EVALUATION OF POSTOPERATIVE AIR LEAK AND CHEST TUBE DRAINAGE SYSTEMS AFTER PULMONARY RESECTION

by

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ABSTRACT

Air leaks after a pulmonary resection continue to be the most common postoperative complication. The presence of an air leak occurs in approximately 30%-50% of patients immediately after surgery. Prolonged air leaks predict an increased hospital length of stay, additional chest tube days and increased pain. The two types of systems used after surgery are digital and traditional chest drainage devices. Eighteen articles from 4 databases were evaluated for this analysis in chest drainage systems and managing air leaks after thoracic surgery. The digital and traditional drainage devices were evaluated. Prolonged air leaks were examined with interobserver variability of air leak assessment and differences in the two systems were addressed. The research gap in the digital system are examining what flow thresholds should be used to safely remove a chest tube after surgery and for what length of time. In future research, the next step is standardizing chest tube management to decrease individual surgeon preference. Treatment of air leaks implementing scientific data instead of personal preference and opinion by a surgeon can lead to earlier chest tube removal, decreased morbidity and a shorter hospital stay.

Keywords: thoracic surgery, air leak, digital

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LIST OF ABBREVIATIONS

CTDS	Chest tube drainage system
COPD	Chronic obstructive pulmonary disease
DLCO	Diffusing capacity of carbon monoxide
LOS	Length of stay
PACU	Post-anesthesia care unit
PAL	Prolonged air leak
RATS	Robotic-assisted thoracoscopic surgery
RN	Registered Nurse
VATS	Video-assisted thoracoscopic surgery

CHAPTER ONE: INTRODUCTION

After a pulmonary resection, air leaks remain the most common surgical complication and lead to longer length of hospital stay (LOS), increased number of chest tube days, significant costs and are a considerable cause of morbidity [1, 2, 3]. An air leak after a pulmonary resection occurs with the movement of air into the pleural space from the bronchial tree. The majority of air leaks after surgery are alveolopleural fistulas that arise from a leak in the visceral pleura distal to the segmental bronchus [4, 5]. Postoperative alveolar changes also increase the risk for air leak. After the fluid and air are removed from the pleural space, the alveoli are overdistended in the resected lung due to an edemagenic state and a larger empty cavity [6]. The alveolar distention occurs in the alveolar epithelial cells and alveolar basement membrane changing the 'mechanical stretch load' in the alveolus [6]. This overdistention increases the probability of an air leak due to changes in the property of the lung parenchymal tissue [6].

Clinical objectives of air leak management include removal of extra pleural air and fostering lung tissue repair. Postoperative chest tube management suggests reduced suction may decrease the air leak duration [7]. Many surgeons continue to place chest tubes to suction until the air leak has resolved and then place the chest tube to waterseal [8]. Traditionally the CTDS has a waterseal chamber where bubbles are present when there is an air leak. A newer CTDS now exists that changes the clinical decision-making dynamic. A quantifiable number is displayed that allows the clinician to objectively determine when a chest tube can safely be removed.

The two-different chest tube drainage systems (CTDS) include a digital system and the traditional drainage system. In the traditional system, an air leak is evaluated by watching for bubbles in the water seal chamber. This evaluation depends on the interpretation of the observer [1]. Digital systems provide continuous monitoring of an air leak with quantifiable information of air leak flow rates [9]. Improving and maintaining consistency in air leak assessment and management can improve appropriate timing of chest tube removal, which can shorten length of stay. Although inpatient care must always reflect individual patient needs and condition, establishing a consistent approach to the postoperative phase of care provides both clinicians and researchers with a requisite foundational element to improving patient outcomes.

Historically, chest tube management has primarily been an art form without the implementation of evidence-based medicine [10]. Clinicians strive to use evidence-based medicine to make decisions, but many clinical decisions remain an art [10]. Removing a chest tube after a pulmonary resection involves the risk of post removal pneumothorax, empyema, subcutaneous air and tube site infection [11]. Protocols and guidelines are given for postoperative chest tube removal, but intuition derived from past experiences also exerts decision influence. Clinical decision making involves intuition, expertise and scientific data [12].

The focus of this dissertation is gaining a better understanding of air leak management with two different CTDS in the robotic-assisted pulmonary resection patient. There are three aims to this study. The first is to evaluate the efficacy of information provided by each type of CTDS with regard to appropriate timing for chest tube removal. Clinical determination of appropriate timing is reflected by chest tube duration. Therefore, time to chest tube removal will be used as the outcome of interest. The second aim is to evaluate the appropriateness of the decision to remove the chest tube based on information provided by the two different CTDS. Inappropriate removal of the chest tube is associated with adverse patient outcomes such as chest tube reinsertion during the same hospitalization or readmission to the hospital due to pneumothorax-related events. Consequently, those two patient outcomes will be used as proxy measures for appropriateness of the decision to remove the chest tube. The last aim is to compare hospital LOS between the two different CTDS.

The current state of the science of chest drainage systems and management of air leaks after a pulmonary resection is discussed in Chapter 2 of this dissertation. Specifically discussed are apical air spaces, digital CTDS, gap analysis of inconsistent flow rates for chest tube removal and need for future research are included. The absence of research in robotic-assisted pulmonary lobectomies is mentioned.

Chapter 3 in this dissertation includes the retrospective research study conducted comparing the traditional and digital CTDS in the robotic-assisted pulmonary lobectomy patients. The aims are evaluated in this specific surgical population. The results demonstrate the digital CTDS with more favorable results compared to the traditional system.

The last chapter, Chapter 4, discusses the postoperative air leak with the digital CTDS with focus on nursing education of the digital device. Bedside nurses play a vital role in air leak assessment and new technology requires thorough education on the device. Educating nurses on the digital system and how it is used allows for competent care and more engaged staff when caring for these patients.

