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# The benefits of digital air leak assessment after pulmonary resection: Prospective and comparative study

*José M. Mier,* Laureano Molins, and Juan J. Fibla*

*Servicio de Cirugía Torácica, Hospital Universitari Sagrat Cor, Barcelona, Spain*

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A B S T R A C T

*Introduction:* Persistent air leaks represent the most common pulmonary complication after elective lung resection. Since there are insufficient data in the literature regarding variability in the withdrawal of postoperative pleural drainages, we have designed a prospective, consecutive and comparative study to evaluate if the use of digital devices (Thopaz and DigiVent) to measure postoperative air leak compared to a Pleur-Evac varies on deciding when to withdraw chest tubes after lung resection.

*Methods:* A prospective, consecutive and comparative trial was conducted in 75 patients who underwent elective pulmonary resection for non small cell lung cancer. This study compared two digitals devices with the current analogue version in 75 patients. The digital and analogue groups had 26, 24, and 25 patients, respectively.

*Results:* Clinical population data were not statistically different between the groups. The withdrawal of the chest tube was Thopaz, 2.4 days; Digivent, 3.3 days and PleurEvac, 4.5 days. Patients and nurses were subjectively more comfortable with digital devices. Surgeons obtained more objective information with digital devices. The safety mechanism of the Thopaz was also subjectively better, and one patient was discharged home without complications after one week.

*Conclusions:* The digital and continuous measurement of air leak instead of the currently used static analogue systems reduced the chest tube withdrawal and hospital stay by more accurately and reproducibly measuring air leak. Intrapleural pressure curves from the Digivent may also help predict the optimal chest tube setting for each patient.

The Thopaz alarm mechanism is very useful to prevent deficiencies in the mechanism and do not required wall suction.



## Beneficios del uso de dispositivos digitales para medir la fuga aérea después de una resección pulmonar: estudio prospectivo y comparativo

*Palabras clave:*
Drenaje torácico

R E S U M E N

*Introducción:* La fuga aérea persistente es una de las más frecuentes complicaciones después de una resección pulmonar. Debido a las diferencias de parámetros subjetivos para la retirada del drenaje en el postoperatorio, nosotros diseñamos un estudio prospectivo, com-

*Corresponding author.
E-mail address: jmmo50@hotmail.com (J.M. Mier).

Fuga aérea prolongada
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parativo y consecutivo para evaluar de una manera objetiva cómo los dispositivos digitales (Thopaz® y Digivent®) pueden medir la fuga aérea comparándolos entre ellos y, a su vez, con Pleur-Evac®, en beneficio de una retirada precoz del drenaje torácico.

*Método:* Estudio prospectivo, comparativo y consecutivo de 75 pacientes a los que se les había realizado de manera electiva una resección pulmonar debido a cáncer de pulmón no microcítico. Comparamos los 2 dispositivos digitales entre sí y, a su vez, con el dispositivo no digital.

*Resultados:* Los resultados poblaciones no fueron significativos entre los 3 grupos. La retirada del drenaje torácico fue el siguiente: Thopaz® a los 2,4 días, Digivent® a los 3,3 días y Pleur-Evac® a los 4,5 días. Los pacientes y el personal de Enfermería se encontraron subjetivamente más cómodos con el dispositivo digital. Los cirujanos obtuvimos información objetiva con el dispositivo digital. Los sistemas de alarma de Thopaz® fueron efectivos para el uso de un paciente de manera ambulatoria.

*Conclusión:* El sistema digital y continuo de medición de la fuga aérea reduce el día de la retirada del drenaje torácico, así como los días de estancia intrahospitalaria. El sistema de alarmas de Thopaz® es muy útil para prevenir las deficiencias del sistema. Hace innecesaria la aspiración desde un sistema centralizado. Las curvas de medición de presión intrapleural y extrapleural pueden hacer predecible la necesidad de un tipo de drenaje para cada paciente según su enfermedad.



