12-14-2011

Chest Tube Dressings: A Comparison of Different Methods

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A Dissertation Submitted to the Graduate School at the University – ST. Louis in

Partial fulfillment of the requirements for the degree

Doctor of Philosophy in Nursing

December 2011

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ACKNOWLEDGEMENTS

I would like to take this opportunity to acknowledge the support I received from Dr. Dawn Garzon throughout my enrollment at University of Missouri St. Louis. Her encouragement and prodding made "eating the elephant" much more palatable. Without Dr. Garzon's help I wouldn't have made it this far. I also would like to thank the members of my dissertation committee, Dr. Jean Bachman, Dr. Margaret Barton-Burke and Dr. Lloyd Richardson. The combined expertise and insight of this amazing group helped to ensure that this research was credible and had the potential to impact nursing practice throughout the world.

Thanks too goes to the nurses and physicians at INTEGRIS Baptist Medical Center in Oklahoma City, especially Jana Williams, RN, BSN, Rachel Allen, RN, BSN, April Merrill, APRN-CNS, DNP, and Tamara Meier APRN-CNS. Each of these individuals as well as the collective staff of the cardio-thoracic intensive care unit and the post cardiac intermediate care unit was instrumental in identifying participants for the study, ensuring the integrity of the randomization and measurements.

The biggest thanks must go to my husband Gary and my sons, Ben and Sam. They sacrificed as much if not more than I did in pursuit of this goal. They have been patient and understanding when I was tired and when I was absent from important events while in St. Louis attending classes. They tell me that it was all worth it to them too and that they are looking forward to the day when they can call me "Dr. Mom". Thank you for your help and support in seeing me through this journey.

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ABSTRACT

This study is an experimental design with randomization comparing the use of standard gauze dressings (SGD) to transparent adhesive dressings (TAD) to cover chest tube insertion sites in post-operative patients who have undergone cardio-thoracic surgery. The study was conducted in a 400 bed, tertiary non-academic teaching hospital in the Midwestern United States. Seventy-nine patients were enrolled in the study; 39 received TAD and 40 received SGD. The non-inferiority margin was set at 15% in keeping with current recommendations (Kaul & Diamond, 2006). The TAD was found to be not inferior to the SGD with regards to the proportional differences in the occurrence of skin irritation (0.024 (95% CI -0.1, 0.15), the proportional differences in occurrence of skin tears (0.024(95% CI -0.08, 0.14), and the proportional difference in cost per dressing change 0.018 (95% CI -0.008, 0.046). The proportional difference in the number of dressing changes required per chest tube day exceeded the 15% non-inferiority margin. It is important to note however that the increased margin favored the TAD by 20% as compared to the SGD (SGD0.51-TAD 0.31). Mann-Whitney test was used to evaluate differences in cost per dressing type U=118, *p* 001, and number of dressing changes required by dressing type U=601, *p*=.01. Both results favored the TAD. Kendall's tau correlation revealed that the costs were significantly greater in patients who received SGD τ (79), *p*<.001. Skin irritation was measured using a color scale and skin tears were measured using the Payne-Martin skin tear assessment tool. Patients did not differ by dressing type in the development of skin irritation (U = 763, *p*= .693), or development of skin tears (U = 761.5, *p* = .584). Based on these findings use of TAD can be recommended as not inferior to the current practice of using gauze and tape. Further study is needed to evaluate whether this non-inferiority is maintained in patients who require chest tubes for longer periods of time.

CHAPTER I

INTRODUCTION

Following the Institute of Medicine's publication of *To Err is Human* (Institute of Medicine, 2000), open discussions regarding the risk of being a patient in the healthcare system became common place. These discussions led to a subsequent publication entitled *Crossing the Quality Chasm* that addressed ongoing quality issues in healthcare (Institute of Medicine, 2001).One of the major emphases of this report is the recommendation that healthcare be based on the use of scientific evidence with demonstrated efficacy. As a result, nursing and other healthcare professionals began to evaluate patient care practices to ensure that safety and efficacy for these therapies exist. Inherent to this evaluation is the necessity that nurses identify and establish scientific support for nursing practice. One such practice that lacks clear evidence is the care and maintenance of thoracostomy tubes.

Thoracostomy tubes, more commonly known as chest tubes, are frequently part of care provided to patients with complicated respiratory disease, such as pleural effusions, cardio-thoracic surgery patients, and trauma patients (Broaddus & Light, 2005; Watson & Harbrecht, 2005). The incidence of pleural effusions in U.S. adults was approximately 1.5 million patients in 2001 (Broaddus & Light, 2005; Watson & Harbrecht, 2005). When the number of patients who undergo cardio-thoracic surgery (approximately 300,000 annually) and those who sustain blunt and penetrating trauma results are summed, more than two million U.S. adults receive chest tubes annually(Epstein, Polsky, Yang, Yang, & Groeneveld, 2011; Wanek & Mayberry, 2004)

Rates of complications in patients with chest tubes have been reported to be as high as 30%. These complications include infections like empyemas, pneumonias, and site infections;

damage to underlying structures; and inappropriate chest tube placement (Ball, et al., 2007; Coughlin & Parchinsky, 2006; Liu, et al., 2004; Luchette, et al., 2000; Tang, Velissaris, & Weeden, 2002). In their 2007 study, Ball and colleagues documented empyema and site infection rates in chest tubes placed by resident physicians to be just under 6% each. Given the millions of chest tubes used annually in the United States, an infection rate of 6% would result in significant patient morbidity and mortality and would result in millions of dollars in preventable healthcare expenditures. As such, research that aims to prevent this complication is meritorious.

