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Lung: Research

Comparison Between Electronic and Traditional Chest Drainage Systems: A Multicenter Randomized Study

Giovanni Maria Comacchio, MD,[1] Giuseppe Marulli, MD, PhD,[2] Paolo Mendogni, MD, PhD,[3] Luigi Gaetano Andriolo, MD,[4] Francesco Guerrera, MD, PhD,[5,6] Debora Brascia, MD,[2] Michele Dario Russo, MD,[1] Sara Parini, MD,[7] Camillo Lopez, MD,[4] Davide Tosi, MD,[3] Giulia Lorenzoni, PhD,[8] Dario Gregori, PhD,[8] Pier Luigi Filosso, MD,[5,6] Ottavio Rena, MD,[7] Lorenzo Rosso, MD,[3] Corrado Surrente, MD,[4] and Federico Rea, MD[1]

ABSTRACT

BACKGROUND Air leak is the major factor that influences the permanence of the chest tube and the in-hospital length of stay (LOS) among patients undergoing lung resections. The aim of this study was to determine whether the use of digital chest drain systems, compared with traditional ones, reduced the duration of chest drainage and postoperative in-hospital LOS in patients undergoing video-assisted thoracoscopic (VATS) lobectomy.

METHODS The study was a prospective, randomized, multicenter trial. Patients undergoing VATS lobectomy were randomized in 2 groups, receiving a digital drain system or a traditional one and managed accordingly to the protocol.

RESULTS Among 503 patients who fulfilled inclusion criteria and were randomized, 38 dropped out after randomization. Finally, 465 patients were analyzed, of whom 204 used the digital device and 261 the traditional one. In the digital group, there was a significantly shorter median chest tube duration of 3 postoperative days (interquartile range [IQR], 2-4 days) vs 4 postoperative days (IQR, 3-4 days; $P = .001$) and postoperative in-hospital LOS of 4 days (IQR, 3-6 days) vs 5 days (IQR, 4-6 days; $P = .035$). Analysis of predictors for increased duration of air leaks showed a relationship with male sex ($P = .039$), forced expiratory volume in 1 second percentage ($P = .004$), forced vital capacity percentage ($P = .03$), and presence of air leaks at the end of surgery ($P = .001$).

CONCLUSIONS In patients undergoing VATS lobectomy, the use of a digital drainage system allows an earlier removal of the chest drain compared with the traditional system, leading to a shorter in-hospital LOS.

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Among patients undergoing lung resections, alveolar air leak is the major factor that influences the permanence of the chest tube and the postoperative in-hospital length of stay (LOS). Management of chest tubes is based on protocols developed during the years by surgeons or institutions, based on the presence or absence of air leaks and on the amount of fluid output.[1,2] Air leaks measurements and grading in traditional drainage systems is based on a "bubbles in a chamber" system, which is a subjective method that depends on the observer's experience and habits: even trained surgeons may disagree about the presence and entity of air leaks.[3,4]

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[1]Thoracic Surgery and Lung Transplant Unit, University Hospital of Padua, Padua, Italy; [2]Thoracic Surgery Unit, University Hospital of Bari, Bari, Italy; [3]Thoracic Surgery and Lung Transplant Unit, Fondazione Istituto di Ricovero e Cura a Carattere Scientifico Ca' Granda Ospedale Maggiore Policlinico, Milano, Italy; [4]Thoracic Surgery Unit, "Vito Fazzi" Hospital, Lecce, Italy; [5]Department of Surgical Science, University of Torino, Torino, Italy; [6]Department of Thoracic Surgery, Azienda Ospedaliera Universitaria Città della Salute e della Scienza di Torino, Torino, Italy; [7]Division of Thoracic Surgery, Ospedale Maggiore della Carità, Novara, Italy; and [8]Unit of Biostatistics, Epidemiology and Public Health, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padua, Padua, Italy

Address correspondence to Dr Comacchio, Thoracic Surgery Unit, Azienda Ospedale Università Padova, Via Giustiniani 2, 35128 Padova, Italy; email: gcomacchio@gmail.com.

The introduction of new digital systems allows an objective measurement of air leaks, reducing the inter-observer variability and optimizing the management of the chest tube. Previous studies have shown contradictory results concerning the reduction of the drainage permanence and in-hospital length of stay (LOS) with these devices,[5-12] but the studies are heterogeneous in the extent of parenchymal resection and surgical approach, making their results hardly comparable.[13]

The primary end point of this study was to determine whether the use of a digital chest system, compared with a traditional one, reduces the duration of chest drainage and postoperative in-hospital LOS in patients undergoing video-assisted thoracoscopic (VATS) lobectomy.

