

**TITLE:** Compact Digital Thoracic Drain Systems for the Management of Thoracic Surgical Patients: A Review of the Clinical Effectiveness, Safety, and Cost-Effectiveness

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## **CONTEXT AND POLICY ISSUES**

Air leaks are among the most common complications after thoracic surgery, and can also be one of the more costly complications to manage. It is estimated that between 30% and 50% of thoracic surgery patients will experience an air leak either immediately or within the first post-operative day.<sup>1</sup> Prolonged air leaks are typically defined as an air leak lasting longer than five days, and can increase the potential for infections, might require re-operation and can lead to prolonged hospital stays to manage chest tubes, pain, and other complications.

Traditionally, air leaks are monitored using water-based systems that allow for the subjective detection and assessment of bubbles in a water chamber. This method is prone to intra-observer variability,<sup>2</sup> and can result in the detection of false air leaks.<sup>3,4</sup>

Digital thoracic drainage systems are becoming more popular for their ability to continuously and objectively monitor air leak flow and intra-pleural pressure through the use of internal pressure sensors. Some digital systems also have the ability to regulate intra-pleural pressure by applying suction as needed based on physician-set levels. The ability of digital systems to record and store real-time air leak and pressure data for subsequent analysis is thought to increase confidence in chest tube management decisions since the decision can be made based on the trend of an air leak as opposed to a single assessment at one point in time.<sup>3</sup> The potential for digital systems to distinguish active air leaks from a pleural space effect<sup>5</sup> or false air leaks due to reverse airflow in traditional three-chamber water-seal systems<sup>4</sup> has also been documented, further suggesting that digital systems could offer a more reliable method of air leak detection.

The purpose of this review is to examine the clinical effectiveness, cost-effectiveness and safety of digital thoracic drainage systems, as compared to the traditional drainage systems, for the post-operative management of thoracic surgery patients.

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## RESEARCH QUESTIONS

1. What is the clinical effectiveness and safety of compact digital thoracic drainage systems for the post-operative management of thoracic surgical patients?
2. What is the cost-effectiveness of compact digital thoracic drainage systems for the post-operative management of thoracic surgical patients?

## KEY FINDINGS

The potential for measurement bias across all included studies cannot be ruled out and the quantity of available evidence is limited. Despite these important limitations, a consistent decrease in duration of chest tube placement and length of hospital stay was observed among studies that compared digital thoracic drainage systems with external suction to traditional chest drainage systems, and digital thoracic drainage systems with external suction as compared to digital systems without external suction, in particular for anatomic versus non-anatomic resections. Results for the comparison of digital devices without suction to traditional systems are uncertain in relation to these outcomes.

There does not appear to be any meaningful impact of the use of digital thoracic drainage systems on any safety related outcomes assessed in this group of studies, including chest tube related and other post-operative complications.

There might be an associated reduction in hospitalization costs, likely related to a shorter length of chest tube duration and hospital stay.

## METHODS

### Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 9), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between January 1 2009 and September 3 2014.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

**Table 1: Selection Criteria**

<b>Population</b>	Patients undergoing thoracic surgery requiring a chest tube
<b>Intervention</b>	Compact digital thoracic drainage system (with or without external suction) used with the intention to monitor air leaks
<b>Comparator</b>	Any different thoracic drainage system used with the intention to monitor air leaks, including: <ul style="list-style-type: none"> <li>• Traditional (“water-seal”) chest drainage system</li> <li>• Digital thoracic drainage system (with or without suction)</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Clinical benefit (e.g., time to chest tube removal, length of hospital stay, quality of life, patient satisfaction)</li> <li>• Clinical harm (e.g., adverse events, complications)</li> <li>• Cost effectiveness</li> </ul>
<b>Study Designs</b>	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies and economic evaluations

**Exclusion Criteria**

Studies were excluded if they did not satisfy the selection criteria, if they were duplicate publications, were case reports or case series, or were published prior to 2009.

**Critical Appraisal of Individual Studies**

The quality of all included studies was assessed using the Downs and Black checklist<sup>6</sup> as a guide. Numerical scores were not calculated; but, instead, the strengths and limitations of individual studies as identified through use of the checklist are summarized and presented.

**SUMMARY OF EVIDENCE**

**Quantity of Research Available**

A total of 297 citations were identified through a search of electronic databases. Following screening of titles and abstracts, 259 citations were excluded. One citation was found through hand searching, leaving 39 potentially relevant reports that were retrieved for full-text review. Of these potentially relevant articles, 32 publications were excluded for various reasons, while 7 publications met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA<sup>7</sup> flowchart of the study selection process. Five RCTs and two cohort studies met the inclusion criteria. One best-evidence topic (i.e. similar to a systematic review) was identified,<sup>8</sup> although was excluded from this report in favour of including the individual studies included in that review.

Additional references of potential interest are provided in Appendix 2. These include reports of one RCT and one uncontrolled trial assessing the effectiveness of a digital thoracic drainage system that would have been included in this review if they met the publication date criteria. Also included are a case report and a report from an RCT assessing the effectiveness of a digital drainage system in the treatment of air leaks among patients with spontaneous pneumothorax.

## Summary of Study Characteristics

A detailed summary of individual study characteristics is provided in Appendix 3.