The Centers for Medicare and Medicaid Services (CMS) is a federal agency responsible for establishing government health insurance standards. These responsibilities include administering Medicare and Medicaid, and ensuring compliance with federal healthcare insurance mandates, even for those with private insurance. As such, their codes and regulations are often adopted by private health payers. CMS has not specifically addressed chest tube infections, but acknowledges the burden of preventable complications to individuals and healthcare systems and established steps to decrease hospital-acquired infections. To ensure compliance with the call to eliminate nosocomial infections, in 2008 CMS eliminated healthcare reimbursement for care costs related to with specific preventable complications (Centers for Medicare and Medicaid Services, 2008). Included in this list of preventable complications are both infection related issues, such as ventilator associated pneumonia and urinary and vascular access associated catheter infections. As a result, healthcare systems are now subject to losing significant financial compensation when these conditions occur.

Another potential complication associated with the use of chest tubes are skin tears. These injuries may result from the removal of dressings used to cover the chest tube insertion site causing patient pain and potentially resulting in infection or permanent scarring. Some

injuries are so severe they require consultation of wound specialists and prolonged hospitalization (Cutting, 2008b; Dykes & Heggie, 2003; Glenn, 2006; Hamersten, Hamersten, & Jemsby, 2003; LeBlanc K, Christensen, Orsted, & Keast, 2008; LeBlanc, 2008; McGough-Csarny & Kopac, 1998; Meuleneire; J. O'Brien & Reilly, 1995; Reddy, 2008). Skin injuries are another of the preventable complications currently under review by CMS.

Nurses and physicians in many specialties routinely provide care for patients who require chest tubes. Despite this, there is little research supporting the current practices regarding the care and maintenance of chest tubes. Since the early 1950's, authors describe the use of gauze and tape dressings as the type of covering that should be used with chest tubes to provide a barrier against infection (Sweet & Arroyo, 1954). Chest tube dressing recommendations remain essentially unchanged today (Allibone, 2003, 2005; American Association of Acute and Critical Care Nurses, 2005; Ball, et al., 2007; Broaddus & Light, 2005; Carroll, 2000; Charnock & Evans, 2001; Coughlin & Parchinsky, 2006; Frisch & Collins, 2004; Godden & Hiley, 1998; Gross SB, 1993; Lazzara D, 2002; Luchette, et al., 2000; Pruitt, 2002; Tang, et al., 2002). Given the dearth of research base for chest tube dressings, it is logical that these practices be evaluated to determine that current practice is both safe and effective.

Clinical Use of Chest Tubes

Chest tubes use has been recorded for centuries. However, chest tube related technology has evolved dramatically in the last 20 years (Ball, et al., 2007; Gross SB, 1993). Two of the most significant changes involve the development of plastic and silastic tubes that influence the size and type of tubes available for drainage of the pleural and mediastinal spaces. Chest tube drainage system similarly evolved from a simple water seal system, to glass bottle suction, to dry seal systems (Carroll, 2000; Coughlin & Parchinsky, 2006; Godden & Hiley, 1998; Gross SB,

1993; O'Hanlon-Nichols, 1996; Schiff, 2000). Despite the changes in chest tube composition and drainage systems, the manner in which chest tubes are dressed has not changed since the 1950's.

Currently, the standard of practice for chest tube dressings is to cover the insertion site with gauze anchored by tape. Numerous publications exist supporting this practice. A review of the evidence supporting these recommendations finds that they are based on expert opinion (Allibone, 2005; Avery, 2000; Charnock & Evans, 2001; Frisch & Collins, 2004; Godden & Hiley, 1998; Roman & Mercado, 2006). Expert opinion is considered valid for evidence based decision making in the absence of the availability of stronger evidence (OCEBM Levels of Evidence Workgroup, 2011).

Because of the similarities between central venous catheter insertion sites and chest tube insertion sites, there is growing interest in the use of transparent adhesive dressings (TAD) as an alternative to the traditional gauze dressing. Transparent adhesive dressings are the used for covering central venous catheter insertion sites and are considered the standard of care. These recommendations are based on well designed experimental studies and have received a Category IA recommendation from the Centers for Disease Control and Prevention, the highest recommendation given (O'Grady, et al., 2011). The use of TAD for covering chest tubes may improve the care and maintenance of chest tube dressings on patients who require chest tubes as part of the disease treatment. This study builds on research and practice guidelines surrounding central venous catheter care and maintenance practices and extrapolates these guidelines and applies them to the care and maintenance practices of chest tubes (Welton, 2008; Welton & Harris, 2007; Welton, Unruh, & Halloran, 2006; Welton, Zone-Smith, & Fischer, 2006).