The research results in the retrospective study of this dissertation have added to the body of knowledge of air leak assessment in the traditional and digital CTDS after a robotic-assisted pulmonary lobectomy. This surgical approach has not been previously studied, so this information will provide the clinical team a more comprehensive understanding of chest tube management postoperatively. This research signifies the need for a randomized control trial in this surgical population and economic evaluation as well (e.g., cost benefit analysis).

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CHAPTER TWO: CHEST DRAINAGE SYSTEMS AND MANAGEMENT OF AIR LEAKS AFTER A PULMONARY RESECTION

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The most frequent complication following a pulmonary resection is an alveolar air leak (1). Approximately 30%-50% of patients present with one postoperatively and are the most important determinant of length of hospital stay (1, 2). A few hours postoperatively, some air leaks spontaneously resolve but others can last for many days. In approximately 8%-15% of patients, an air leak can last longer than 5 days which is considered a prolonged air leak (PAL) by definition of the Society of Thoracic Surgeons Database (1-3). A PAL complicates postoperative recovery with associated poorer outcomes and increased morbidity (1, 3). Factors associated with increased hospital costs and length of stay after a pulmonary resection are prolonged air leaks, inadequate pain management and postoperative chest tube duration (2). There is increased pressure by hospitals and insurance companies to standardize care and optimize post-operative recovery. Digital chest drainage systems provide continuous monitoring of air leak flow that provides quantifiable, reproducible and objective data (2). Evaluating the air leak flow can allow clinicians to more rapidly differentiate between patients with indications of a PAL and those who may benefit from fast-tracked care (2, 4). In contrast, the traditional chest drainage system air leak assessment is instantaneous and subjective by observing the water seal column for bubbling. In the traditional system, suction is obtained from the wall and the degree of negative pressure may vary from the set level due to the fluid in the tubing and where the drainage system is placed in relation to the patient (5). The aim of this paper is to evaluate two different chest drainage systems with air leak management after pulmonary resections and identify gaps in the research that could help standardize postoperative care.

Methods

Five databases were used in this search: PubMed, Cochrane Central Register of Controlled Trials, European Journal of Cardiothoracic Surgery and Interactive CardioVascular and Thoracic Surgery Journals and U.S. National Library of Medicine. The search terms used were: air leak, digital and thoracic surgery. These three words were used in each of the databases searched. There was no modification necessary for the individual databases.

Articles were included if they addressed air leak evaluation with the different chest drainage systems. Either independently evaluating the air leak with one drainage system or comparing the two devices were allowed. The drainage systems had to be evaluated on post-operative thoracic surgical patients. The articles were peer-reviewed, in English and published from 2002 to 2016.

Articles were excluded if they were review, commentary or editorial articles. Air leaks due to medical reasons such as: tracheobronchial stenosis, bronchopleural fistula and spontaneous pneumothorax were left out. Air leak evaluation using different intra-operative tissue sealants, suction versus water seal, endobronchial valve implantation, how many chest tubes used after surgery and evaluation of postoperative air leaks that did not include the chest drainage systems were discarded. Different types of surgical technique (video-assisted thoracoscopic surgery-VATS versus open lobectomies) used to evaluate air leaks were also excluded.

Search Results

Database searches returned 277 articles, and all were screened to determine their relevancy. Thirteen were duplicates and removed. Another 225 articles were excluded after abstract review revealed they did not meet inclusion or met exclusion criteria. Full review was completed on 39 articles and 18 of those were included in the final analysis.

Synthesis of the Research

Chest drainage systems differ with regard to the information produced for clinicians. Management of air leaks after pulmonary resections can vary depending on physician preference and scientific data. Many factors influence the decision to remove chest tubes and how prolonged air leaks are evaluated and managed. These factors greatly influence hospital length of stay, postoperative pain and number of chest tube days.

Apical Spaces and Prolonged Air Leaks after a Pulmonary Resection

After a pulmonary lobectomy, an expected finding is a postresection apical space. This residual space does not have clinical significance unless the patient is symptomatic (1). Upper lobectomies have a higher incidence of air space problems than other lobar resections. Initially after surgery, the remaining lung tissue does not fill the pleural space volume and match the hemithorax shape (1, 8). Physiological changes that occur to fill the space are shift of the mediastinum, diaphragm elevation, ipsilateral lung hyperinflation and narrowing of the intercostal spaces (1, 8).

Many factors contribute to the size of an air leak such as the condition of the lung parenchyma and position of the chest tube (9). Risk factors for a PAL include: chronic obstructive pulmonary disease (COPD), bilobectomy, upper lobectomy, diffusing capacity of carbon monoxide (DLCO) less than 80% predicted and steroid use (3, 7). Postoperative air leaks are not just an annoyance that prolongs hospitalization, they can be a surrogate marker for increased morbidity and complications like postoperative atrial fibrillation and pneumonia (10).

The length of hospital stay (LOS) averages 5 to 13 days with a PAL since most patients remain in the hospital until the air leak resolves (7, 13). Only a small percentage of patients can be discharged from the hospital and go home with a portable chest drainage system (13). The potential complications from a PAL include pneumonia, atelectasis, empyema and longer chest tube days (2, 7, 12).

Digital Chest Drainage Systems

Digital chest drainage systems have also provided a much more accurate air leak reading. These systems provide quantifiable information and continuous monitoring of postoperative air leak flow rates (5, 12, 13). Digital systems provide reproducible data, eliminate subjective interpretation, decrease intraobserver variability, and increase observer agreement rates for chest tube removal (5, 12, 13).

The digital system works by maintaining the intrapleural pressure at a steady level within 0.1cm H20 by a pressure sensor with minimal variability. Maintaining a consistent pleural pressure with minimal oscillations, may promote the sealing of air leaks (12). The regulated suction adjusts according to the condition or need in the pleural cavity. The device will apply suction to keep the pleural cavity at the preset level. If the patient does have an air leak with suction, the device will intermittently apply suction to restabilize the pleural space according to the degree of the air leak (15). Thopaz (Medela®, Switzerland), a digital chest drainage system recommends removal of the chest tube when air leak flow is less than 50 millimeters/minute without large variation for the prior 6 - 12 hours

Interobserver Variability

The digital system has demonstrated decreased interobserver variability when deciding to remove chest tubes. It objectifies much of the subjective information and can be replicated among several observers (10). The level of agreement significantly increased in nurses, surgeons and residents (6, 12, 15, 16). This system enables the health care team, regardless of their experience or level of education, to accurately report the status a patient's air leak (10, 15).