### *Study Design*

Overall, seven studies were included in the review: five RCTs<sup>9-13</sup> and two cohort studies.<sup>14,15</sup>

### *Country of origin*

Four of the five included RCTs originated in Italy,<sup>10-13</sup> while another RCT was a multi-centre international study that included data from Italy in addition to data collected in the United States, the United Kingdom, and China.<sup>9</sup> One of the observational studies was also conducted in Italy,<sup>14</sup> with the other observational study conducted in Spain.<sup>15</sup>

### *Patient Population*

Each of the included RCTs included adult patients who underwent some form of lung resection, including lobectomy,<sup>9-13</sup> segmentectomy,<sup>9,10,13</sup> thoractotomy,<sup>10,13</sup> or wedge resection.<sup>10,13</sup> Two of the RCTs included specifically adult patients who underwent pulmonary lobectomy for primary lung cancer,<sup>11,12</sup> one of which focused on patients with moderate chronic obstructive pulmonary disorder.<sup>11</sup> The average age of participants across studies was between 63 and 70 years of age, although one study reports an age range of 16 to 79 years.<sup>13</sup> Males and females are equally represented in two of the RCTs,<sup>9,13</sup> while the other three RCTs included a larger proportion of males than females.<sup>10-12</sup>

One of the included observational studies included adult patients with an average age of 66.7 years for the intervention group and 68.5 years for the control group. All participants in this study underwent pulmonary lobectomy for reasons other than lung cancer and their sex was not reported.<sup>14</sup> The other observational study included adult patients with an average age of 65.6 years for the intervention group (69% male) and 62.04 years (71% male) for the control group. In this study all participants underwent either pulmonary lobectomy or another limited resection.<sup>15</sup>

### *Intervention and comparators*

Six of the seven studies included a digital chest drainage system as the intervention either with external suction (e.g., Thopaz, Drentech Simple PLUS P.A.L.M.)<sup>9,11,14,15</sup> or without external suction (e.g., Digivent, Drentech)<sup>12,13,15</sup> as compared to a traditional chest drainage system (Pleur-Evac, unspecified). The other included study assessed a digital chest drainage system with suction as the intervention, as compared to a digital system without suction as the control.<sup>10</sup> Of note, one study had three study groups representing patients who were treated with the digital system with suction, digital system without suction, or the traditional chest drainage system.<sup>15</sup> This group of studies therefore allows for three main comparisons:

- a) digital chest drainage system with external suction as compared to a traditional chest drainage system<sup>9,11,14,14</sup>
- b) digital chest drainage system without external suction as compared to a traditional chest drainage system<sup>12,13,15</sup>

- c) digital chest drainage system with external suction as compared to a system without external suction<sup>10,15</sup>

A summary of study findings is presented according to these three comparisons.

### *Outcomes Measured*

All included studies assessed the effectiveness of digital thoracic drainage systems by measuring the duration of chest tube placement<sup>9-15</sup> or the number of people with a chest tube on post-operative day 7.<sup>10</sup> Additionally two studies assessed patient satisfaction.<sup>9,13</sup> Four studies assessed cost and resource use outcomes including hospital length of stay,<sup>9,11-14</sup> hospitalization costs,<sup>11,14</sup> post-operative costs,<sup>12</sup> and number of post-operative chest X-rays.<sup>13</sup> Three studies measured safety-related outcomes including post-operative complications<sup>10,12</sup> and chest tube-related complications.<sup>14</sup>

### **Summary of Critical Appraisal**

A summary of critical appraisal of individual studies can be found in Appendix 4.

Overall, the quality of included studies was moderate. Most of the studies provided a detailed description of the study objectives, outcomes and eligibility criteria<sup>9,10,12-14</sup> but poor reporting of other study design elements (e.g., power calculations, randomization and allocation concealment procedures) made it difficult to assess some potential biases in individual studies. Further, due to the nature of digital thoracic drainage systems, blinding of patients, clinicians and outcome assessors is not possible. A lack of blinding raises the potential for bias in the measurement of study outcomes for all included studies.

Three RCTs<sup>9,10,12</sup> reported power calculations, providing confidence the study sample sizes were adequate to detect a clinically important difference (i.e. 1 day) in the duration of chest tube placement<sup>9,10</sup> or proportion of patients with a chest tube on post-operative day 7 due to persistent air leak (PAL) (i.e. 30% decrease).<sup>10</sup> Two of the RCTs<sup>11,13</sup> and both observational studies<sup>14,15</sup> reported use of a consecutive sample without justification for the total number of participants enrolled. Poor reporting of sample size calculations raises the potential for some studies to be underpowered to detect a clinically important difference in their primary outcome in addition to being underpowered to detect meaningful differences in secondary outcomes, in particular adverse events and complications.

Two RCTs<sup>9,13</sup> reported adequate randomization and allocation concealment procedures, while one<sup>10</sup> described an adequate randomization procedure without any details about allocation concealment and two other RCTs did not report any details about randomization or allocation concealment.<sup>11,12</sup> Inadequate reporting of these processes precludes an assessment of any potential bias in group assignment. Three RCTs<sup>9,10,12</sup> report balanced treatment groups in terms of major potential confounders for example FEV<sub>1</sub>, diabetes, steroid use or type of resection. The other two RCTs report limited information on the topic: one<sup>11</sup> included only patients with chronic obstructive pulmonary disease, defined as FEV<sub>1</sub>% between 50% and 70%, who underwent lobectomy but did not report data on other important confounders; the other<sup>13</sup> reported data on type of resection but no other important confounders. Both observational studies<sup>14,15</sup> reported balanced treatment groups, while one of those observational studies<sup>14</sup> also provided an explicit description of an adequate matching procedure to control for confounding.