Healthcare systems currently work under increasingly rigorous financial restraints. The advent of the Affordable Care Act of 2010 establishes that cost containment while ensuring the

safety and efficacy of healthcare is the cornerstone of future healthcare in the United States. It is unclear what the financial costs or savings would be if the types of dressing used to cover chest tubes changed in practice. Therefore, it is essential to conduct research that validates or refutes the current care of chest tube dressings and that also considers the financial implications of such a change.

Study Aims

The goal of this study is to determine the effectiveness of two different chest tube dressings, to document the development of chest tube associated infections, skin irritation and skin tears, and to contrast the costs associated with the two different dressing in a sample of adult post cardio-thoracic surgical patients.

This study sought to answer the following questions:

1. Is there a significant difference in the incidence of chest tube (CT) site infections in adult post cardio-thoracic surgical patients whose chest tubes are dressed with standard gauze dressing (SGD) and those whose chest tubes are dressed with transparent adhesive dressings (TAD)?
    a. Null hypothesis: There is no significant difference in the incidence of chest tube site infections in adult post cardio-thoracic surgical patients whose chest tubes are dressed with SGD and those whose chest tubes are dressed with TAD.
2. Is there a significant difference in the incidence of CT associated empyema development in adult cardio-thoracic surgical patients whose CT is dressed with SGD and those whose chest tubes are dressed with TAD?

   a. Null hypothesis: There is no significant difference in the incidence of CT associated empyema development in adult cardio-thoracic surgical patients whose CT is dressed with SGD and those whose chest tubes are dressed with TAD.

3. Is there a significant difference in the frequency of skin irritation in the area in contact with the chest tube dressing in adult post cardio-thoracic surgical patients whose CT are dressed with SGD and those who are dressed with TAD?
   a. Null hypothesis: There is no significant difference in the frequency of skin irritation in the area in contact with the CT dressing in adult cardio-thoracic surgical patients whose CT are dressed with SGD and those who are dressed with TAD.
4. Is there a significant difference in the number of times dressing changes are required in adult post cardio-thoracic surgical patients whose CT are dressed with SGD and those who receive TAD?
   a. Null hypothesis: There is no significant difference in the number of times dressing changes are required in adult cardio-thoracic surgical patients whose CT are dressed with SGD and those who receive TAD.

Secondary questions related to cost of providing care with each type of dressing include:

1. Is there a significant difference in the cost of the two dressing types?
   a. Null hypothesis: There is no significant difference in the cost of the two dressing types.
2. How long does it take nurses to properly change each type of dressing?
3. What are the product costs for each type of dressing?
4. What are the mean nursing salaries for direct care nurses within the institution?

These data were used in an attempt to determine the cost per dressing change for each type of dressing used.

Implications for Nursing Practice

The intensity of nursing care needed by individual patients is one of the single most important determinants of where patient care occurs (Bauerhaus, 2010; Welton, 2008; Welton, Meyer, Mandelkehr, Fakhry, & Jarr, 2002). Patients admitted to acute care hospitals require care and monitoring that is too complex and time intensive to occur in other parts of the patient care continuum. High-quality, evidence based nursing care is key to ensuring patients have the best possible outcomes. The understanding of the importance of nursing care continues to grow. Many of the hospital acquired conditions and complications identified by the Centers for Medicare and Medicaid Services are considered nurse sensitive. Nurse sensitive indicators "reflect the structure, process and outcomes of nursing care" (American Nurses Association, 2011). This study questions the current structures and process used in caring for patients with chest tubes and seeks to identify new effective and efficient methods for providing this care.

The findings of this study have the potential to change the way patients with chest tubes are cared for across the world. Current practice dictates that the gauze dressings are changed at least daily to assess the chest tube insertion site. Nurses and other members of the healthcare team are only able to observe the site during the few minutes when the dressing is removed. Transparent dressings may remain in place for as long as seven days and allow all members of the healthcare team direct observation of the insertion site at any time. This ability to assess the site through the dressing is efficient and effective for both the nurse and the patient. Fewer dressing changes may also result in greater overall patient comfort associated with chest tubes.

Implications for Nursing Research

The science and practice of nursing has grown substantially over the past 50 years, but much of the care provided continues to be based upon expert opinion. Nursing research that incorporates experimental design provides strong evidence that can be used by the healthcare team to inform their practice and to assist patients in decision making decisions. The injury prevention framework can be used to study other nurse sensitive patient outcomes. Pressure ulcer and fall prevention are two such outcomes that require further study. Much work has been done to identify the factors that put patients at risk for falls and pressure ulcers, but greater research is needed to determine the impact of specific interventions that may prevent their occurrence.

This research seeks to establish the evidence base for a standard nursing treatment while decreasing a nurse sensitive medical complication. This work may serve as the platform for other nurse scientists to investigate non-chest tube related nursing treatments that are currently supported only by expert consensus but not by a research base.