There is interobserver variability and assessment with a traditional system can be error prone (10, 15). With differing opinions among clinicians and the inability to accurately ascertain an improving air leak, can lead to longer chest tube days and increased length of hospital stay. If chest tubes are removed prematurely because of an inaccurate reading, there may be a subsequent need for chest tube reinsertion (15).

Gap Analysis

In the majority of the research studies there was inconsistent airflow rates in the digital drainage system or a dedicated number of hours before chest tubes were removed. Table 1 provides 6 studies and their flow threshold for chest tube removal with the Thopaz® digital system after a pulmonary resection which shows wide variation in when chest tubes are removed.

Table 1: Thopaz Airflow Threshold for Chest Tube Removal

Authors	Thopaz® digital chest tube drainage system airflow threshold for chest tube removal postoperatively
Brunelli et al., 2011	<10 ml/min during last 6 hours
Gilbert et al., 2015	≤ 40ml/min with negative pressure (> 8mm Hg) or ≤ 20 ml/min on gravity mode (≤ 8mm Hg) for at least 12 hours
Lijkendijk, et al., 2015	≤ 20ml/min for 6 consecutive hours or ≤ 50ml/min for 12 consecutive hours without spikes
Marjanski et al., 2013	0-20 ml/min for 6 consecutive hours
Miller et al., 2016	0 mL/min flow and no spikes for at least 12 hours
Pompili et al., 2011	< 40 ml/min for more than 8 hours without spikes above 40 ml/min
Pompili et al., 2014	< 30ml/min for at least 8 hours without significant oscillations

After a pulmonary resection, there is no agreement in the number of chest tubes, whether suction should or should not be used or if chest tubes should be clamped before removal (6, 13, 15). Variations in clinical practice is an important determinant that can lengthen hospital stay. Improving and maintaining consistency in air leak assessment can lead to a more timely removal of chest tubes with a shorter length of hospital stay. The wide variation in air leak flow in the digital systems before removal adds to the complication of chest tube management.

Currently there have been no studies evaluating robotic-assisted pulmonary resections and air leak assessment with the digital or traditional chest drainage systems. Robotic surgery uses 3-dimensional, high-definition visualization allowing surgeons to intuitively perform complex resections (18). The accuracy and advanced imaging provided by the daVinci® robot offsets the reduced tactile feedback missing in robotic surgery (18). Evaluating the traditional and digital chest drainage systems with robotic surgery would provide more information for the thoracic surgery team, using a different surgical approach, to assist in patient care post-operatively.

In the digital drainage system, implementing a consistent and reliable flow level for a specified time that could be used by all surgeons would remove all the variations that currently exist. These recommendations could only be implemented if surgeons removed their opinions and supported the scientific research.

Future Research

There has been a lot of research with the new technology in chest drainage systems. There is much more to be examined to translate the research into practice and incorporate new standards of care.

Practice

- Standardizing chest tube management based on scientific data versus clinician preference
- Educating clinical staff on air leak assessment with digital and traditional systems to decrease variability of findings
- Evaluating patients early postoperatively for signs of a prolonged air leak to assist with discharge planning

Research

- Clinical trials to evaluate safe air leak flow thresholds to remove chest tubes
- Satisfaction evaluation and learning curves with clinical staff using new technology
- Evaluation of chest drainage systems with robotic-assisted pulmonary resections

Once this research is complete, chest tube management will have less variation with either the digital or traditional chest drainage systems. Clinicians will be more educated on air leaks and how to efficiently and safely care for patients postoperatively.

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CHAPTER THREE: THE BENEFITS OF DIGITAL DRAINAGE SYSTEM VERSUS TRADITIONAL AFTER ROBOTIC-ASSISTED PULMONARY RESECTION

Abstract

Postoperative air leaks are the most common complication after a pulmonary resection. There is no data in the literature comparing the traditional and digital chest drainage system after a robotic-assisted pulmonary lobectomy. In 182 eligible patients, this retrospective study evaluated the association between digital and traditional drainage systems with postoperative chest tube days, hospital length of stay, chest tube reinsertion during hospitalization, and 30-day readmission for pneumothorax following a robotic-assisted lobectomy. The groups did not differ significantly in terms of age, gender, BMI, smoking, adhesions or neoadjuvant therapy. Patients with the digital drainage system had a mean chest tube duration of 2.07 days compared with 2.73 days for the traditional drainage system ($p = 0.003$). Hospital length of stay was also significantly reduced with the digital drainage system. Patients using the digital drainage system had a mean hospital length of stay of 4.02 days compared with 5.06 days with the traditional drainage system ($p = 0.010$). Although chest tube reinsertion occurred four times more frequently with traditional drainage system, the difference did not achieve the level of statistical significance ($p = 0.059$). The frequency of readmission due to pneumothorax was very low (1 patient per group), which prevented comparative statistical analysis. In the digital drainage system there are shorter chest tube days and hospital length of stay after a robotic-assisted lobectomy. The decision to remove chest tubes in the traditional drainage system is burdened with uncertainty. The digital drainage system reduces intraobserver variability allowing for improved decision making in chest tube removal.

Introduction

Alveolar air leaks after a pulmonary lobectomy are a considerable cause of morbidity, increased number of chest tube days and longer length of hospital stay (LOS) that significantly increase costs [1]. The literature reports air leaks in 28-60% of patients immediately postoperatively, 26-48% on postoperative (POD) day 1, 22-24% of patients on POD 2, and 8% on POD 4 [2]. Up to 5% of patients still have an air leak when they are ready for discharge [3]. Various intraoperative techniques are used to help prevent air leaks, including pleural tents, buttressing of the suture or staple lines, visceral sealants and glue and different strategies with chest tube management [1, 4]. Postoperative air leaks are evaluated differently with the information provided by the traditional and digital chest tube drainage systems (CTDS).