One observational study had the objective to assess the existence and duration of a learning curve with use of a digital device;<sup>14</sup> but, none of the remaining studies included a description of training or experience with study interventions, raising the potential for measurement error. Further, one of the three studies that included cost-related data provided information regarding the source of cost data as well as included fixed and variable costs,<sup>12</sup> while one indicated the source as the hospital's accounting and pharmacy data system but not what was included in total cost<sup>14</sup> and the other did not provide any information as to the source nor included costs but only provided an average cost for one day stay in the unit.<sup>11</sup> Poor reporting of cost-related data could indicate unreliable and invalid measurement of this outcome. Finally, one RCT<sup>11</sup> and observational study<sup>15</sup> showed evidence of incomplete outcome reporting.

For each of the included studies participants were sampled from major centres with qualified surgeons who regularly practice thoracic surgery with limited exclusion criteria, suggesting the samples are representative of the people for whom the digital chest drainage systems are intended for use. However, four RCTs<sup>9,10,12,13</sup> described excluding patients post-operatively (i.e. after they were enrolled in the study) if they required mechanical ventilation or repeat surgeries, as these criteria are major confounders within chest tube management. Excluding these patients from the analysis raises the potential for measurement bias in these studies. Of note, one observational study<sup>15</sup> likewise excluded patients with this type of post-operative complication, while the other observational study did not report eligibility criteria.<sup>14</sup>

## Summary of Findings

The main findings of included studies are summarized in detail in Appendix 5.

### *Duration of chest tube placement*

a) Digital chest drainage system with external suction as compared to a traditional chest drainage system: Each of the two RCTs<sup>9,11</sup> and two observational studies<sup>14,15</sup> that assessed duration of chest tube placement between these groups demonstrated a statistically significantly shorter chest tube placement with the digital system. The decrease in duration of chest tube placement was less in the RCTs (0.9 days<sup>11</sup> and 1.1 days<sup>9</sup>) than the observational studies (1.9 days<sup>14</sup> and 2.1 days<sup>15</sup>).

b) Digital chest drainage system without external suction as compared to a traditional chest drainage system: Each of the two RCTs<sup>12,13</sup> that assessed duration of chest tube placement between these groups demonstrated a shorter chest tube placement with the digital system: one of which reached statistical significance (0.9 day decrease,  $P < 0.001$ )<sup>12</sup> while the other approached but did not reach statistical significance (0.6 day decrease,  $P = 0.056$ ).<sup>13</sup> The observational study that compared these two systems likewise demonstrated a non-statistically significant decrease in duration of chest tube placement (1.2 day decrease,  $P = 0.47$ ).<sup>15</sup>

c) Digital chest drainage system with external suction as compared to a system without external suction: One RCT<sup>10</sup> and one observational study<sup>15</sup> assessed duration of chest tube placement between these groups. In the RCT, the analysis was stratified based on whether patients underwent an anatomic or a non-anatomic resection. For those patients who underwent an anatomic resection, there was a statistically significant decrease in duration of chest tube placement (number of people with persistent air leak on post-operative day 7: 25 versus 14,  $P = 0.05$ ); but no difference for those who underwent a non-anatomic resection (number of people with persistent air leak on post-operative day 7: 9 versus 11,  $P = 0.80$ ).<sup>10</sup> In the observational

study, there was a statistically significant decrease in duration of chest tube placement for the group with external suction (0.9 days;  $P = 0.01$ ).<sup>15</sup>

#### *Hospital length of stay*

a) Digital chest drainage system with external suction as compared to a traditional chest drainage system: Two RCTs<sup>9,11</sup> and one observational study<sup>14</sup> compared either hospital length of stay or post-operative length of stay, and each reported a statistically significant decrease in the average length of stay. The RCTs reported a decrease of 1.0 day ( $P < 0.0001$ )<sup>9</sup> and 2.8 days ( $P < 0.001$ ),<sup>11</sup> while the observational study reported a decrease of 1.5 days ( $P = 0.0003$ ).<sup>14</sup>

b) Digital chest drainage system without external suction as compared to a traditional chest drainage system: Two RCTs<sup>12,13</sup> compared hospital length of stay: one reported a statistically significant decrease of 0.9 days ( $P = 0.007$ ),<sup>12</sup> while the other reported a non-significant decrease of 0.6 days ( $P = 0.09$ ).<sup>13</sup>

#### *Post-operative Complications*

a) Digital chest drainage system with external suction as compared to a traditional chest drainage system: One observational study assessed chest tube related complications, although no such complications were reported in either study group.<sup>14</sup>

c) Digital chest drainage system with external suction as compared to a system without external suction: One RCT assessed post-operative complications, including pleural, pulmonary, cardiac, surgical and other complications.<sup>10</sup> For pleural post-operative complications only (e.g., persistent air leak, pneumothorax), the proportion was lower in the group treated with external suction versus those treated without external suction (14% vs. 22.4%;  $P = 0.01$ ). For all other complications, there was no difference between treatment groups. One RCT<sup>13</sup> assessed cardiopulmonary complications only, reporting no difference between treatment groups.

#### *Patient Satisfaction*

a) Digital chest drainage system with external suction as compared to a traditional chest drainage system: In one RCT patient satisfaction was assessed using an unvalidated investigator developed questionnaire.<sup>9</sup> Responses suggested patients were satisfied with the digital system in terms of their ease getting out of bed ( $P < 0.008$ ), convenience for themselves and healthcare personnel ( $P = 0.02$ ) and their comfort being discharged home with the device if needed (non-significant  $P = 0.06$ ). There was no reported difference between groups in terms of ability to walk around alone, carry the device, social comfort, or comfort at night in bed.

b) Digital chest drainage system without external suction as compared to a traditional chest drainage system: One RCT assessed patient satisfaction, also using an unvalidated investigator developed questionnaire.<sup>13</sup> In this RCT, patients reported significantly ( $P = 0.002$ ) greater ease moving around with the digital system (94%) as compared to the traditional system (31%).