CHAPTER II

REVIEW OF THE LITERATURE

Each year, over two million Americans require chest tubes to manage acute medical and surgical conditions (Broaddus & Light, 2005; Watson & Harbrecht, 2005). Caring for patients with chest tubes is a common part of nursing practice, especially for those nurses who work with patients with complicated respiratory problems or undergo cardio-thoracic surgery. It is imperative that nurses and other members of the healthcare team use the best available evidence in making decisions regarding these patients' care. This chapter presents the research and conceptual framework for this study. A review of the current literature regarding chest tube usage, complications and care is also included.

Chest Tubes

Chest, also called thoracostomy tubes are pliable tubes placed into either the pleural or mediastinal space to drain accumulated fluid or air. This type of accumulation may result in altered cardiac output and/or altered ventilation (Allibone, 2003, 2005; Ball, et al., 2007; Etoch, 1995; Lawrence, 2005; Lazzara D, 2002; Liu, et al., 2004; Mattison, Coppage, Alderman, Herlong, & Sahn, 1997; Parkin, 2002; Pruitt, 2002; Tang, et al., 2002). Chest tubes placed in the mediastinal and pleural spaces are commonly used in the post-operative cardiac surgery patient to evacuate accumulated air and fluid. Additionally, chest tubes provide nurses and physicians with the ability to monitor for excessive blood loss after surgery. Post-surgical mediastinal chest tubes are placed to drain of acute or chronic pericardial effusions. Common indications for the placement of post-surgical pleural chest tubes include treatment of pleural effusion, hemothorax and pneumothorax (Aguilar, Battistella, Owings, & Su, 1997; Allibone, 2003, 2005; Charnock & Evans, 2001; Coughlin & Parchinsky, 2006; Etoch, 1995; Godden & Hiley, 1998; Gross SB,

1993; Lawrence, 2005; Lazzara D, 2002; Liu, et al., 2004; O'Hanlon-Nichols, 1996; Parkin, 2002; Spanjersberg, et al., 2005; Tang, et al., 2002).

Despite their common use, there are a number of chest-tube associated complications that are commonly seen in practice. Individuals with chest tubes experience complications from this treatment in up to 30% of cases (Ball, et al., 2007; Luchette, et al., 2000; Tang, et al., 2002) These complications fall into three broad categories: insertional, positional, and infectious. Insertional complications include problems such as pain and injuries to blood vessels or underlying organs. Positional complications are associated with inadequate drainage of the fluid or air as a result of the position or location of the chest tube. Infectious complications range from an infection at the insertion site to development of an empyema as a result of the chest tube (Ball, et al., 2007; Coughlin & Parchinsky, 2006; Liu, et al., 2004; Luchette, et al., 2000; Tang, et al., 2002).

Much has been written regarding insertional chest tube complications. The most frequently cited insertional complications include injury to intercostal nerves and/or blood vessels, and injury to the lung and/or diaphragm. Other reported, but less common, injuries include laceration of the liver, kidney, pericardium, and damage to the great vessels and the thoracic duct (Ball, et al., 2007; Coughlin & Parchinsky, 2006; Tang, et al., 2002). These complications are usually apparent shortly after chest tube insertion. Factors reported to influence insertional complications are training of the person placing the chest tube, the setting in which the chest tube is placed and the frequency with which the person placing the chest tube performs the procedure. (Ball, et al., 2007; Etoch, 1995; Gross SB, 1993; Mattison, et al., 1997; Schmidt, et al., 1998; Spanjersberg, et al., 2005; Tang, et al., 2002).

Positional complications are associated with inadequate drainage of the fluid or air as a result of poor position or location of the chest tube. Positional and complications may not be immediately apparent and may present subtly. There are several types of positional complications associated with chest tubes. One type of positional complication is inadequate drainage of fluid or air. When this occurs, the chest tube may have to be repositioned or it may require placement of additional chest tubes to achieve adequate drainage. Also reported is movement of the chest tube resulting in erosion of underlying tissue resulting in bleeding if it is caused by erosion of an underlying vessel, or development of a fistula between the lung parenchyma and the pleural space. Other positional complications include the development of subcutaneous air in the tissue surrounding the insertion site related to partial chest tube dislodgement. Subcutaneous air may be restricted to a small area or it may spread to include much of the thorax, neck, and head. The partial dislodgement of the chest tube may result in the development or worsening of air accumulation in the pleural space (Allibone, 2003, 2005; Ball, et al., 2007; Etoch, 1995; Godden & Hiley, 1998; Gross SB, 1993; Lazzara D, 2002; Mergaert, 1994; Parkin, 2002; Tang, et al., 2002).

Infectious complications range from an infection at the insertion site to development of an empyema as a result of the chest tube and often present subtly after the initial insertional period. Infectious complications vary from inflammation around the insertion site, to site infection or empyema. Factors associated with infectious complications are provider skill at insertion, technique used and care of the site (Allibone, 2003, 2005; Avery, 2000; Ball, et al., 2007; Coughlin & Parchinsky, 2006; Liu, et al., 2004; Luchette, et al., 2000; Tang, et al., 2002). Incidence of infections varies from 1% to as high as 56% in liver failure patients. The most commonly reported incidence of chest tube infection is approximately 18% (Liu, et al., 2004;

Luchette, et al., 2000). Luchette et al., (2000) evaluated studies for developing guidelines for prophylactic antibiotic use in trauma patients with chest tubes and reported a 5% empyema incidence. Ball et al., (2007) reported complication rates of medical resident-inserted tubes as approximately 6% each for both empyema and site infections.

