Thopaz™
Current Research Findings

PROVIDING ADVANCED TREATMENT WITH EASE
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Does External Pleural Suction Reduce Prolonged Air Leak After Lung Resection? Results from the AirINTrial After 500 Randomized Cases


Study Background & Design

The aim of this study was to test the hypothesis if external suction may reduce the rate of prolonged air leak. Portable suction devices, such as Thopaz, became interesting as they record a large amount of data on airflow and intrapleural pressure, which have been suggested as being predictors of prolonged air leak. Furthermore, increased mobility due to portable suction may play a role in promoting lung healing. This study presents results of the first interim analysis after randomization of 500 cases, with 250 in each of the external suction and no external suction (control) groups.

Results

There was no significant difference (p>0.05) between the two groups in terms of demographic and clinical characteristics of the population after randomization. On postoperative day 7, the chest drain was still in place in 25 patients in the external suction group and in 34 patients in no external suction group. The difference between the two groups was significant (p<0.05) in favor of the external suction group and in those patients undergoing anatomical compared to non-anatomical resection. The results show that external suction reduces the prolonged air leak rate in this subgroup of patients (Figure 1). There was no significant differences (p>0.05) observed between the two groups in any other post-operative outcomes.

Figure 1: Number of patients with Prolonged Air Leak on POD7. Comparison between the external suction and no external suction (control) groups for both Anatomic and Nonanatomic resections. *(p<0.05)
Conclusions

1. Routine use of external suction reduces the rate of prolonged air leak after anatomic lung resection.
2. Use of external suction reduces the rate of pleural complications, specifically pneumothoraces.
Regulated tailored suction vs regulated seal: A prospective randomized trial on air leak duration

A. Brunelli, M. Salai, C. Pompili, M. Refai, A. Sabbatini

Study Background & Design

This study was aimed to compare the air leak duration of two regulated chest tube modes following pulmonary lobectomy by using an electronic regulated suction system. 100 patients with consecutive pulmonary lobectomies performed for lung cancer were included in the trial, group 1 with regulated individualized suction mode (range: -11 to -20 cmH₂O, according to lobectomy type; n=50) and group 2, with regulated seal mode (-2cmH₂O; n=50). The duration of air leak was the main endpoint calculated from the end of the operation to a value consistently below 20ml/min.

Results

The two groups were well matched for baseline and surgical characteristics with exception of more males and lower FEV1/FVC ratio in the regulated seal group. No crossovers occurred between groups. There was no significant difference (p>0.05) between right side of lobectomy, upper side of lobectomy, pleural adhesions, length of stapled parenchyma, pleural effusion in first 48h, and percentage of patients with an air leak at 5 or 7 days.

Figure 1: Duration of air leak, chest tube duration and length of hospital stay (days).
Figure 2: Percentage of patients with an air leak greater than 5 and 7 days.

Figure 3: Amount (ml) of pleural effusion in the first 48 hours.

Conclusions

- Regulated seal mode has the same effect as the regulated suction in managing chest tubes following lobectomy.
- The study demonstrates with objective data the non-superiority of regulated suction vs regulated seal and may assist in future studies on regulated pleural pressure.
- The study confirms, under controlled conditions, previous observations about the substantial equivalence between suction and no suction.
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.


Study Background & Design

This study aimed to determine the duration of learning Thopaz, when first introduced into a clinical environment, and the impact it has on chest tube duration, length of stay and hospital costs. Using propensity score case-matched analysis, the first consecutive 51 lobectomy patients managed with Thopaz were compared to 51 controls managed with a traditional chest drain. There was no significant difference in the characteristics of the two matched groups (p > 0.05). In both groups, patients were placed on -15cm H2O during the day and whilst sleeping were placed on Water Seal (traditional systems) or Gravity Mode (Thopaz). Criteria for removing the drain at -15cm H2O were as follows: Traditional systems required an absence of air leak following repeated expiratory efforts, whilst on Thopaz required a flow of < 40ml/min, stable on the graph for 8h. On both systems a pleural effusion < 400ml/24h was required.