#### *Post-Operative Costs*

a) Digital chest drainage system with external suction as compared to a traditional chest drainage system: One RCT<sup>11</sup> and one observational study<sup>14</sup> reported significantly lower hospitalization costs in the group treated with the digital system. The RCT reported an average

decrease of 2,800€ ( $P < 0.01$ )<sup>11</sup> while the observational study reported an average decrease of 751€ ( $P = 0.0002$ ).<sup>14</sup> Neither of the reports specified what was included in the 1,000€<sup>11</sup> or 400€<sup>14</sup> average daily hospital costs used in the calculations.

b) Digital chest drainage system without external suction as compared to a traditional chest drainage system: One RCT included an assessment of post-operative costs, reporting an average decrease of 476€ in post-operative costs for the digital group, including patient-care supplies, food, radiographic film, laboratory reagents, medications, post-operative therapeutic procedures, employee salaries, building maintenance, and utilities.<sup>12</sup> A separate RCT assessed the number of post-operative x-rays, reporting a non-significant decrease in the number of post-operative x-rays between groups (4 vs. 5,  $P = 0.09$ ).<sup>13</sup>

## Limitations

The evidence to support an assessment of the clinical effectiveness of compact digital thoracic drainage systems in terms of shortening the duration of chest tube placement or length of hospital stay is limited in quantity and quality. First, by nature of the intervention, blinding of patients, clinicians and outcome assessors was not possible, which raises the potential for bias in outcome measurement across all studies. Further, while seven studies, including five RCTs, were included in this review, the overall variability in surgical and hospital procedures across centres limits the generalizability of the findings. Across studies, there were inconsistent protocols for chest tube removal, and no outlined protocol for hospital discharge. In different studies chest tubes were removed if pleural fluid output was less than 200mL/day,<sup>11,15</sup> 250ml/day,<sup>13</sup> 300mL/day,<sup>10</sup> or 400mL/day<sup>12,14</sup>. In one multi-centre study, there was no overall study defined protocol for when chest tubes should be removed, although it is reported that protocols vary across the individual centres from between 300 and 400 mL/day.<sup>9</sup> In addition, the number of chest tubes used among thoracic surgical procedures varied across studies. In some studies single chest tubes were used,<sup>9,13-15</sup> in others two tubes were used<sup>11,12</sup> and in one study either one or two tubes were used depending on the surgical procedure.<sup>10</sup> The type of digital thoracic drainage system also varied across studies, in terms of manufacturer in addition to devices with and without external suction. While the findings are summarized according to devices with and without external suction, the number of studies within any one comparison is limited and within group variation is likely due to different software and technologies within each device.<sup>3</sup>

The data to support an assessment of the safety and cost-effectiveness of compact digital thoracic drainage systems is also limited by the nature of published studies. The potential for outcome measurement bias likewise exists for these outcomes, because blinding was not possible and the small number of studies assessing each outcome makes it difficult to draw confident conclusions. Further, it was impossible to appropriately assess other potential sources of bias due to poor reporting of important study design elements. For example, a small number of safety outcomes were assessed in three included studies: one RCT that did not report any randomization or allocation concealment procedures,<sup>12</sup> and one RCT<sup>13</sup> and one observational study<sup>14</sup> with moderate sample sizes but that did not report power calculations. Further, of the three studies that provided cost data<sup>11,12,14</sup> only one<sup>12</sup> provided a definition for what was included in total costs. While poor reporting of these important study design elements does not indicate the studies are of low quality, it does mean the potential for important biases within these studies cannot be ruled out.

## CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

This review provides a summary of seven studies published in the past five years regarding the clinical effectiveness, cost-effectiveness and safety of digital thoracic drainage systems. The evidence in this field is limited, most importantly because blinded studies are not possible due to the nature of the intervention, which raises the potential for measurement bias. Further, while seven studies were included, the variety in digital systems used across studies means the number of studies assessing any one type of system is even more limited. Four studies assessed a digital chest drainage system with external suction as compared to a traditional chest drainage system,<sup>9,11,14,14</sup> three assessed a digital chest drainage system without external suction as compared to a traditional chest drainage system<sup>12,13,15</sup> and two studies assessed a digital chest drainage system with external suction as compared to a system without external suction.<sup>10,15</sup>

While the potential for measurement bias cannot be ruled out and the quantity of available evidence is limited, each of the included studies reported a decrease—although not all were statistically significant—in the duration of chest tube placement<sup>9,11-15</sup> and length of hospital stay<sup>9,11-14</sup> with a digital system as compared to a traditional chest drainage system. The trend towards a decrease in chest tube placement and length of hospital stay holds for RCTs and observational studies that compared digital devices with external suction to traditional systems, and for digital devices with suction compared to digital devices without suction, in particular among anatomic versus non-anatomic resections. Some non-significant results in the comparison between digital devices without suction and traditional systems raise uncertainty about the effectiveness of digital devices without suction in relation to these outcomes. There does not appear to be any meaningful impact on any safety related outcomes assessed in this group of studies,<sup>10,12,14</sup> including chest tube related and other post-operative complications, but there might be an associated reduction in hospitalization costs, likely related to a shorter length of chest tube duration and hospital stay.