Chest Tube Dressings

Although much attention has been paid to the complications associated with chest tubes themselves, there is a paucity of information regarding best practice in chest tube dressings. Chest tube dressings provide an air tight seal around the insertion site, facilitate proper tube function, and prevent site infection (Frisch & Collins, 2004; Holloway, 1984; Keen, 1975; Luckman, 1980; Sweet & Arroyo, 1954; von Hippel, 1970). A review of surgical and nursing textbooks for specific information regarding chest tube dressing procedures was conducted in addition to a review of MEDLINE and CINHAL for journal articles on the topic (Holloway, 1984; Keen, 1975; Luckman, 1980; Stacy, 1994; Sweet & Arroyo, 1954; von Hippel, 1970). Twenty of 21 articles and textbook chapters reviewed related to nursing care of patients with chest tubes included a discussion of chest tube dressings.

Recommendations for dressing type have changed little in the past 20 years. Early recommendations included the use of petroleum gauze around the chest tube itself. More recently, wound healing research suggests that macerated skin, skin that remains moist over a prolonged period of time, increases the likelihood of infection (Rhody, 2000). As a result of this information, the use of petroleum gauze is no longer routinely recommended (Lazzara D, 2002). All of the articles and textbooks that addressed chest tube dressing procedures suggested the use of gauze dressings secured by tape (Allibone, 2003, 2005; American Association of Acute and Critical Care Nurses, 2005; Avery, 2000; Charnock & Evans, 2001; Coughlin & Parchinsky,

2006). However, no references, and thus no research, were presented to support these recommendations. Recommendations for the frequency of dressing change also varies, from changing the dressing daily to changing the dressing every three days. Again these recommendations appear to lack a basis in research (Allibone, 2003, 2005; American Association of Acute and Critical Care Nurses, 2005; Author & Unknown, 1996; Avery, 2000; Charnock & Evans, 2001; Coughlin & Parchinsky, 2006; Godden & Hiley, 1998; Gross SB, 1993; Lawrence, 2005; Lazzara D, 2002; Luckman, 1980; Mergaert, 1994; Parkin, 2002). It is the lack of evidence for what is considered standard practice that prompted the development of this study.

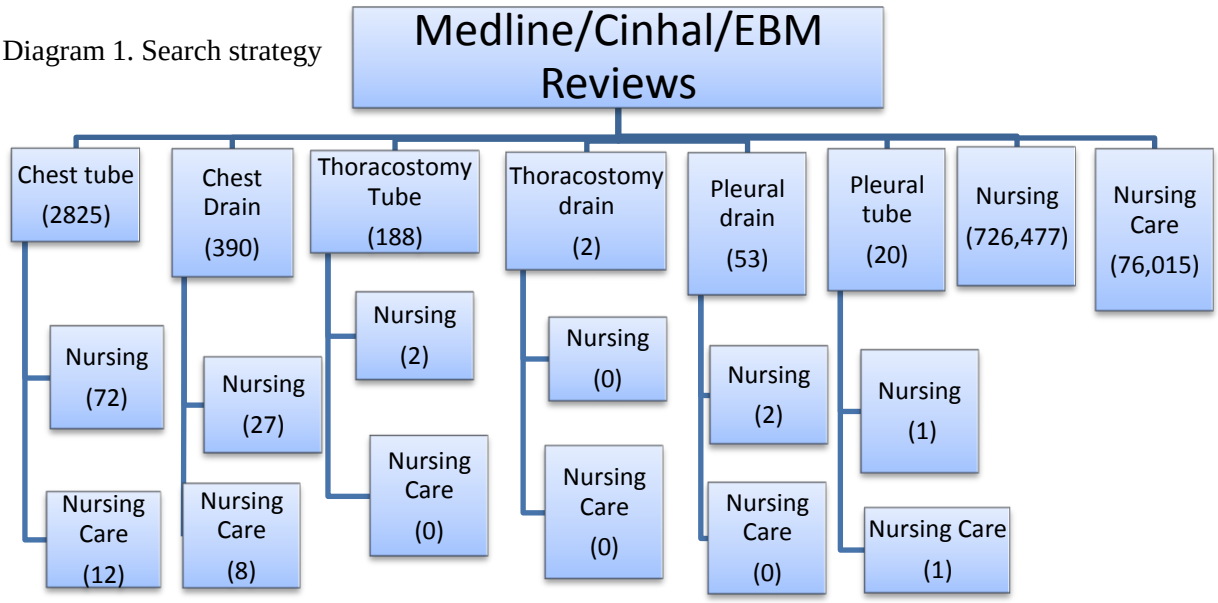
Research Base for Chest Tubes and Dressings