Results

Patients managed with Thopaz had a significantly shorter duration of chest tube drainage (P < 0.0001) and shorter hospital stay (P < 0.001) when compared to patients on traditional systems (Figure 1).

![Figure 1: Length of chest drainage and length of hospital stay for patients on traditional systems compared to Thopaz.](image-url)
The use of Thopaz significantly ($P < 0.001$) reduced hospital costs by an average of €751 per patient (Figure 2).

**Figure 2:** Per patient cost and savings associated with using Thopaz.

<table>
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<tr>
<th>Hospital savings per patient</th>
<th>Hospital cost per patient</th>
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<td>€2,553</td>
<td>€1,802</td>
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Benefits of Thopaz were evident from the first patient, however the maximum benefit was achieved by patient number 40.

**Figure 3:** Learning curve of Thopaz, showing that maximum benefit in using Thopaz, as measured by duration of chest drainage, is achieved after 40 patients.

**Conclusions**

- Compared with traditional devices, the use of Thopaz was beneficial from its initial application.
- The learning curve was short and did not affect the efficiency of the system.
- Thopaz reduced the duration of chest tube drainage and length of stay thereby significantly reducing the costs to the hospital.
- Study limitations include prior experience with digital drainage devices in this hospital, and that the study population included only pulmonary lobectomies.
Study Background & Design

Traditional chest drainage has been achieved by connecting the chest drain bottles to wall suction. However, the negatives include; impaired patient mobility, variable suction applied to the patient, infection risk, and the assessment of air leak being subjective. Thopaz is a portable chest drain which allows for mobilization of the patient, and has scientific digital flow recordings with an inbuilt alarm system. After 2.5 months of using Thopaz on 120 patients, 15 clinical staff on a thoracic ward were asked to evaluate Thopaz in a structured format. Staff responses graded their satisfaction on a scale of Excellent, Very good, Good, Satisfactory, Needs Improvement, or Poor. Patients with pneumo-thoraces who had chest drains and wall suction prior to surgery who then had Thopaz following surgery were also requested to give their feedback.

Results

The results of the survey of clinical staff satisfaction of Thopaz are as follows:

Figure 1: Assessment on the instructions for use of Thopaz.

Figure 2: Assessment on the functionality of Thopaz.
Additional, subjective feedback from patients was that they liked the light, compact design, and the quietness compared to the sound of bubbling. Clinical feedback was that they liked the mobilisation of the patients and scientific removal of chest drain.

Conclusions

- Thopaz was found to be user friendly and liked by staff and patients.
- Additional clinical benefits cited were objective decision making on when to remove the chest tube, improved patient mobilisation and therefore physiotherapy, a reduction in use of x-rays, and improved infection control due to reduced risk of spillages.
The benefits of digital air leak assessment after pulmonary resection: Prospective and comparative study

J. M. Mier, L. Molins, J. J. Fibla

Study Background & Design

With traditional systems, the grading of air leaks still relies on the measurement of “bubbles in a chamber”, a method inherently prone to subjective interpretation and observer variability. To this end a prospective, consecutive and comparative study was performed to evaluate the efficacy of digital devices (Thopaz and the now defunct DigiVent) in measuring the postoperative air leak compared to a traditional device and how this impacts upon the decision to withdraw chest tubes after lung resection. A total of 75 patients who underwent elective pulmonary resection were equally divided into the three groups. There was no significant difference between the groups regarding demographics or respiratory function. Negative pressure set on the systems was -15cmH₂O from the closure of the chest wall muscle to the time when the drain was removed. The chest drain was removed when < 10 ml/min for digital devices and no bubbles for the traditional system was maintained for 12 h. Pleural effusion needed to be below 200 ml in 24 h.

Results

Chest tube removal occurred earlier for Thopaz than occurred for DigiVent and the traditional system.

![Figure 1: The length of drainage in days for a Traditional Chest Drain, DigiVent and Thopaz.](image)
The standard deviation for the traditional system was far greater than occurs for either DigiVent or Thopaz, demonstrating that inter-observer differences were reduced when using digital devices.