Further well-designed RCTs are needed that include explicit definitions for chest tube removal, hospital discharge, adverse events and hospitalization costs, perhaps following consensus-based guidelines in the field.<sup>3</sup> Importantly, given the variation in digital thoracic drainage systems available on the market, which use different software and technologies,<sup>3</sup> comparative studies are also needed to begin to understand whether there are important differences among systems. Given the limited number of published studies in the field, the current review could not address this question. Implicit to the study of different digital drainage systems is the question of whether or not external suction (through any suction device, digital or not) should be applied to help manage the pleural space. This debate does not appear to be settled, with a recent systematic review indicating no difference in terms of incidence of persistent air leak, drainage time, length of hospital stay or incidence of postoperative pneumothorax between patients treated with any external suction device as compared to traditional water seal systems without suction.<sup>16</sup>

Despite uncertain data regarding the clinical effectiveness, safety and cost-effectiveness of digital thoracic drainage systems, there is some literature to support that digital systems offer a reliable method of monitoring air flow and pleural pressure.<sup>4,17</sup> Reports of failures among digital systems also appear rare. No digital failures were reported among any of the studies included in this review, although one comparative case series that documented chest tube management strategies across four German thoracic surgery units includes a report of one participant (out of 80) that had to be excluded from the study due to damage of the respective digital file.<sup>18</sup> Further,

there is some data to suggest that nurses and patients might prefer digital systems over the traditional water based systems. For example, it has been reported that patients appreciate that digital systems are portable, whereas not all traditional water systems are, as well as compact and lightweight, which improves mobility and independence.<sup>19,20</sup> Nurses have also expressed a perception that the digital devices are safer, and a preference for working with digital systems.<sup>15</sup> One observational study included in this review explored the concept of a learning curve for the implementation of a digital chest drainage system, and concluded that a learning curve is limited to approximately 40 patients.<sup>14</sup>

While the utility of digital thoracic drainage systems in surgical care remains equivocal, there appears to be momentum in terms of using digital devices for research purposes, reportedly due to the inherently more objective nature of air flow and pressure measurements with the digital systems.<sup>21-25</sup> The ability of digital devices to record real-time and continuous air leak data has also allowed further exploration of the characteristics of air leaks. For example, in one study using a digital system, researchers observed that air leaks can be intermittent, and that the difference in pressure between post-operative day 1 and 2 might be predictive of future persistent air leak.<sup>26</sup> Other researchers have used data derived from the digital system to measure air flow and subsequently to develop a risk model to predict persistent air leak.<sup>1</sup> This type of work has important implications as researchers and clinicians in the field work to standardize chest drain removal procedures.

**PREPARED BY:**

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

[www.cadth.ca](http://www.cadth.ca)

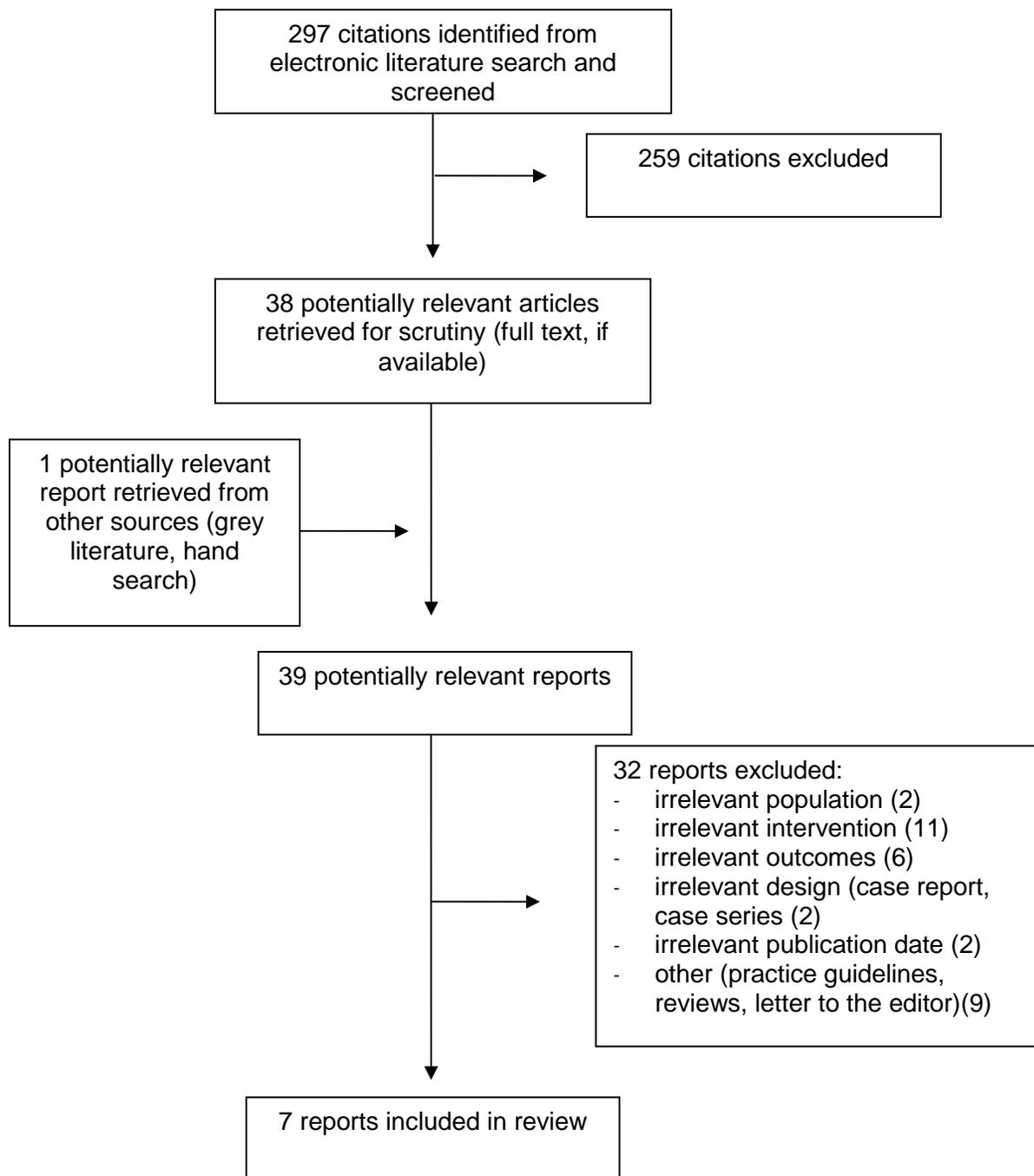
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APPENDIX 1: Selection of Included Studies