Chest tubes

A review of the literature was performed to determine the best practice regarding the nursing care of patients with chest tubes. A literature search of MEDLINE, CINHAL and Evidence Based Medicine Reviews were performed using the following terms: chest tube, chest drains, thoracostomy tube, thoracostomy drain, pleural drain, and pleural tube, nursing and nursing care. When each term was searched separately nearly 730,000 articles were identified. Each individual search term (chest tube, chest drains, thoracostomy tube, thoracostomy drain, pleural drain, and pleural tube) was then combined with nursing and nursing care and is represented in Diagram 1. A total of twenty-one articles were identified for review. Twenty of the 21 identified articles made reference to chest tube dressings. One article referenced only indications and complications associated with chest tubes. The bibliographies of the twenty articles with information pertaining to chest tube dressings were reviewed in an attempt to identify additional articles with chest tube dressing related content for review. No new articles

were identified in the bibliography review. A total of twenty articles with content related to chest tube dressings were reviewed.

Diagram 1. Search strategy



A search performed August 20, 2010 yielded only two articles not identified during the original search performed a year earlier. Neither of these articles specifically addressed chest tube dressings while the chest tube was in place. The same search was repeated in April 2011 and again in July 2011 and no new articles found.

There are two systematic reviews of the research regarding chest tube care (Charnock & Evans, 2001; Godden & Hiley, 1998), but neither of these published reviews included meta-analyses. Godden and Hiley (1998) reviewed 43 articles and 10 book chapters published between 1972 and 1996 pertaining to nursing care of patients with chest tubes. Categories of information reviewed included advice on taping drain connections, when to change drainage collection bottles, type of dressing used, and whether the chest tubes should be milked or stripped. Seventy-

seven percent of the information reviewed provided no advice regarding chest tube dressings. Of the 33% that made recommendations, 11% recommended occlusive dressings, 6% recommended dry dressings, 4% suggested dressings be changed as needed, and 2% recommended padding. These authors did not identify research specifically related to type of dressing that should be used nor were there any studies that evaluated the frequency of chest tube dressing changes. As a result, this review did not look at the quality of the evidence upon which the recommendations were made. The advice provided by the authors was based on, recommendations made by the authors of the reviewed articles.

Charnock and Evans (2001) performed a systematic review of the literature related to nursing management of chest drains. They sought to identify randomized control trials (RCT) addressing at least one aspect of nursing care of patients with chest tubes. Failing to identify RCTs, other research articles were reviewed. Their search for studies addressing the type of chest tube dressings and frequency of chest tube dressing change failed to yield either RCTs or studies of any type. They identified recommendations in published articles, but these articles were without a research basis.

There has been no published research since 2001, when the systematic reviews were performed, that differs from the Charnock and Evans and Godden and Hilley findings. All articles published after 2001 made suggestions for care but lacked a research basis for the recommendations (Allibone, 2003, 2005; Coughlin & Parchinsky, 2006; Lawrence, 2005; Roman & Mercado, 2006). All published works related to routine chest tube care recommend the use of gauze dressings and site observation for signs of infection.

Chest tube dressings are an effective means of infection prevention (Allibone, 2003; American Association of Acute and Critical Care Nurses, 2005; Coughlin & Parchinsky, 2006;

Luchette, et al., 2000). The published literature suggests the reasons for changing the dressing are to assess for signs of infection and subcutaneous air around the chest tube insertion site. However repeated removal of adhesive dressings to observe the site presents a new set of potential problems related to injury of the patient's skin (Allibone, 2003; American Association of Acute and Critical Care Nurses, 2005; Avery, 2000; Ball, et al., 2007; Coughlin & Parchinsky, 2006; Etoch, 1995; Frisch & Collins, 2004; Godden & Hiley, 1998; Gross SB, 1993; Keen, 1975; Lawrence, 2005; Lazzara D, 2002; Lehwaldt & Timmins, 2005; Luckman, 1980; Mergaert, 1994; Roman & Mercado, 2006; Stacy, 1994; Watson & Harbrecht, 2005).

Skin Integrity

The skin is the largest organ in the body and acts as the initial defense against organisms seeking to gain access to the human body. The skin is comprised of three layers each with a distinct purpose. The outer most layer is the epidermis. The epidermis serves as a barrier, is involved in recognition of allergens and is also involved in synthesis of vitamin D in addition to other functions. These cells regenerate and are replaced every 28 days (Baranoski, Ayello, & Tomic-Canic, 2007). The next layer of skin is the dermis. The dermis gives structure to the skin and contains the supporting tissue, blood vessels and nerves. It is the part of the skin that provides the mechanical strength and resists shearing forces. The innermost layer of skin is the hypodermis or subcutaneous layer. This layer acts to insulate the body from heat loss and to protect underlying structures from injury due to pressure and force (Baranoski, et al., 2007). The skin's ability to function is affected by numerous factors including age, hydration, and exposure to sun, soaps, medication and other chemicals (Wysocki, 2000). The greatest age related skin changes after the first year of life occur in adolescence and after the age of 40 years. Lifetime sun exposure plays a significant role in skin changes in later life.