PATIENTS AND METHODS

The study was designed as a multicenter, randomized, investigator-initiated clinical trial. Between January 2017 and November 2020, patients from 6 Italian centers undergoing VATS lobectomy were included. The Consolidated Standards of Reporting Trials (CONSORT)[14] statement was followed, and the flow of patients through each stage of the trial has been reported (Supplemental Figure 1). The Ethics Committee of each hospital involved in the study approved the study, and all patients gave their informed consent to participate. The protocol was registered on clinicaltrials.gov (NCT 03536130) and previously published.[15]

All patients were evaluated and operated on by qualified thoracic surgeons. Criteria for study enrollment included an adequate respiratory function for surgery, in particular, a predicted postoperative forced expiratory volume in 1 second (FEV_1) >30%, a predicted postoperative diffusion capacity of the lung for carbon monoxide >30%, and maximum oxygen consumption >10 mL/kg/min.

Main exclusion criteria were the need for postoperative intensive care unit observation or the intraoperative conversion to thoracotomy.

The company producing the digital device had no role in study design, conduct, data acquisition or monitoring, analysis, or writing of the article.

STUDY PROTOCOL. Briefly, all patients underwent VATS lobectomy, associated with lymphadenectomy in case of malignant disease. At the end of the procedure, the presence of air leaks was evaluated with a water submersion test, with a standard airway pressure of 25 cm H_2O and air leaks measured by a volumetric system. Significant air leaks observed intraoperatively were reduced with parenchymal sutures. Sealants, pleural tents, or buttressing materials were not permitted. A single apical 28F chest tube was put in place at the end of the procedure.

Each center randomized its own patients in 2 groups with a 1:1 ratio. The assignment to 1 of the 2 devices was performed using closed envelopes containing notes reading "T" for the traditional water seal system or "D" for the digital system. One of the surgeons in the surgical theater did the randomization at the end of the VATS lobectomy, after having verified that all criteria were met, by opening the envelope assigned to the patient.

The digital group received the Drentech Palm Evo (REDAX) digital system connected with the chest tube right after closure (Figure 1). The suction pump was set to −20 cm H_2O for 24 hours, then the pump was set to 0 cm H_2O. The traditional group received a traditional drainage system. This system requires a connection to wall suction to apply a negative pressure. Pressure was set at −20 cm H_2O for 24 hours and then disconnected from wall suction.

Air leak and pleural fluid loss were evaluated during morning and afternoon rounds by 2 clinicians. In patients belonging to the digital group, the chest drainage was removed if the Palm Evo system displayed air leaks <20 mL/min for 8 hours (with the system set to 0 cm

FIGURE 1 Digital chest drain used in the study.

TABLE 1 Patients' Baseline Characteristics

Variable	Digital Group (n = 204)	Traditional Group (n = 261)
Sex		
Female	79 (39)	112 (43)
Male	125 (61)	149 (57)
Age, y	69.9 (62-75)	69.0 (62-74)
Comorbidities	152 (75)	203 (78)
Emphysema/COPD	29 (14)	31 (12)
Diabetes mellitus	26 (13)	37 (14)
Cerebrovascular disease	4 (2)	7 (3)
Cardiovascular disease	11 (5)	30 (12)
FEV_1, %	95 (79-110)	95 (80-110)
Forced vital capacity, %	100 (87-112)	100 (89-114)
Tiffeneau-Pinelli Index	76.8 (69.4-84.2)	77.4 (70.9-84.1)
DLCO, %	79 (67-94)	79 (68-94)
Induction chemotherapy	11 (5)	4 (2)

Data are median (interquartile range) for continuous variables and absolute n (%) for categorical variables. COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; DLCO, diffusion of the lung for carbon monoxide.

H_2O) without significant excursions on the graphic (air leak spikes). In patients belonging to the traditional group, the chest tube was removed if no bubbles were seen in the water seal column by having the patients cough (with no wall suction applied). In both groups, <300 mL/24 hours of liquid loss and a chest roentgenogram showing a full lung reexpansion were required before considering chest tube removal.