## APPENDIX 2: Other References of Potential Interest

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**APPENDIX 3: Summary of Characteristics of Included Studies**

First Author, Publication Year, Country(s)	Study Design	Patient Population	Intervention, Number and Characteristics of Patients	Comparator, Number and Characteristics of Population	Outcomes Measured
<b>Randomized Controlled Trials (RCTs)</b>					
Pompili, <sup>9</sup> 2014, Italy, United States, United Kingdom, China	RCT	391 patients who underwent lung resection	Digital chest drainage system (Thopaz), n=191, 66.5 mean years of age, 49% male	Traditional chest drainage system, n=190, 65.9 mean years of age, 55% male	Duration of chest tube placement, post-operative length of stay, patient satisfaction
Leo, <sup>10</sup> 2013, Italy	RCT	500 patients who underwent lung resection	Digital chest drainage system with external suction (Thopaz), n=250, median 62 years of age, 64.8% male	Digital chest drainage system without external suction (Drentech), n=25, median 64 years of age, 64.0% male	Number of people with chest tube on post-operative day 7 due to PAL, post-operative complication rate
Bertolaccini, <sup>13</sup> 2011, Italy	RCT	100 patients who underwent lung resection	Digital chest drainage system without external suction (Drentech), n=49, median 67 years of age, 48% male	Traditional chest drainage system (unspecified), n=49, median 64 years of age, 51% male	Duration of chest tube placement, hospital length of stay, number of postoperative chest X-rays, patient satisfaction

First Author, Publication Year, Country(s)	Study Design	Patient Population	Intervention, Number and Characteristics of Patients	Comparator, Number and Characteristics of Population	Outcomes Measured
Filosso, <sup>11</sup> 2010, Italy	RCT	31 patients with moderate COPD who underwent lung resection for lung cancer	Digital chest drainage system (Drentech Simple PLUS® P.A.L.M.), n=15, 68.7 mean years of age, 66.7% male	Traditional chest drainage system, n=16, 70.4 mean years of age, 68.8% male	Duration of first chest tube placement, duration of second chest tube placement, hospital length of stay, hospitalization costs
Brunelli, <sup>12</sup> 2010, Italy	RCT	166 patients who underwent lung resection for lung cancer	Digital chest drainage system without external suction (Digivent), n=82, 66.1 mean years of age, 70% male	Traditional chest drainage system (Pleur-Evac), n=77, 67.3 mean years of age, 77% male	Duration of chest tube placement, hospital length of stay, post-operative costs, post-operative complication rate
<b>Observational Studies</b>					
Pompili, <sup>14</sup> 2011, Italy	Matched cohort study	102 patients who underwent lung resection	Digital chest drainage system (Thopaz), n=51, 68.5 mean years of age, sex=not reported	Traditional chest drainage system (unspecified), n=51, 66.7 mean years of age, sex=not reported	Duration of chest tube placement, hospital length of stay, hospitalization costs, chest tube-related complications

First Author, Publication Year, Country(s)	Study Design	Patient Population	Intervention, Number and Characteristics of Patients	Comparator, Number and Characteristics of Population	Outcomes Measured
Mier, <sup>15</sup> 2010, Spain	Retrospective cohort study	75 patients who underwent lung resection for lung cancer	Digital chest drainage system (Thopaz), n=26, 65.6 mean years of age, 69.2% male	Digital chest drainage system without external suction (Digivent), n=24, 62.0 mean years of age, 70.8% male  Traditional chest drainage system (Pleur-Evac), n=25, 66.0 mean years of age, 80.0% male	Duration of chest tube placement