Air leak assessment using the traditional CTDS consists of visualizing bubbles in the water seal chamber. It is an immediate, subjective reading that can vary among clinicians. The clinician's evaluation of whether an air leak is present is contingent on when the chamber is visualized. In the traditional system, the air leak decision is burdened with uncertainty because the chamber was not continuously monitored, allowing a small, intermittent air leak to go unrecognized. Differing opinions and the inability to accurately ascertain an air leak can lead to longer chest tube days and increased hospital LOS [5, 6, 7].

Digital CTDS air leak assessment is a quantified measure that is both continuous and objective. It reduces interobserver variability which improves decision making regarding chest tube removal [4, 8, 9, 10, 11]. Having the information provided by the digital system reduces uncertainty surrounding the decision of when it is appropriate to remove the chest tube. It shifts the decision from one based heavily on gestalt to one guided by valid and reliable patient-specific information.

Previous studies have reported inconsistent findings when comparing digital and traditional chest drainage systems following lobectomies using either open thoracotomy or video-assisted thoracoscopic surgery (VATS). Two studies reported the digital CTDS was associated with significantly shorter chest tube days and shorter hospital length of stay [1, 10]. Three other studies reported no significant differences between digital and traditional CTDS groups for chest tube days or hospital LOS [12, 13, 14]. Comparing the two CTDS in the robotic-assisted thoracoscopic surgical approach (RATS) has not yet been studied and can provide relevant clinical data on air leak management to promote fewer chest tube days, shorter hospital LOS and reduction in morbidity.

The aim of this retrospective study was to compare two chest tube drainage systems on chest tube days, hospital length of stay, reinsertions of chest tube during hospitalization and readmission due to pneumothorax after RATS lobectomy.

Methods

Ethics

Institutional review board (IRB) approval was obtained from Florida Hospital, and The University of Central Florida.

Design

This study is a retrospective, descriptive, correlational design to evaluate the association between digital and traditional CTDS with postoperative chest tube days, hospital LOS, chest tube reinsertion during hospitalization, and 30-day readmission for pneumothorax following a RATS lobectomy.

Setting

The same cardiothoracic surgeon performed all RATS lobectomies. All subjects underwent elective surgery at a quaternary care hospital in Orlando, Florida.

Sample

All adult lung cancer patients admitted to the hospital for a RATS pulmonary lobectomy, lobectomy with wedge resection, or bilobectomy due to an incomplete fissure between January 2014 and December 2017 were eligible for inclusion in this study.

Exclusion criteria were as follows: patient younger than 18 years, post-operative mechanical ventilation, previous thoracic surgery, robotic-assisted requiring conversion to open thoracotomy, more than one type of drainage system used, patient discharged home with a chest tube, more than one chest tube placed perioperatively (6 patients), or post-operative death (1 patient).

Surgical Procedure

An experienced robotic thoracic surgeon utilized a DaVinci Xi (Intuitive Surgical Inc., Sunnyvale, CA, USA) console while employing a four-port technique in which there were four 8mm robotic ports including the camera port and a 15 mm accessory port for CO2 insufflation and specimen egress. The initial 8 mm incision for the camera was placed at the 7th -8th intercostal space, midaxillary line. Another port was placed at the 8th-9th intercostal space in the posterior axillary line and the next 8mm port was at the auscultatory triangle. An 8mm accessory port was inserted at the 4th or 5th intercostal space laterally. The insufflation system used in this accessory port was the AirSeal insufflator to maintain constant positive pressure within the chest cavity to maintain lung collapse during surgery. This port uses carbon dioxide insufflation administered to a pressure of 10-15 mm Hg increasing up to 20 mm Hg if necessary with a flow of 6 mL/min until the lung is deflated. This accessory port was used to retrieve lymph nodes and small specimens, needles, and sponges. By enlarging the skin to 20-25 mm later in the operation it became a working port to remove the lobe of the lung. The surgical arms then placed the specimen in the Endo Catch (Covidien) pouch which was then removed from the patient in the contained pouch. A variety of tissue management techniques were used including the combination of the robotic and nonrobotic staplers. The Ethicon 35mm endosurgical power stapler was used to ligate the vasculature and the Ethicon 60mm power robotic stapler was used for the lung parenchyma and bronchus. Various staple loads were used depending of the specimen thickness being ligated.

Progel sealant was routinely used to prevent intraoperative leaks until 2016, when it was no longer available. No buttressed staple lines or pleural tents were used. A single apical 24F chest tube was placed anteriorly at the end of the procedure via the most anterior 8 mm port.

Clinical Course

Chest Tube Drainage System Management and Air Leak Evaluation

In both the digital and traditional chest drainage systems, -20cm H_20 suction was applied for the first 8 hours post-operatively then the patient's chest tube was placed to waterseal. With the traditional system, waterseal was removal of suction and with the digital system, suction was placed to a physiologic mode of -8 cm H_20 which is the normal intrapleural pressure at the end of inspiration [15]. Air leak evaluation was completed and charted by registered nurses (RN) every 15-30 minutes during the first post-operative hour in the post-anesthesia care unit (PACU). Air leak evaluations were then completed every hour for 1-2 hours. Patients were then transferred to the cardiothoracic progressive care unit where air leak evaluations were completed by RNs every 4 hours until chest tube removal.

Evaluation for Pneumothorax or Effusion

If the immediate post-operative chest x-ray in the PACU showed a pneumothorax of greater than 20-30% of the hemithorax, suction was maintained throughout the night and reassessed by the post-op day (POD) 1 morning chest x-ray. Pleural effusion threshold for removal was 400ml/day. The chest tube was not clamped on any patient.