TABLE 2 Patients' Intraoperative Characteristics

Variable	Digital Group (n = 204)	Traditional Group (n = 261)
Lobectomy		
Right upper	59 (29)	72 (28)
Right middle	17 (8)	27 (10)
Right lower	36 (18)	57 (22)
Left upper	59 (29)	58 (22)
Left lower	33 (16)	47 (18)
Surgical time, min	155 (110-195)	150 (120-190)
Lymphadenectomy		
Radical	149 (73)	152 (58)
Sampling	54 (26)	107 (41)
Not done	1 (0)	2 (1)
Air leaks at end of surgery, mL/min	8 (1-15)	11 (1-15)
Blood loss at end of surgery, mL	52.5 (30-100)	50 (30-100)
Tumor histology		
Adenocarcinoma	119 (58)	145 (56)
Squamous cell carcinoma	38 (19)	60 (23)
Carcinoid	22 (11)	34 (13)
Metastasis	13 (6)	14 (5)
Other	12 (6)	8 (3)
Stage		
I	130 (73)	167 (70)
IIa	7 (4)	9 (4)
IIb	30 (17)	36 (15)
IIIa	12 (7)	23 (10)
IIIb	0 (0)	4 (2)

Data are median (interquartile range) for continuous variables and absolute n (%) for categorical variables.

For the purpose of this study, the air leak duration was calculated in days, starting from the day of surgery until air leaks were no longer detectable. Patients in both groups with prolonged air leaks (PALs) were managed according to each center's protocol, and data were collected for 8 days. PALs were defined as air leaks lasting >7 postoperative days (POD). Crossover between the 2 groups was not allowed. Postoperative treatment was focused on early mobilization, physical and respiratory rehabilitation, and antithrombotic prophylaxis. Pain control was obtained by using analgesic drugs (epidural catheters, intercostal blocks, or mixed techniques) so that its value was <4 on the visual analog scale during the first 48 to 72 hours. Each center adopted its own pain management protocol based on its usual postoperative routine.

STATISTICAL ANALYSIS. The study was powered based on its primary end points, which were the duration of chest tube placement and the in-hospital LOS. The sample size was calculated to detect a difference in duration of the chest tube placement and hospital LOS after VATS lobectomy of at least 1 day (SD, 3) and based on previously published data.[8] A sample size of 382 patients (191 patients per group) was determined based on 90% statistical power, with a significance level of 0.05, and allowing for dropouts. Per-protocol and intention-to-treat analysis were both performed.

Descriptive statistics are reported as median and interquartile range (IQR) for continuous variables and percentages and absolute numbers for categorical variables. Wilcoxon and Pearson χ^2 tests were performed to compare the distribution of continuous and categorical variables, respectively. *P* values of primary and secondary outcomes underwent Benjamini-Hochberg correction to account for multiplicity of testing. Univariable gamma models were used to identify predictors of air leaks duration, given the nonnormal distribution of the outcome. The marginal effect was computed considering the partial derivatives of the marginal expectation. Results are reported as the average marginal effect (AME), 95% CI, and *P* value. Analyses were performed with R software (R Core Team, http://www.r-project.org/index.html) within the rms package.

RESULTS

The study screened 612 patients, and 109 were excluded intraoperatively. The remaining 503 patients were

TABLE 3 Patients' Postoperative Characteristics

Variable	Digital Group (n = 204)	Traditional Group (n = 261)	*P*
Postoperative complications	36 (18)	48 (18)	.83
Cardiovascular	13 (6)	11 (4)	.65
Pulmonary	18 (9)	28 (11)	.63
Prolonged air leaks (>7 days)	6 (3)	5 (2)	.47
Other	6 (3)	6 (2)	.66
Duration air leaks, d	0 (0-2)	0 (0-2)	.92
Primary outcomes			
Chest drain removal POD	3 (2-4)	4 (3-5)	.001
Postoperative length of stay, d	4 (3-6)	5 (4-6)	.035

Data are median (interquartile range) for continuous variables and absolute n (%) for categorical variables. POD, postoperative day.

randomized in the 2 groups: 229 in the digital group and 274 in the traditional one. Respectively, 25 and 13 patients dropped out during the postoperative period, so 204 patients for the digital group and 261 patients for the traditional group were ultimately included in the final analysis (Supplemental Figure).

Baseline characteristics did not significantly differ between the 2 groups, except for a higher incidence of cardiovascular disease in the traditional group (Table 1).

Intraoperative and pathologic data are reported in Table 2. Surgical and pathologic data were comparable, except for a higher proportion of radical lymphadenectomy in the digital group. In the postoperative period, there were no deaths in either group and no differences in the incidence of postoperative complications ($P = .836$). In the digital group, 6 patients (3%) experienced persistent air leak 7 days after surgery compared with 5 patients (2%) in the traditional group ($P = .47$); 12 (6%) and 18 patients (7%), respectively, experienced PAL for >5 days, still without a statistically significant difference ($P = .06$) (Table 3).