During adolescence, increased hormone production leads to increase in numbers of hair follicles and sebaceous glands, resulting in the appearance of secondary sexual characteristics. The changes that occur from adolescence to maturity are more subtle. Dermal thickness decreases by as much as 20% (Wysocki, 2000). Skin cell turnover time doubles between 21 and 35 years of age. Protection against ultra violet rays decreases with age as the number of melanocytes diminish. Also, as skin ages its ability to resist and recover from injury is diminished resulting in increasing problems with irritation, inflammation and tearing. The elasticity of skin decreases as a result of age and sun exposure. Additionally, aging decreases the skin's ability to provide protection from pathogenic organisms. Older adults often lose their ability to regulate temperature effectively as a result of loss of subcutaneous tissue with age. Thinning of the hypodermis puts older individuals at greater risk for pressure necrosis and injury from mechanical trauma, especially shearing forces(Wysocki, 2000).

Assessment of this very important structure is a daily part of nursing care. Skin assessment involves evaluation of temperature, color, moisture, tugor and integrity (Baranoski, et al., 2007). It is the specific component of skin integrity that will be one of the major focuses of this study. No established scale for classifying skin irritation was identified during the review of the literature. Several articles related to skin irritation associated with injury due to radiation therapy were reviewed (D'Haese, et al., 2005; Noble-Adams, 1999). Noble-Adams identifies questions to be asked of patients undergoing radiation therapy and their responses to the irritated skin. This scale is not appropriate for use with this study as many of the patients who have chest tubes are unable to answer specific questions due to sedation and mechanical ventilation. Subsequently, skin irritation that does not include skin tearing was reported by presence or absence of discoloration of the skin.

Skin Tears

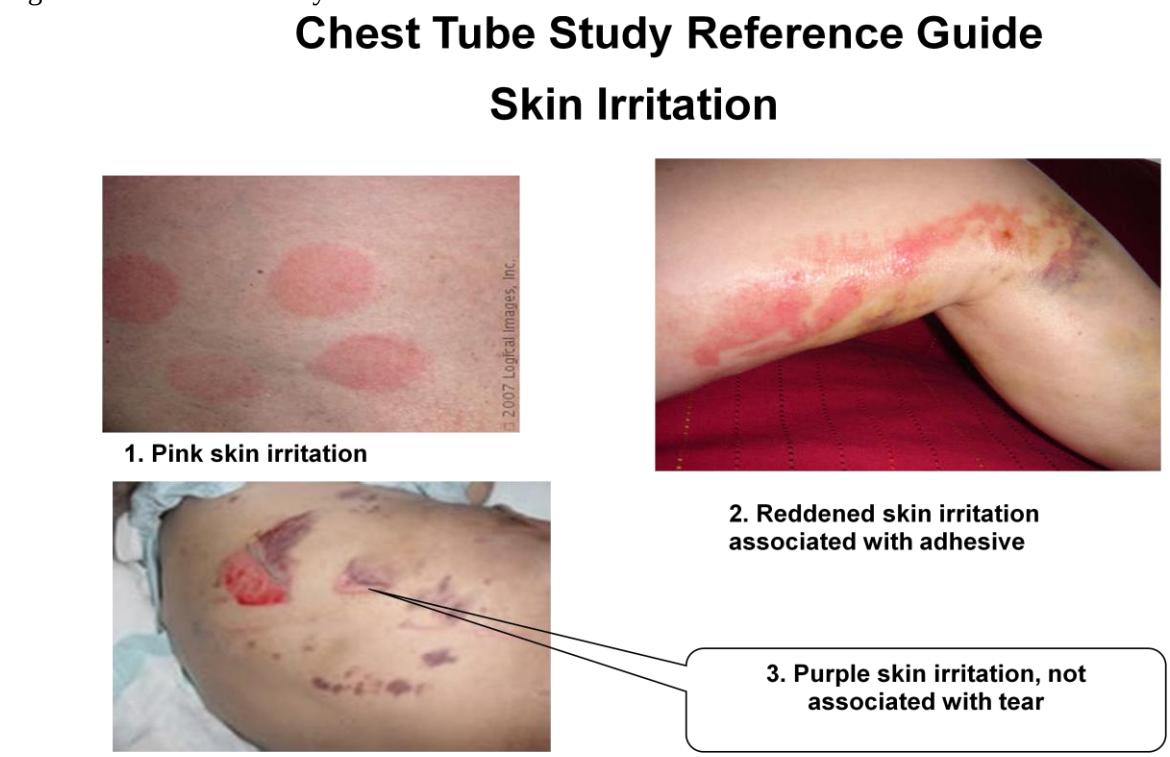
Skin tears, also known as skin stripping injuries, are a result of blunt force, friction or shearing injuries to the skin. These injuries are common in individuals with frail skin but can be seen in others as a result of mechanical injury such as with tape removal (E. A. Ayello, 2003; Baranoski, 2003; Baranoski, et al., 2007; LeBlanc, 2008; J. O'Brien & Reilly, 1995; Ousey, 2009). Injury to skin as a result of application and removal of adhesive dressings is well documented in the literature (Bryant, 2000; Cutting, 2008b; Dykes & Heggie, 2003; Glenn, 2006; Hamersten, et al., 2003; Ousey, 2009). Although commonly observed by nurses and other healthcare professionals, the prevalence of skin injury related to removal of dressings is unclear as documentation of these injuries is often poor.