## Introduction

One of the worst and most frequent complications in thoracic surgery is prolonged air leakage after lung resection. It is a condition that prolongs hospital stay, considerably increases costs and also increases the risk of infections and the number of reinterventions.[1,2] As a result, a number of products, such as sealants, aerostatic agents, etc. have been developed in recent years.[3,4]

The main goal of surgical treatment is to cure the patient, but it is essential to provide comfort and wellbeing. This means offering freedom of movement, so the proper administration of postoperative analgesic treatment is a basic need.[5,6] This allows the chest drain to be removed as soon as possible, whether after open or thoracoscopic surgery.[7] This is the basic goal for many groups in the world and in particular, our own.

Many centres in the world today continue to remove the drains if any air leaks are noted when using the classical device connected to the pleural space. And while some techniques for measuring air leaks have been devised,[8] they are not accurate enough. Therefore, a number of various digital devices have been designed, which provide quantitative values to make the drain removal time safer.[9,10] The aim of our study was to report our experience by comparing the performance of two digital devices and, in turn, that of the one normally used.

## Patients and methods

Between February 2008 and February 2009, 75 patients underwent pulmonary resection in one of our surgery centres, due to the diagnosis of non-small cell lung cancer. They are classified into 3 groups: comparative, prospective and consecutive, according to the availability of the different devices: 1) Thopaz®, Medela, Switzerland, 2) Digivent®, Millicore, Sweden, and 3) Pleur-Evac® A-6000 Series, Teleflex, NC. The same group of surgeons operated on all patients. The sample size was based on the number of free digital devices made available by the companies.

The surgical technique was the same for all: a posterolateral thoracotomy was performed by observing the serratus for resection of the lower lobes, with a previous thoracotomy without section of the latissimus dorsi for the resection of the middle and upper lobes. In all cases, a complete mediastinal lymphadenectomy was performed. A chest drain was placed, and chest closure performed with absorbable sutures, and the neurovascular bundle of the rib was preserved.[6]

The preoperative evaluation of patients was the same and they evaluated by the Anaesthesia Department. All patients gave informed consent which specified the use of a chest drain. Our study was approved by the Sagrat Cor University Hospital Ethics Committee.

There were no significant differences in any groups regarding age, sex or respiratory function, after testing (Table 1). One of the three groups was assigned the digital drainage device A, which measured the air leak in ml/min, with a graphical representation of time and amount of leakage. A second group was given the device B, which measured the air leak in ml/min and the intrapleural pressure scale; while the third group received the non-digital device C, with an air leak scale of 0-7 (Robert David Cerfolio).

All patients were connected to a continuous suction of –15 cm $H_2O$ from the closure of the chest wall muscle to the time when the drain was removed, with disconnection intervals

**Table 1 – Population characteristics**

| Variables | A | B | C | P |
|---|---|---|---|---|
| *Age* | 65.6 | 62.04 | 66 | n/s |
| *Sex* | | | | |
| Men, n | 18 | 17 | 20 | n/s |
| Women, n | 8 | 7 | 5 | n/s |
| *Procedure* | | | | |
| Lobectomy, % | 61.5 | 66.6 | 72 | n/s |
| Limited resection, % | 38.5 | 31.9 | 28 | n/s |
| FEV1 | 77±17 | 75±18 | 78±22 | n/s |

A: Thopaz®; B: Digivent®; C: Pleur-Evac®; FEV1 indicates forced expiratory volume in one second; n/s, not significant.

so the patient could walk outside the room. As an initial reference, the air leak was recorded in ml/min for digital devices and a scale of 0-7 for the non-digital device when the patient was taken to the recovery room. The final value was obtained when the removal of the drain in the room was considered appropriate. The drain was removed when values under 10 ml/min for digital devices and 0 for the non-digital device were maintained for over 12 h. Rx verification was also performed to demonstrate proper re-expansion of the lung parenchyma, as well as when liquid use was less than 200 ml in 24 h.

A questionnaire was distributed among nursing staff to assess the degree of satisfaction and safety of digital devices used:

1) Is the device easy to understand? (1=Difficult, 2=easy, 3=very easy).
2) Is it easy to handle? (1, 2 or 3 as above).
3) Is it easy to see the air leak and quantify the liquid use? (1-3).
4) Do you consider it safe for the patient? (Yes or no).
5) Which of the three devices would you choose to work with? (A, B or C).