Median duration of air leaks was 0 POD (IQR, 0-2 days), with no differences between the 2 groups ($P = .928$), whereas the median duration of chest tube stay was significantly shorter in the digital group (3 POD [IQR, 2-4 days] vs 4 POD [IQR, 3-4 days], $P = .001$) (Table 2, Figure 2). Consequently, the postoperative hospital LOS in the digital group was shorter (4 POD [IQR, 3-6 days] vs 5 POD [IQR, 4-6 days], $P = .035$) (Table 2, Figure 3). Intention-to-treat analysis showed comparable results, except for a loss of significance of postoperative LOS (Supplemental Tables 1-3).

Analysis of predictors for increased duration of air leaks showed a relationship with male sex (AME, 0.61; 95% CI, 0.02-1.19; $P = .039$), FEV_1% (AME, −0.02; 95% CI, −0.03 to −0.006; $P = .004$), forced vital capacity percentage (AME, −0.01; 95% CI, −0.03 to −0.001; $P = .03$), and presence of air leaks at the end of surgery (AME, 0.05; 95% CI, 0.02-0.08; $P = .001$), whereas no association was found for radical lymphadenectomy (AME, 0.51; 95% CI, −0.08 to 1.1; $P = .09$), side of lobectomy (AME, 0.48l; 95% CI, −1.08 to 0.11; $P = .11$), and upper lobectomies (AME, −0.15; 95% CI, −0.002 to 0.008; $P = .6$).

COMMENT

Among patients undergoing major lung resections, alveolar air leak is the main factor that influences the permanence of the chest tube and therefore the postoperative in-hospital LOS. PAL is also associated with an increased morbidity in the postoperative period.

Air leaks measurement and grading in traditional drainage systems is based on a "bubbles in a chamber" system, which is a subjective method that depends on the observer's experience and habits; in fact, even trained surgeons may disagree on air leaks presence and entity. No guidelines are available, and particularly for air leakage assessment, tube management conventionally depends on the experience of individual surgeons.[1,2]

The introduction of electronic drainage systems has allowed objective air leaks measurement, possibly reducing the interobserver variability and optimizing the chest tube management.[4] In a previous study, we demonstrated the potential of the Drentech Palm Evo digital evaluation to influence the clinical management in 13 of 25 patients (52%), allowing early chest tube removal due to the recognition of false-positive air leaks with a traditional system in 9 patients (36%) and to the identification of residual pleural space effect in 4 (16%).[16]

The improvement in the chest tube management could be associated with an early removal and a shorter in-hospital LOS. Brunelli and associates[5] proved a decrease in LOS of 0.9 days (5.4 vs 6.3 days) when comparing digital vs traditional systems; similar outcomes were also described by Miller and associates[6] and Shoji and associates.[7] Furthermore, Pompili and associates[8] showed a decrease in the duration of air leaks together with a reduction of chest tube stay and postoperative LOS by using a digital system.

Other authors, however, did not find any difference between the 2 systems.[9-12] However, all of these studies were performed with different electronic devices and different technologies: some used an airflow meter to directly measure the airflow through the chest tube, whereas others derived airflow data from an algorithm based on the intrapleural pressure. Moreover, the study populations were also highly heterogenous, including

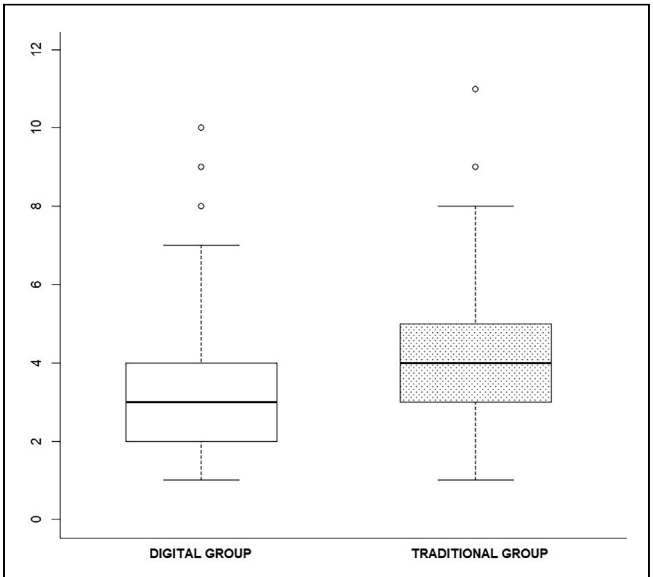

FIGURE 2 Chest tube length of stay (days) in the 2 groups. The line in the middle of each box indicates the median, the top and bottom borders of the box mark the 75th and 25th percentiles, respectively, the whiskers mark the maximum and minimum ranges, and the circles indicate outliers.

different types of surgical resections, from wedges to lobectomies, performed through both open and thoracoscopic approaches.