**APPENDIX 4: Summary of Critical Appraisal of Included Studies**

First Author, Publication Year	Strengths	Limitations
<b>Randomized Controlled Trials (RCTs)</b>		
Pompili, <sup>9</sup> 2014	<ul style="list-style-type: none"> <li>• Objective and main outcomes explicitly stated</li> <li>• Adequate randomization and allocation concealment</li> <li>• Power calculation performed to determine sample size based on clinically significant difference</li> </ul>	<ul style="list-style-type: none"> <li>• No protocol defined procedure for chest tube removal decisions (primary outcome)</li> <li>• No long term follow up, for example to determine a re-intervention rate</li> <li>• Use of non-validated investigator developed questionnaire to assess patient satisfaction</li> <li>• Blinding not possible</li> </ul>
Leo, <sup>10</sup> 2013	<ul style="list-style-type: none"> <li>• Objective, outcomes and participant description explicitly stated</li> <li>• Power calculation performed to determine sample size based on clinically significant difference</li> <li>• Adequate randomization</li> </ul>	<ul style="list-style-type: none"> <li>• Some control patients switched to external suction, and some external suction patients had the suction reduced or discontinued due to complications. Data analysis techniques unclear for these crossover patients.</li> <li>• Allocation concealment procedures not reported</li> <li>• Blinding not possible</li> </ul>
Bertolaccini, <sup>13</sup> 2011	<ul style="list-style-type: none"> <li>• Objective, outcomes and participant description explicitly stated</li> <li>• Explicit reporting of complications and adverse events</li> <li>• Adequate randomization and allocation concealment</li> <li>• Moderate sample size (n=100)</li> </ul>	<ul style="list-style-type: none"> <li>• No data provided regarding potential confounders and their distribution between groups</li> <li>• No power calculation reported</li> <li>• No long term follow up, for example to determine a re-intervention rate</li> <li>• Blinding not possible</li> </ul>
Filosso, <sup>11</sup> 2010	<ul style="list-style-type: none"> <li>• Study population representative of patients who would receive intervention at this hospital</li> <li>• Intervention representative of clinical practice</li> </ul>	<ul style="list-style-type: none"> <li>• Randomization and allocation concealment procedures not reported</li> <li>• Small sample size, with no power calculation reported</li> <li>• No data provided regarding potential confounders and their distribution between groups</li> <li>• No description of how cost variables were calculated</li> <li>• Blinding not possible</li> <li>• Incomplete outcome reporting</li> </ul>

First Author, Publication Year	Strengths	Limitations
Brunelli, <sup>12</sup> 2010	<ul style="list-style-type: none"> <li>• Objective, outcomes and participant description explicitly stated</li> <li>• Power calculation performed to determine sample size based on clinically significant difference</li> <li>• Explicit reporting of complications and adverse events</li> </ul>	<ul style="list-style-type: none"> <li>• Randomization and allocation concealment procedures not reported</li> <li>• Blinding not possible</li> </ul>
<b>Observational Studies</b>		
Pompili, <sup>14</sup> 2011	<ul style="list-style-type: none"> <li>• Objective, outcomes and participant description explicitly stated</li> <li>• Explicit and adequate adjustment for potential confounders</li> <li>• Moderate sample size (n=102)</li> </ul>	<ul style="list-style-type: none"> <li>• No power calculation reported</li> <li>• No description of how cost variables were calculated</li> <li>• Blinding not possible</li> </ul>
Mier, <sup>15</sup> 2010	<ul style="list-style-type: none"> <li>• Study population representative of patients who would receive intervention at this hospital</li> <li>• Moderate sample size (n=75)</li> <li>• Intervention representative of clinical practice</li> </ul>	<ul style="list-style-type: none"> <li>• No power calculation reported</li> <li>• Non-randomized design with no explanation as to how patients were assigned to treatment groups</li> <li>• Inclusion/exclusion criteria not specified</li> <li>• No long term follow up, for example to determine a re-intervention rate</li> <li>• Some incomplete outcome reporting</li> <li>• Blinding not possible</li> </ul>

**APPENDIX 5: Summary of Findings of Included Studies**

First Author, Publication Year	Main study findings	Authors' Conclusions
<b>Randomized Controlled Trials (RCTs)</b>		
Pompili, <sup>9</sup> 2014	<p>Average duration of chest tube placement                      Digital: 3.6 days                      Traditional 4.7 days                      p &lt; 0.0001 (SD not reported)</p> <p>Average post-operative length of stay                      Digital: 4.6 days                      Traditional: 5.6 days                      p&lt;0.0001 (SD not reported),</p> <p>Patient Satisfaction:</p> <ul style="list-style-type: none"> <li>• improved ability to arise from bed (p &lt; 0.008)</li> <li>• perceived improved system convenience for patients and personnel (p &lt; 0.02),</li> <li>• patients felt more comfortable being discharged home with the device if needed (p &lt;0.06).</li> <li>• Preference to change the system with another observed in another patient, (12 versus 25) (p &lt; 0.0001)</li> <li>• No change in terms of ability to walk around alone, ability to carry around the device, social comfort, comfort at night in bed.</li> </ul>	<p>“We found that patients managed with digital devices had a 1 day shorter duration of chest tube placement and hospital stay compared with those managed with a traditional device.” p.494</p> <p>“We found that patients managed with the electronic device had a more positive perception of the chest drainage system, in particular related to its comfort, portability, and convenience for personnel and patients compared with those managed with the traditional device.” p. 495</p>

First Author, Publication Year	Main study findings	Authors' Conclusions
Leo, <sup>10</sup> 2013	<p>Number of people with chest tube on post-operative day 7 due to PAL Digital with suction, for anatomic resections: 14 Digital without suction, for anatomic resections: 25 p=0.05</p> <p>Digital with suction, for nonanatomic resections: 11 Digital without suction, for nonanatomic resections: 9 p=0.80</p> <p>Pleural post-operative complications Digital with suction: 56 Digital without suction: 35 p=0.01</p> <p>Pulmonary post-operative complications Digital with suction: 15 Digital without suction: 26 p=0.07</p> <p>Cardiac post-operative complications Digital with suction: 27 Digital without suction: 23 p=0.6</p> <p>Surgical post-operative complications Digital with suction: 16 Digital without suction: 15 p=1.0</p> <p>Other post-operative complications Digital with suction: 3 Digital without suction: 9 p=0.1</p> <p>Deaths: Digital with suction: 2 Digital without suction: 2 p=1.0</p>	<p>“External suction reduced persistent air leak after anatomic lung resection [...] After nonanatomic lung resection, no difference was detected between groups.” p.1237</p> <p>“A benefit of post-operative suction has been identified in the subgroup of patients who underwent anatomic resection...” p.1237</p> <p>“Suction does not reduce the overall post-surgical complication rate...” p. 1237</p>