Chest Tube Removal Decision

The decision to remove the chest tube was made by the cardiothoracic nurse practitioner, physician's assistant, the surgeon, or some combination of all three.

Digital CTDS Group

- Air leak flow was less than 50ml/min for at least 6 hours
- Patient ambulated with no flow spikes > 50ml/min
- Morning chest x-ray showed sufficient expansion
- Pneumothorax < 20-30% of the hemithorax
- No dyspnea on exertion
- SPO_2 >92% without supplemental oxygen (unless oxygen dependent preoperatively)

Traditional CTDS Group

- No bubbles observed or recorded in the waterseal chamber for at least 6 hours immediately post-operative
- Morning assessment on POD 1 no bubbles observed with the patient coughing 2-3 times
- Morning chest x-ray showed sufficient expansion
- Pneumothorax < 20-30% of the hemithorax
- No dyspnea on exertion

- SPO_2 >92% without supplemental oxygen (unless oxygen dependent preoperatively)

Statistical Analysis

A power analysis was conducted with difference in means to determine an adequate sample size with the retrospective sample. To achieve a power of 80%, a minimum sample size of 172 (86 for each group) was needed for moderate effect size and $\alpha = 0.05$. Continuous data were presented as means and standard deviation. Normal distribution of variables was evaluated by Shapiro-Wilk normality test. If continuous data were normally distributed, comparisons were made using the students t-test. Non-normally distributed continuous variables were compared using Mann Whitney U test. Categorical data were summarized as n and percentages. Comparisons of categorical data were made using the chi-squared or Fisher's exact test. An α-level of 0.05 was used to establish statistical significance.

Results

Demographics

During 2014-2017, RATS lobectomies were performed on 182 eligible patients. The majority of patients (92.3%) underwent a lobectomy. Lobectomy with wedge resection was required in 5.5% of patients while bilobectomies compromised 2.2% of the study population.

A summary of the patient demographic characteristics is shown in Table 1. The study population was majority female (62.6%) with mean age of 68 ± 11 years. The digital CTDS was used in a larger proportion of patients (63.7%). The groups did not differ significantly in terms of age, gender, BMI, smoking, adhesions or neoadjuvant therapy.

Patient Outcomes

Chest tube duration was significantly shorter with digital CTDS use (see Table 3 and Figure 1). Patients with the digital CTDS had a mean chest tube duration of 2.07 days compared with 2.73 days for the traditional CTDS ($p = 0.003$).

Hospital length of stay was also significantly reduced with the digital CTDS (see Table 3 and Figure 2). Patients using the digital CTDS had a mean hospital length of stay of 4.02 days compared with 5.06 days with the traditional CTDS ($p = 0.010$). Although chest tube reinsertion occurred four times more frequently with traditional CTDS use, the difference did not achieve the level of statistical significance ($p = 0.059$). The frequency of readmission due to pneumothorax was very low (1 patient per group), which prevented comparative statistical analysis.

Table 2. Patient Characteristics

Variable	Traditional (n = 66)	Digital (n = 116)	p value
Age	68.5 ± 10.6	67.2 ± 11.1	.453
Gender			
Male	25 (37.9)	43 (37.1)	.914
Female	41 (62.1)	73 (62.9)	
BMI (kg/m2)	27.8 ± 6.0	28.4 ± 5.9	.485
Smoking status (yes)	60 (90.9)	91 (78.4)	.079
Lobectomy			.315
Right upper lobe	14 (21%)	35 (30%)	
Right middle lobe	3 (5%)	12 (10%)	
Right lower lobe	15 (23%)	24 (21%)	
Left upper lobe	18 (27%)	21 (18%)	
Left lower lobe	9 (14%)	17 (15%)	
Lobectomy + wedge resection	5 (2.7%)	5 (2.7%)	
Bilobectomy	2 (1.0%)	2 (1.0%)	
Pleural adhesions	17 (25.8)	30 (25.9)	.988
History of neoadjuvant therapy	2 (3.0)	6 (5.2)	.713

Continuous variables are expressed as mean ± standard deviations with p-values from Student's t-test. Categorical variables are expressed as count (percentages) with p-values from chi-square.

Table 3. Primary Outcomes

Drainage System	Traditional (n = 66)	Digital (n = 116)	p value
Chest tube (days)	2.73 ± 3.0	2.07 ± 1.99	.003
Hospital stay (days)	5.06 ± 4.21	4.02 ± 3.00	.010
Chest tube reinsertion during hospitalization	4 (6.1)	1	0.59
Readmission for pneumothorax	1	1	N/A

Continuous variables are expressed as mean ± standard deviations with p-values from Mann Whitney U test. Categorical variables are expressed as count (percentages) with p-values from the Fishers exact tests.

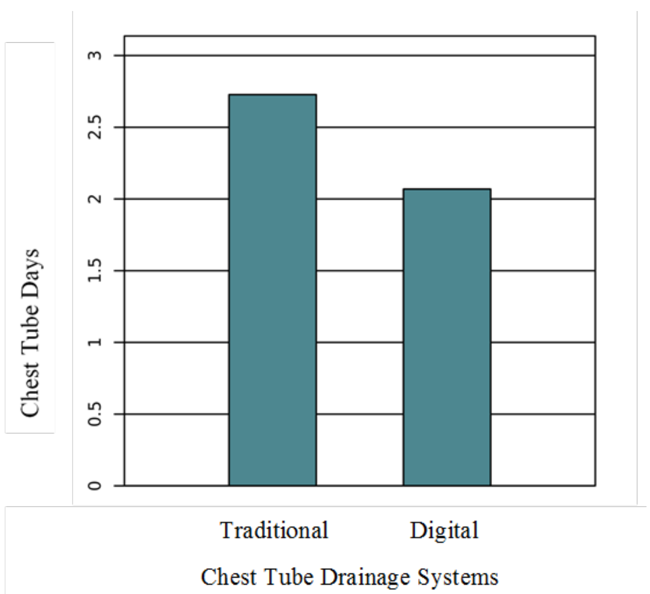

Figure 1. Mean Chest Tube Days in the Traditional and Digital Chest Drainage Systems