### *Statistical analysis*

The analysis was performed using SPSS v13 (Chicago, IL, USA), and the data adjusted to a distribution according to the applicability or not of parametric tests using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used for non-parametric data distribution. Probabilities of <0.05 were considered significant.

To compare the digital systems expressed in ml/min and the non-digital one expressed in the Robert David Cerfolio scale of 0-7, a calculation was made using the value published by Robert J. Cerfolio and Cerfolio as a reference.[11]

Two patients were eliminated from each group, as they needed to be discharged home with a Heimlich valve due to the air leak. We believe that the leak was not attributable to any of the devices, but to the remaining lung parenchyma conditions on both patients.

## Results

The results shown in Table 2 and Figure were obtained after comparing the two digital drain devices with each other and with device C, along with comparison of the air leak at insertion and removal of the drain, as well as the amount of days with the chest tube and length of hospital stay. The average drain removal times were very similar for the two digital systems. However, the results were statistically significant only when comparing device A with C and when comparing device A with B. Digital systems were always removed when giving a reading of less than or equal to 10ml/min. Technically, a pneumothorax may have been found after drain removal, but no such case was seen in our sample.

For the nursing staff, the simplest system to use was device C. However, all agreed that after receiving training for the digital devices, they may be just as simple to use. The big difference was found in assessment of the air leak, which was higher for digital devices, and provided greater patient comfort and safety. Eighty percent of nursing staff said they would rather work with the digital devices than with the traditional (Table 3).

**Table 2 – Air leakage±standard deviation (ml/min) and days before withdrawal**

| | Initial leak | Leakage at withdrawal | Days to withdrawal |
|---|---|---|---|
| A | 369±320 | 3.5±3.6 | 2.4±1.0 |
| B | 103±83 | n/d | 3.3±1.0 |
| C | 89±57 | 6.3±20.1 | 4.5±3.6 |
| *P* | | | |
| A vs C | 0.00 | 0.00 | 0.00 |
| C vs B | 0.55 | 0.19 | 0.47 |
| A vs B | 0.00 | 0.00 | 0.01 |

A: Thopaz®; B: Digivent®; C: Pleur-Evac®. n/d indicates not detected.

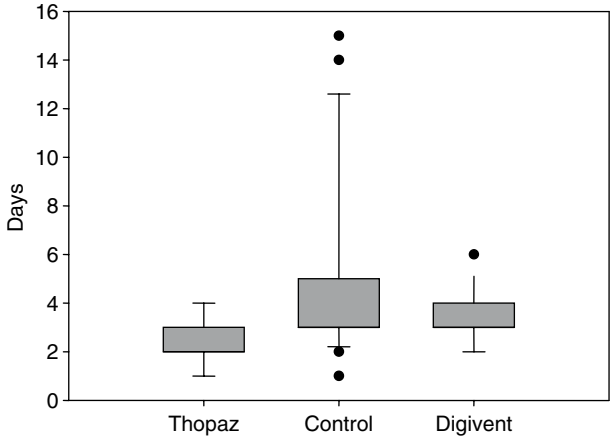


**Figure – Comparison of withdrawal time.**

**Table 3 – Nursing staff survey results**

| Device | Qa | Qb | Qc | Qd | Qe |
|---|---|---|---|---|---|
| Thopaz®, % (option) | 85 (2) | 75 (2), 20 (1) | 100 (3) | 95 (yes) | 35 |
| Digivent®, % (option) | 90 (2) | 80 (2), 15 (1) | 100 (3) | 90 (yes) | 45 |
| Pleur-Evac®, % (option) | 95 (2) | 100 (3) | 50 (2), 25 (1) | 85 (yes) | 20 |

(1)=difficult, (2)=easy, and (3)=very easy.
Q indicates question.