First Author, Publication Year	Main study findings	Authors' Conclusions
Bertolaccini, <sup>13</sup> 2011	<p>Average duration chest tube placement                      Digital: 5.5 days                      Traditional: 6.1 days                      p=0.056</p> <p>Average hospital length of stay                      Digital: 6.5 days                      Traditional: 7.1 days                      p=0.09</p> <p>Number of postoperative chest X-rays<sup>1</sup>                      Digital: 4                      Traditional: 5                      p=0.09</p> <p>Patient satisfaction (proportion of people who identified ease moving around with the device)                      Digital: 94%                      Traditional: 31%                      p=0.002</p>	<p>“Although not statistically significant, the difference in hospital stay is half a day shorter in PG [PALM group]; lack of statistical significance is probably related to the small sample size. Technological advances are usually considered a cause of increase in costs of medical care. The digital evaluation of AL [air leak] compared with standard evaluation of AL is, on the contrary, a cost-saving procedure. Unnecessary operational inefficiency is removed by the use of digital evaluation of AL, and length of hospital stay is reduced. In our experience, the number of chest radiographs is also reduced; however, this datum is valuable only for intra-service evaluation.” p. e131</p>

<sup>1</sup> It is unclear from the publication whether this is a group average, or the total number of x-rays by group

First Author, Publication Year	Main study findings	Authors' Conclusions
Filosso, <sup>11</sup> 2010	<p>Number of patients with first chest tube removed in 2<sup>nd</sup> post-operative day                      Digital: 5                      Traditional: 1                      p=0.001</p> <p>Average duration of second chest tube placement<sup>2</sup>                      Digital: 3.9 days                      Traditional: 4.8 days                      p=0.005</p> <p>Average hospital length of stay<sup>3</sup>                      Digital: 6.4 days                      Traditional: 9.2 days                      p&lt;0.001</p> <p>Average hospitalization costs<sup>4</sup>                      Digital: 6,400 Euro                      Traditional: 9,200 Euro                      p&lt;0.001</p>	<p>“Using Drentech Simple PLUS we obtained a significant result in managing chest tube, when compared to the traditional system. Both the anterior and posterior chest tube were, in fact, removed earlier in the digital drainage group of patients. This positively influences patients’ outcome: group A patients were, in fact, earlier discharged at home, and overall hospitalization costs were significantly lower.” p. 433</p>
Brunelli, <sup>12</sup> 2010	<p>Average duration of chest tube placement                      Digital: 4.0 days                      Traditional: 4.9 days                      p&lt;0.001</p> <p>Average hospital length of stay                      Digital: 5.4 days                      Traditional: 6.3 days                      p=0.007</p> <p>Average post-operative costs                      Digital: 2,391 Euro                      Traditional: 2,867 Euro                      P=0.008</p> <p>Cardiopulmonary complications                      Digital: 14                      Traditional: 11                      P=0.6</p>	<p>“We showed that the application of a new protocol of chest tube removal taking advantage of objective recorded data about air leak was safe and feasible and was able to reduce postoperative stay and costs compared to patients managed with our traditional chest tube removal protocol based on instantaneous subjective assessment of air leaks.” p. 60</p>

**Observational Studies**

<sup>2</sup> Calculated by CADTH based on raw data presented within the publication

<sup>3</sup> Calculated by CADTH based on raw data presented within the publication

<sup>4</sup> Calculated by CADTH based on raw data presented within the publication

First Author, Publication Year	Main study findings	Authors' Conclusions
Pompili, <sup>14</sup> 2011	<p>Average duration of chest tube placement                      Digital: 2.5 days                      Traditional: 4.4 days                      p&lt;0.0001</p> <p>Average hospital length of stay                      Digital: 4.5 days                      Traditional: 6.0 days                      p=0.0003</p> <p>Average hospitalization costs                      Digital: 1,802 euro                      Traditional: 2,553 euro                      p=0.0002</p> <p>Number of chest tube-related complications                      Digital: 0                      Traditional: 0                      p=1.0</p>	<p>“We found that patients managed with the Thopaz system had an approximately two days’ shorter duration of chest tube usage, and a 1.5-day shorter hospital stay, with a consequent saving of approximately €750 per patient.” p. 492</p> <p>“We were able to demonstrate that the introduction to clinical practice of a novel electronic system to manage chest tubes following pulmonary lobectomy had a short learning curve. However, compared with the use of a traditional system, the benefits in terms of the duration of chest tube usage were evident from the initial cases.” p. 493</p>
Mier, <sup>15</sup> 2010	<p>Average duration of chest tube placement:                      Digital A: 2.4 days                      Digital B: 3.3 days                      Traditional: 4.5 days                      p(Digital A vs Digital B)=0.01                      p(Digital A vs Traditional)&lt;0.001                      p(Digital B vs Traditional)=0.47</p>	<p>“We demonstrated that interobserver 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...As reflected in our results, it is possible to remove the drain significantly earlier in patients with digital device A.” p. 388</p>