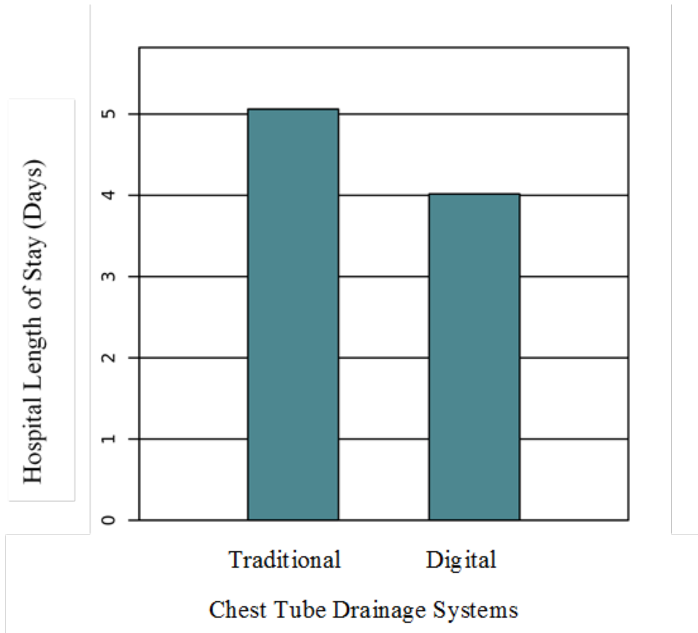

Figure 2. Mean Hospital Length of Stay in the Traditional and Digital Chest Drainage Systems

Discussion

Main Findings

Postoperative air leaks after a pulmonary resection continue to be problematic for the patient and frustrating for the surgical team. Patients using the digital CTDS had nearly a one day decrease in chest tube days and a full day shortened hospital LOS. This finding is consistent with previous studies, even when more conservative chest tube removal flow threshold criteria were used [1, 10]. This decrease in chest tube days and hospital length of stay may be strongly influenced to the objective data collection and reduced uncertainty associated with the digital system in air flow readings.

A concern for pneumothorax after chest tube removal or readmission due to a pneumothorax has been presented in the literature. One of the most frequent causes of readmission to the hospital after a pulmonary lobectomy is a pneumothorax [16]. The American College of Surgeons National Surgical Quality Improvement Program evaluated 9,510 patients admitted between 2012 and 2015 for a 30-day related, unplanned postoperative readmission after an anatomic lung resection for primary lung cancer. They compared thoracoscopic versus open resection and found a pneumothorax occurred in 17.6% of patients [17]. Unexpected postoperative readmissions are a primary burden financially to the healthcare system and as part of the Affordable Care Act, mandates public reporting of hospital readmission rates with monetary penalties with the Hospital Readmission Reduction Program [18].

In one study that extracted data from the Surveillance Epidemiology and End Results (SEER) database, evaluated 11,432 patients, age 65 or older admitted for pulmonary resection for lung cancer. The 30-day readmission rate was 12.8%. Of the readmitted patients, 13.7% were due to a pneumothorax. Early readmission after lung cancer resection is the strongest risk-factor for 90-day mortality and is associated with a 6-fold increase in death [18].

Our experience in this study revealed that a pneumothorax after chest tube removal was a rare event. Our readmission rate due to a pneumothorax was substantially lower than previously reported data.

There are no standards with pleural fluid drainage and chest tube removal. Our study used 400 ml/24 hours. Previous study findings described 450 ml/24 hours as a safe threshold of pleural fluid drainage for chest tube removal in over 2000 patients after a pulmonary resection [19].

Robotic-Assisted Thoracoscopic Surgery

Evaluating CTDS options following RATS can positively impact postoperative care. However, such a comparison has not yet been completed in this unique and growing patient population. Robotic thoracic surgery has rapidly gained popularity among thoracic surgeons. The U.S. National Cancer Data Base reported a tripling in the percentage of robotic lobectomies from 2010 to 2012 (3% vs. 9%) [20]. A recent analysis predicts robotic lobectomies have nearly doubled again to 15% in 2015 [20]. As this patient population continues to grow, evaluation of clinical decisions and care processes will have correspondingly increased impact. Furthermore, such evaluations can effectively guide postoperative air leak management by the thoracic surgery team as they collaborate to improve patient outcomes. This study will add to the literature by including another surgical approach when comparing two different chest drainage system and air leak management.

Limitations

Our study included one surgeon at a single-center study. Although this reduces variability intraoperatively and in postoperative chest tube management, it limits the generalizability of the result and a multi-institutional study is superior. This investigation is limited by the data accuracy and quality of completeness of the primary database. Retrospective data lacks randomized sampling allowing for equal number of participants in each group. Our study had unequal groups that may have influenced the outcome variables. Selection bias cannot be excluded. Our low occurrence of postoperative pneumothorax and readmission may require a larger patient population to increase statistical power and allow for stronger conclusions to be made. The cost savings of a decreased hospital length of stay and the increased cost of the digital system were not evaluated but should be addressed in future evaluations. The argument against robotic thoracic surgery costs compared to VATS have conflicting results. One study found costs higher in robotic surgery versus VATS [21]. Another study found RATS lobectomies were less expensive than VATS lobectomies [22]. Many of these limitations could be addressed with a randomized controlled study in the future. Preoperative pulmonary function tests were not routinely done on all patients included in this study. Patients respiratory system function should be evaluated with measurements of FEV1 (forced expiratory volume in 1 second) and DLco (carbon monoxide lung diffusion capacity) before surgery. Impaired lung function would useful in evaluating the risk of complications, such as a postoperative air leak.