Our large study compared 2 cohorts of patients who underwent the same surgical procedure. Our results show that in patients managed with an electronic device, the chest drain is removed 1 day earlier than with a traditional one, despite not having found differences in air leak duration. This could be explained by a higher degree of confidence on the actual absence of air leaks detected through the digital system. Indeed, the "bubble in the chamber" method only allows an instant evaluation; therefore, a subtle air leak could be misdiagnosed. On the contrary, the digital device enables a continuous recording of air leaks, therefore making the clinician much more confident with the drain removal. In our study, earlier removal of the chest tube allowed a shorter postoperative in-hospital LOS.

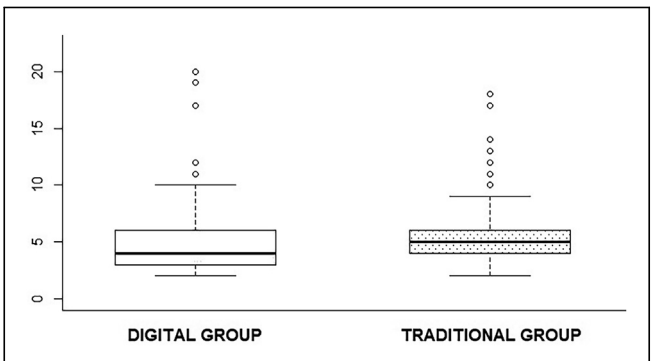

FIGURE 3 Postoperative length of stay (days) in the 2 groups. The line in the middle of each box indicates the median, the top and bottom borders of the box mark the 75th and 25th, percentiles, respectively, the whiskers mark the maximum and minimum ranges, and the circles indicate outliers.

Moreover, continuous monitoring allows the clinician to distinguish an active air leak, often associated with a continuous transpleural flow >20 mL/min from a pleural space effect (<10 mL/min).[5]

Air leak represents one of the most common postoperative complications after lung surgery, with an incidence of 20% to 33% after elective pulmonary resections,[17,18] whereas rates of PALs vary in the literature from 6% to 26%.[19-21] Air leak has already been demonstrated to be one of the most important factors contributing to prolonged in-hospital LOS and, consequently, to overall hospital costs,[1,22,23]

To date, there is no consensus about the definition of PALs; some studies define PAL as lasting >5 days, whereas others consider 7 days as a cutoff value.[24,25] In our study, we considered a period of 7 days; however, we did not find any differences between the 2 groups when we also considered the cutoff of 5 days.

Different authors have tried to find predictors of PALs[23,26,27]; particularly, the risk of PAL was related to sex, FEV_1, body mass index, presence of pleural adhesions, and upper lobectomies. In our study, PALs were associated to older age, male sex, lower FEV_1%, lower forced vital capacity percentage, and to the amount of air leaks at the end of surgery. These results, which were outside the scope of this study, are consistent with what has been previously published by others.[23,26,27]

This study has some limitations. First, because of its nature, the study was unblinded for both patients and investigators. The possibility of a systematic bias in the postoperative management of patients across treatment and control groups cannot be ruled out entirely.

Another possible limitation of the study is that for the digital system, there was a clear indication for drain removal, in air leaks entity, whereas drain removal for the traditional system was left to the surgeon's choice. Indications were not strict, however, and could be influenced by local habits; this may explain the difference between the time of air leaks end and the one of the drain removal; however, this influenced both groups comparably.

Furthermore, traditional air leaks evaluation was not performed according to a standardized classification system; for this reason, the presence of 2 clinicians to evaluate the presence of air leaks was useful to reduce the interobserver variability.

In addition, the percentage of patients with PAL seems lower than the percentage reported in the literature, which could be explained by the strict inclusion criteria that may have excluded patients at higher risk by developing PAL. More studies are needed to investigate the possible roles and advantages of the digital system in this subgroup of high-risk patients.

In conclusion, this study demonstrates that in patients undergoing VATS lobectomy, the electronic drainage system may allow an earlier removal of the chest drain compared with the traditional system, leading to a shorter in-hospital LOS.

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DISCLOSURES

The authors have no conflicts of interest to disclose.

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