![Bar chart showing standard deviation for length of drainage in days for Traditional Chest Drain, DigiVent, and Thopaz.]

Figure 2: The standard deviation for length of drainage in days for a Traditional Chest Drain, DigiVent and Thopaz.

Additional, subjective feedback was that patients and nurses were more comfortable with digital devices, whilst the surgeons felt they obtained more objective information.

Conclusions

- The digital and continuous measurement of air leak instead of the currently used traditional systems reduced the chest tube withdrawal and hospital stay by more accurately and reproducibly measuring air leak.
- The Thopaz alarm mechanism is very useful and the integrated suction provides significant independence to the patient.
- It is possible to remove the drain significantly earlier in patients with Thopaz. Had the sample size been larger, the result might have been even more conclusive.
- Study limitations were that the sample size was small and the lack of randomised groups.
Study Background & Design
The aim of this study was to measure inter-observer variability and its impact upon deciding when to withdraw chest tubes after lung resection and to evaluate if the use of an electronic device to measure postoperative air leak decreased variations in clinical practice. In a prospective randomized study, 61 patients undergoing pulmonary resection were randomly assigned to either the digital group (using the now defunct DigiVent chest drain) or the traditional group (on standard water seal). Having established the chest tube withdrawal criteria, two thoracic surgeons with comparable clinical experience independently evaluated whether to withdraw the chest tube. Each was blinded to the decision of their counterpart. Fifty-four observations were recorded in the traditional group and 67 observations were recorded in the digital group. The inter-observer variability and kappa coefficient were calculated.

Results
The inter-observer variability on when to remove the chest tube is much greater for the Traditional System when compared to the Digital System.

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<tr>
<th>Observation 1 Decision to Remove Chest Tube</th>
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<td>No</td>
<td>1</td>
<td>31</td>
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<tr>
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<tbody>
<tr>
<td>Yes</td>
<td>22</td>
<td>12</td>
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<tr>
<td>No</td>
<td>5</td>
<td>15</td>
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Figure 1: Showing the inter-observer variability for the Traditional and Digital Systems.
The Kappa Coefficient shows poor agreement between observers for the Traditional System and good agreement for the Digital System.

![Figure 2: Kappa Coefficient showing agreement between clinical decisions on whether to remove the chest tube for the Traditional System and Digital System. A low Kappa Coefficient suggests poor agreement between observers, whereas a high Kappa Coefficient suggests good agreement between observers.](image)

**Conclusion**

There was a high rate of disagreement as to when to remove chest tube after lung resection for the traditional water seal system, and a high rate of agreement when an electronic device with a digital air flow meter was used.
Study Background & Design

Air leaks are the most frequent cause of prolonged hospital stay, increased cost and patient dissatisfaction. The management of chest tubes in patients with air leaks is optimized when the air leak is scientifically evaluated. To eliminate subjectivity, companies have developed digital pleural drainage systems that are able to quantify the size of air leaks in ml/min. In this study, 98 patients undergoing elective pulmonary resection were recruited, 48 into the Thopaz group and 50 into the traditional system group. Patient age, body mass index, pulmonary function tests and types of procedures were similar in both groups.

Results

Comparison shows that patients on Thopaz have a significantly reduced duration of chest drainage than those on the Traditional System. There was a reduction in length of hospital stay for the Thopaz group, however this did not reach significance.

![Figure 1: Showing a comparison between a Traditional System and Thopaz in the duration of chest drainage, and length of hospital stay.](image-url)
Comparison shows that pneumothorax patients on Thopaz have a significantly reduced length of hospital stay than those on the Traditional System.

![Comparison between Traditional System and Thopaz in hospital stay](image)

**Figure 2:** Showing a comparison between a Traditional System and Thopaz in the length of hospital stay for pneumothorax patients.

**Conclusion**

- Treatment of air leaks has evolved to improved chest tube management through the use of scientific measures, leading to the earlier removal of chest tubes, decreased pain and morbidity and the early discharge of patients.

- There is little question that digital air leak devices are the future of the bedside management of air leaks.

- Further studies are needed to determine their efficacy on all patients requiring drainage, and to determine costs savings.