Conclusions

Our study demonstrated shorter chest tube days and hospital length of stay in the digital CTDS after a RATS lobectomy by improved chest tube management. These findings are consistent with previous research. This retrospective study can be used to validate the necessity of a multicenter randomized study.

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CHAPTER FOUR: POSTOPERATIVE AIR LEAK ASSESSMENT WITH DIGITAL CHEST TUBE DRAINAGE SYSTEM

Introduction

Removing air and fluid from the pleural space are basic goals after a pulmonary resection [1]. An air leak after a pulmonary resection occurs with the movement of air into the pleural space from the bronchial tree. The majority of air leaks after surgery are alveolopleural fistulas that arise from a leak distal to the segmental bronchus [2, 3]. Another type of air leak is a bronchopleural fistula (BPF) which arises from a segmental bronchus or airway that is more proximal. A BPF has different risk factors than an alveolopleural fistula and normally requires surgical intervention [2].

Reasons for a Chest Tube Postoperatively

A chest tube is placed to remove postoperative air and fluid. The tube prevents drained fluid and air from returning to the pleural space and allows the lung to reexpand [4]. Following a pulmonary resection, the most frequent complication is an alveolar air leak [5]. Clinical objectives of air leak management include removal of extra pleural air and fostering lung tissue repair. A smaller portion of lung parenchyma must fill up the pleural cavity and the compliance of the remaining lung tissue is decreased. [6]. Apical placement of the chest tube, to the least gravity-dependent portion of the pleural space, displaces the remaining lung tissue towards the apex [7]. This minimizes post-operative pneumothoraces. Chest tube suction placed to -20 cm H_20 immediately after surgery, insures the amount of air evacuated exceeds or equals the volume of air entering the pleural space while breathing which keeps the lung inflated [8]. Suction may be placed for a limited time due to complete air removal causing an over distention for the remaining lung and may cause an air leak, edema, or hydrothorax. Suction set at a transpulmonary pressure comparable with the postoperative pressure can prevent overdistention of the remaining lung tissue [9].

Postoperative Air Leak

An air leak after a pulmonary resection is the most common complication. Many factors contribute to the size of a postoperative air leak such as the condition of the lung parenchyma and position of the chest tube [10]. Risk factors for a postoperative air leak include: preexisting conditions such as chronic obstructive pulmonary disease (COPD), type of surgical resection (e.g., bilobectomy, upper lobectomy), intraoperative considerations (e.g., incomplete fissures and pleural adhesions), and factors associated to chronic steroid use [11, 12]. Postoperative air leaks are not just an annoyance that prolongs hospitalization, they can be a surrogate marker for increased morbidity and complications like postoperative atrial fibrillation and pneumonia [13].

Digital Chest Tube Drainage System Clinical Applications

Thoracic medicine has significantly changed and advanced over the last two decades. The traditional chest tube drainage systems (CTDS) has been the only option when the digital CTDS was introduced ten years ago. The traditional system involves complex decision-making for clinicians due to subjective assessment. There is interobserver variability of air leak with a traditional system and air leak assessment can be error prone [13, 14]. Differing opinions among clinicians, and the inability to accurately ascertain an improving air leak in the traditional system, complicates decision making when a chest tube should be removed. In health care, innovation indicates development and progress. New technology using evidenced-based practice improves efficiency, productivity and increases uniformity and quality of care while decreasing costs [15]. Technological advancements with a digital system now offer an alternative CTDS that mitigates many of the issues associated with the traditional system.

The digital CTDS displays a number giving clinicians a quantifiable assessment of air flow in the pleural space. Shifting air leak assessment from the subjective traditional system to a more objective digital approach provides clinicians with more certain and consistent assessment findings. The digital CTDS decreases interobserver variability when assessing for air leaks and deciding when it is appropriate to remove chest tubes. Significantly higher interobserver reliability was noted in multiple disciplines including nurses, attending surgeons and residents [14, 16, 17, 18]. Digital systems enable the health care team, regardless of their experience or level of education, to accurately assess and consistently report the status a patient's air leak [1, 14]. This consistency is associated with positive patient outcomes such as significant reductions in both chest tube days and hospital length of stay [19, 20].

These significant decreases in chest tube days and reduced LOS using the digital CTDS are noted regardless of the surgical approach. Improved outcomes were reported following lobectomies using both open thoracotomies and video-assisted thoracoscopic surgery [16, 20].

Using the Digital Chest Drainage System

The steps for setting up and managing the digital CTDS are simple. Table 4 describes the set-up and adjusting the system.

Table 4. Set up and Adjustment of the Digital System

Setting up the Digital System	• Select single or double tubing for the correct canister • Open the sterile tubing • Insert tubing into the system, ensure the tubing does not bend and is tight against the system • Ensure the sealing ring is in place • Attach canister to the system by placing the bottom pins in the tracks, clip the top of the canister into the system, ensuring it is tight against the system [21]
Turning the System On	• Press the power button and wait for the self-test to complete • Confirm whether a new patient is connected or not by pressing yes or no • If a new patient, the system will issue a new therapy number • If the same patient, press no and the same therapy number remains [21]
Change the Pressure	• Press both arrow buttons simultaneously to highlight pressure • Use up/down arrows to select the desired pressure level or waterseal mode • Press the OK button [21]
Silence the Alarms	• The alarm will beep and a description will display on the screen • To silence alarm push the up/down arrow buttons simultaneously [21]
Removal of Chest Tube	• Manufacturer recommendations of flow 50 ml/min or less, for 6-12 hours without any spikes in flow

On the display monitor there is a 24-hour graph for the clinician to evaluate the status of the air leak (Figure 3). The device is compact and does not connect to wall suction, which allows for patients to ambulate more quickly and easily (Figure 4).The digital device is easy to use with the common alarms and troubleshooting in Table 5.

Figure 3. The monitor displays the suction amount and the air flow in the pleural space.

Figure 4. The digital device is small and easy for the patients to carry.