## Discussion

Natural trends in medicine lead us to express results numerically: with analyses, vital signs, monitoring, etc. As a further aid, tables of values providing normal ranges can be used. Since its inception, the chest drain has always been a subjective pulmonary air leak analysis method. Only recently, has a scale to assess air leaks[8] proved to be effective. However, it is not accurate enough to determine when the drain should be removed from a patient. Digital devices provide reliable and safe objective values in this regard.

The publication by Anegg et al,[10] who used the AIRFIX® (TEUPs Ltd, Deutschlandsberg, Austria) in 2006, shows the benefits of a digital measurement system that does not require drainage clamping and testing prior to its removal. Subsequently, it appears system B, which was tested on several series of patients,[9,11] has shown clear benefits compared to the traditional device and eliminated inter-observer differences at drainage withdrawal.[12] We recently tested device A (Medela, Switzerland).[13] Another descriptive study was published online by Robert J. Cerfolio and Cerfolio. To our knowledge, our protocol was the first comparison between 2 prospective digital systems and the traditional system. We clearly share the prospect of the ideal device expressed by other authors,[11] but we know that this is not yet available. We propose that each device has specific indications depending on the patient and the parameters to be evaluated.

Digital devices are easy to use and well accepted by patients and nursing staff. In our study, we demonstrated that inter-observer differences were eliminated regarding the day of drain removal, when compared to the classic system. Device A's integrated suction system gives significant independence to the patient for moving around. The weight of these devices is less than the traditional one, if one takes into account the weight of the 3 when full. If there is any problem (excessive air leak, system disconnection or unnoticed pinching), the alarm system in A is very useful. This system can be used in outpatients (one in our series). The software package included allows useful charts to be obtained for analysis and attaching to the patient's file.

As reflected in our results, it is possible to remove the drain significantly earlier in patients with digital device A. We believe that if the sample had been larger or had been measured in hours instead of days, the result might have been even more conclusive, and probably significant also with device B.

When we removed devices B and used the software package (not available during the study), we realised that the air leak was giving a zero reading days before withdrawal. If we had had this discussion during the daily visits, it would have been possible to optimise it even more, as the drain could have been removed beforehand. The intrapleural pressure information this system offers is valuable, not only for thoracic surgeons but also for the pulmonologist group. This is because they can predict which patient might be a good candidate for effective pulmonary rehabilitation, as it is possible to assess the response of supporting muscles when examining the device graphs, as well as the response to anti-inflammation treatment and its impact on improving the breathing pattern. Studies regarding this matter could give us more information in the future.

As mentioned earlier, continued air leaks prolong hospital stay and concomitant costs for the institution. The digital system may open a field for the outpatient (one in our series), as well as those currently discharged with the Heimlich valve. This does not give us any extra information, whereas the digital device detects if the patient has an air leak at all times. In addition, device A's alarm system warns if there is another problem. Companies developing these devices are currently researching a computerised support to send all this information to a PDA, providing up-to-the-minute information for medical staff.[13]

Device B showed that, at times, continuous suction can be detrimental to the patient, as it can encourage young barotrauma in a patient with an already diseased lung parenchyma. This information was not available to us until the end of the study. If the intrapleural pressure is observed to be high and the air leak low during the daily rounds, the suction may be decreased or even withdrawn. The benefits of discontinuous suction have been demonstrated in other studies.[14]

Among the limitations of our study was the sample size, which was reduced due to the lack of digital devices. Also, they were not randomised groups, as we did not have all types of drainage from the very beginning, and they were used consecutively. A randomised, multicentre study with more patients would give more conclusive results. It is worth mentioning that our department had one of the lowest average hospital stay times.[15] If the study had been carried out in centres with a wider average hospital stay, the

results would have been even more spectacular. Cerfolio also managed to decrease hospital stay from 4.0 to 3.3 days.[11] If this was extrapolated to hospitals with a 6-7 day average, the results would have been even more significant.

Digital devices may be used as research tools[13] for rehabilitation and physical therapy after surgery, for development of aerostatic agents and to investigate with more certainty whether or not using these devices results in fewer chest drain days. In conclusion, we are convinced that digital drainage is here to stay, and that, in the coming years, we will see many more studies supporting this work.

## Conflicts of interest

The authors declare no conflicts of interest.

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