.

By using ROC analysis, we were able to identify a threshold effect for both variables and generate classes of risk, accordingly. Patients with a flow lower than 50 ml min⁻¹ and a differential pressure lower than 10 cm H₂O had a PAL incidence of only 4%. On the other hand, those with a flow greater than 50 ml min⁻¹ and a large differential showed a risk of PAL as high as 52%. The effect of the differential pleural pressure applies on both patients with small or large air leak. As this differential of maximal and minimal pleural pressures during the respiratory cycle may be an expression of the extent of residual pleural space, this particular piece of clinical information may have potential clinical implications for the institution of an active pleural management strategy in selected patients with air leak. The use of pumps with controlled suction capable of generating a stable and controlled intrapleural pressure and minimizing its variations may favor lung expansion by maintaining a more consistent and negative intrapleural pressure. This type of pump was not used in this study and future prospective investigations are needed to test this hypothesis.

The authors recognize the following potential limitations of this study. In this study, all patients were connected via their chest tube and digital drainage device to a wall suction unit with a level of ≈20 cm H₂O and all measurements used for the analysis were recorded during the 6th postoperative hour. Although during that period all patients were resting in bed in a 30° upright position, uncontrolled changes in position or ventilation may have affected the intrapleural measurements. The value of averaging the data derived over that 60-min period should have the effect of minimizing any such aberrant fluctuations.

The number of chest tubes used in this series was not standardized. Whereas some patients used two chest tubes, others, mostly in the latter period of the series, used only one chest tube. Several randomized trials have shown no difference in terms of duration of air leak or complications [17–19] showing that one chest tube is as effective as two in
draining air and fluid from the pleural space. Furthermore, we assessed whether there was any difference in terms of intrapleural pressure or flow recorded in patients with single versus double chest tubes and we were not able to find any difference [20]. Where double chest tubes were used, they were connected through a Y piece to a single chest drainage unit.

Chest tube managements in the two participating centers differed after the first postoperative night (when all patients were on suction at –20 cm H2O). As chest tube management has been shown to potentially influence the duration of air leak, this could have affected the results. However, previous studies have shown that alternate suction [7] and no suction have similar effect on the duration of air leak.

Although the digital device used in this study (Digivent) is no longer available in the market, we are confident that the findings of the present study can be used to implement similar measurement software in the existing digital products.

In conclusion, we were able to find an association between the airflow and pleural pressure measured early after lobectomy and the incidence of PdL. The clinical use of digital chest drainage units, which permit quantitative measurement and recording of air leak flow and intrapleural pressure, appears to add to the prediction and management of air leak after pulmonary resection. The use of risk scores based on these digital measures may set the stage for future investigations of active pleural management aimed at treating air leak by tailoring the level of intrapleural pressure to the needs of individual patients. Furthermore, the early postoperative knowledge of an increased likelihood of a PdL may be useful in prompting either early active intervention or conversion to a one-way valve system (Heimlich valve) that would allow for outpatient management and therefore early dismissal from the hospital.

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Appendix A. Conference discussion

Dr H. Eid (Dubai, UAE): Have you compared your results with the regular drainage system, not the digital, because the digital may have given an idea about the pressure difference but it didn’t solve the problem of air leak.

Dr Brunelli: I didn’t clearly understand your question. We didn’t compare digital with traditional devices.

Dr Eid: With traditional drainage?

Dr Brunelli: No, this was not the purpose of this investigation.

Dr Eid: But the digital didn’t affect the duration of air leak?

Dr Brunelli: Digital drains?

Dr Eid: Yes.

Dr Brunelli: One of the main messages of this investigation is that along with the air flow, even the pressure inside the chest probably has an impact on the duration of air leak. Probably with this new digitalized system we can influence the negative level and the pleural pressure by using controlled suction systems. So if we are able to reduce the differential pressure, which probably indicates a reduced expansion of the lung and is associated with a prolonged air leak, we may be able to use these digital devices not only for monitoring but also for treating air leak, for active pleural management.

Dr L. Francesco (Milan, Italy): You mentioned that you used two different protocols of aspiration according to the institution. My question is, did you record any difference between the two protocols in your study? In other words, was the alternating aspiration better than simply water seal drainage?

Dr Brunelli: It was not the purpose of this study to assess duration of air leak in relation to different protocols, and all patients at the time of the measurements were on suction at the 6th postoperative hour. Of course, we cannot rule out that the different protocols of suction, which is no suction or alternate suction, may have an influence on the duration of air leak.

Personally I think this didn’t affect the results very much. But we didn’t compare the two protocols in terms of duration of air leak.

Dr F. Dettterbeck (New Haven, CT, USA): Alex, I am always impressed by your knowledge of statistics, so I want to ask you just about that. It seems to me that when you looked for parameters that show a difference, and then on top of it you draw your dichotomy point at the optimal point, you were stacking the deck to find something that looks good in this cohort of patients. Do you
need to validate this in another set of patients in order to be more comfortable with it? I mean, it makes some sense, but I wonder about that, and since you know statistics so well, what do you think?

**Dr Brunelli**: I absolutely agree. This risk score needs to be validated. This methodology is not new. It was first used in other studies that, instead of a logistic equation, try to have a risk score for clinical purposes. But I totally agree with you that by stratifying the risk, by forming groups, by consolidating values, we lose information. From a statistical point of view, it is always better to keep the continuous numeric variables as continuous. And I agree with you that we need to validate this scoring system in an external population.

**Dr D. Kraus (Nuernberg, Germany)**: What is the suction pressure that you start with after lobectomy?

**Dr Brunelli**: We use −20 cm H₂O for the first night.

**Dr Kraus**: Did you use less suction pressure? Did you work with less pressure?

**Dr Brunelli**: We also use −10 or −15. Personally I don’t think this makes any difference at all in terms of duration of air leak. Also, I think all these different values of negative suction, tested in the literature with traditional chest drainage units, are totally empirical. One of the other merits that these digital devices could have is that we probably could be able to tailor the negative level, the suction level, to individual operations and individual patients. This is my belief. It is my belief that the optimal level of suction for all patients doesn’t exist. These studies on pleural pressure using digital devices could help us to better understand the ideal suction level for each class of patient, each operation.

**Dr Kraus**: I think if you started with less pressure, it may be possible that your pain would diminish.

**Dr Brunelli**: The air leak you mean?

**Dr Kraus**: Yes.

**Dr Brunelli**: Well, we had to standardize this between the two centers. So it is possible that if we had to use −10, the absolute value of the air flow recorded during the sixth hour would have been less than 86 ml min⁻¹ (our recorded value). However, it remains to be proven that a different level of flow would have changed the results of the analysis. Maybe we can test it in another study.