Table 5. Common Alarms and Troubleshooting

Major Alarms	**How to Resolve**
Leak In System	• Alarm will beep and will be displayed on the screen • Hold down standby button until standby mode is enabled • Clamp the tubing • Press blue button to release canister • Ensure the sealing ring is still in place • Remove and reinsert tubing into the system, ensuring tubing end does not bed and is tight against the system • Reattach canister, release clamp on tubing and continue treatment by pressing the on button
System Clogged	• Alarm will beep and System Clogged will be displayed on the screen • Hold down standby button until standby mode is enabled • If there is an obvious kink or clot in the system, then remove that • If it is not visible, clamp the tubing, hold the down arrow for 3 seconds to place the system in standby, remove and dispose of the canister and tubing, replace with new tubing and canister, release clamp, turn system on
Low Battery	• System will alarm when there is 30 minutes left on the battery and screen will • Plug power cord directly into the system to maintain charge
Pump Not Running	• Check if the device is turned on and plugged in [21]

Clinical Applications

Postoperative bedside nursing assessments include monitoring for presence of postoperative air leak, detecting any changes in an air leak and maintaining the CTDS. The expected clinical course is for any air leak is gradual reduction and eventual seal. The nurse should attempt to determine if the air is leaking from the system or pleural space. Extrapleural system leaks can occur at the chest tube connections or at the insertion site. If a connection is loose, it is important to attach the correct adapter, so the connections fit tightly. If the chest tube is outside of the pleural space, the nurse should call the clinician, so the tube can be removed. In an effort to prevent system leaks, nurses may apply tape to all connections, however, this is not a recommended practice. If connections are taped, they cannot be easily visualized and assessed to determine if the connection has come apart, causing a leak in the system. Regardless of the cause, it is important for the nurse to communicate air leak assessment and changes to the surgical team.

Advantages of the Digital System

The digital CTDS system allows the nurse to report an air flow number. With manufacturer recommended guidelines, the clinician will know when it is safe to remove a chest tube. Changing out the canister or tubing is simple and only requires one person. The nurse can assist the patient and ambulate down the hall with this small device that maintains suction in the pleural space. If the device tips over, there is no concern about the need to change the cannister, as there is in the traditional system. Patients have found the digital device more portable and comfortable that the traditional device and was more convenient for the nursing staff [20].

Conclusions

Bedside nurses caring for postoperative lobectomy patients must be familiar with thoracic physiology and have a thorough understanding of proper chest tube management. A postoperative air leak is a common and challenging problem in this patient population. Digital CTDS provide a mechanism for consistent and objective air leak assessment by everyone caring for the patient. Air leak assessment can be communicated effectively to the surgical team without uncertainty. The system is easy to care for by the bedside nurse and convenient and safe for the patient. The digital system has also been found to decrease hospital LOS and chest tube days postoperatively [16, 19, 20]. The nurse plays an important role in caring for these patients and understanding why a chest tube is placed along with what complications to assess for which can help the patient recover more quickly from surgery.

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APPENDIX A: COPYWRIGHT PERMISSION LETTER

Permission form

Requestor Information:

Name: Kristina Baringer

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APPENDIX B: FLORIDA HOSPITAL IRB

Florida Hospital
Institutional Review Board
901 N. Lake Destiny Road
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Maitland, FL 32751
Telephone: (407) 303-5581
Fax: (407) 303-2567
FWA: 00002060

September 13, 2018

To: Kristina Baringer

On September 13, 2018 the IRB approved the following through September 12, 2019 inclusive.

Review Type:	Expedited Review
Title:	Digital versus Traditional Chest Drainage Systems after a Robotic-Assisted Pulmonary Lobectomy
Principal Investigator:	Kristina Baringer
IRB number:	1312924-1
Expedited Category:	5
Documents reviewed:	• Application Form - IRB FH Baringer-HRP-200 FORM - Initial Review Application.pdf (UPDATED: 08/24/2018) • HIPAA Waiver - HIPPA form-Baringer.pdf (UPDATED: 09/10/2018) • HIPAA Waiver - VOID HIPAA.pdf (UPDATED: 08/24/2018) • Other - IRB FH Baringer HRP-201 FORM - Research Personnel REV 090418.pdf (UPDATED: 09/4/2018) • Protocol - Protocol (1)_mlm comments REV 090418.docx (UPDATED: 09/4/2018) • Protocol - VOID Protocol.docx (UPDATED: 08/24/2018)

Before September 12, 2019, you are to submit a continuing review to request continuing approval or closure. If the IRB does not grant continuing review, approval of this protocol ends after September 12, 2019.

Copies of any approved consent documents, consent scripts, or assent documents are published.

In conducting this study, you are required to follow the requirements in "POLICY: Investigator Obligations (HRP-070)."

If you have any questions, please contact the Florida Hospital IRB at 407-303-5581 or FH.IRB.general@flhosp.org. Please include your project title and IRBNet ID number in all correspondence with this office.

Sincerely,

IRB Office

APPENDIX C: UNIVERSITY OF CENTRAL FLORIDA IRB

University of Central Florida

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Notice that UCF will Rely Upon Other IRB for Review and Approval

From : **UCF Institutional Review Board**
FWA00000351, IRB00001138

To : **Kristina Baringer**

Date : **October 29, 2018**

IRB Number: **SBE-18-14487**

Study Title: **Digital versus Traditional Chest Drainage Systems after a Robotic-Assisted Pulmonary Lobectomy**

Dear Researcher:

The research protocol noted above was reviewed by a University of Central Florida IRB Designated Reviewer on 10/29/2018. The UCF IRB accepts the Florida Hospital Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the Florida Hospital Institutional Review Board and the consent process will be the process approved by that IRB.**

This project may move forward as described in the protocol. It is understood that the Florida Hospital IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the Florida Hospital IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions and a copy of the form must be kept on file at the IRB office of both institutions.

This letter is signed by:

Signature applied by Adrienne Showman on 10/29/2018 09:31:43 AM EDT

Designated Reviewer