There are several classification systems for skin assessment. The Braden Scale is commonly used to assess a patients risk for pressure ulcer development (Bergstrom, Braden, Laguzza, & Holman, 1987). The three-group risk assessment tool is used for assessing the risk of skin tear development in the elderly (E. Ayello & Sibbald, 2008). The Payne-Martin Skin Tear Classification system is used to classify the severity of skin tears once they have occurred (E. Ayello & Sibbald, 2008) . For the purpose of this study, the Payne-Martin Classification System for skin tears will be used. The Payne-Martin Classification System was developed in 1990 and revised in 1993. This system provides a description of the unique characteristics for each category of skin tear. Category I skin tears may be linear or flap in nature but occur without tissue loss. Category II skin tears are those that demonstrate partial tissue loss. Complete tissue loss is unique to Category III skin tears (Payne & Martin, 1990; Payne & Martin, 1993).

This skin tear classification scale was introduced by Payne and Martin in their 1990 publication. This included the initial discussion about the need for the scale and the classification

breakdown. In their 1993 paper, Payne and Martin discuss the challenges of establishing internal validity, external validity and the utility of classification taxonomies. In this later paper, they discuss the importance of the categories being unique and mutually exclusive. They describe the internal validity of this classification system as uniquely describing each category of tear. No Kappa or alpha statistics were provided. The 1993 paper established external validity by expert consensus. Payne and Martin state that their taxonomy provides a common language for interdisciplinary discussion of identification and classification of skin tears (Payne & Martin, 1990; Payne & Martin, 1993). The Chest Tube Study Reference Guide (Figure 1) is a pictorial representation of each of the three categories of skin tears. Although no formal evaluation of the validity of this classification system could be found, there are numerous studies using the Payne-Martin classification system for skin tears as a means to categorize, compare and plan treatment for individuals who have sustained skin tears. Use of the Payne-Martin Classification System for skin tears is represented as standard practice in much of the wound care literature (Ball, 2002; Baranoski, 2001, 2003; Brillhart, 2006; Fleck, 2007; McGough-Csarny & Kopac, 1998; Milne & Corbett, 2005; Ousey, 2009; Reddy, 2008; Roberts, 2007; Thomas, Goode, LaMaster, Tennyson, & Parnell, 1999).

Figure 1. Chest Tube Study Reference Guide



Nursing knowledge regarding chest tubes

Lehwaldt and Timmons (2005, 2007) suggest there is ongoing confusion around proper chest tube care. These authors (2005) identified significant variability in practice related to chest tube care and suggested that this might be related to lack of education and lack of evidence-based nursing care guidelines. They surveyed nurses who care for patients with chest tubes to identify the nurses' knowledge level and how they kept informed about care of patients with chest tubes. Half of the surveyed nurses reported they never attended an educational program specific to care of chest tubes. Of the remaining half, 30% reported attending program within the previous four years. In their subsequent study, Lehwaldt and Timmons (2007) determined that although nurses seemed to have a "reasonable understanding" of patient positioning during chest tube insertion, determination of air leak presence, and chest tube removal techniques, they had "poor" knowledge about chest tube dressings.

Survey of Current Chest Tube Dressing Policies

The literature review suggested that gauze and tape was the standard method for covering chest tubes but the frequency of dressing change recommendations varied. A review of the chest tube dressing change policy at the research site revealed that nurses were expected to change chest tube dressings at minimum every day in adult patients. The policy also specified that gauze and tape was to be used for chest tube dressings. No petroleum gauze was to be used. The chest tube dressing policy for pediatric and neonatal patients described using small gauze square covered by a transparent adhesive dressing. No petroleum gauze was used. The policy called for these dressings to be changed only when soiled. In an attempt to learn how other hospitals were covering chest tubes in adult patients, the researcher submitted a request for adult chest tube care policies to two electronic list serves (Advanced Nursing Practice in Acute & Critical Care

(ANPACC) and the National Association of Clinical Nurse Specialists list serve (CNS listserv). In addition to these two list serves, the researcher also requested adult chest tube care policies from colleagues from other regions of the country. The information provided in Table 1 is the result of a survey of 14 hospitals that were willing to share their current policies regarding chest tube dressing type, change frequency and use of petroleum gauze.

Table 1. Results of electronic survey of current practice.

Geographic region	**Type of Dressing**	**Frequency of Dressing Change**	**Petroleum Gauze Used**	**Dressing on removal**
Northeastern U.S.	Gauze and Tape	Daily and prn	Yes	Not specified
Midwestern U.S.	Occlusive- not specified	Every 2-3 days	Yes	Petroleum gauze, gauze and tape
Northeastern U.S.	Gauze and Tape	Not specified	May use	Not specified
South Central U.S.	Gauze and Tape	48 hours and prn	May use	Vaseline, gauze, tape/ remove 48 hours
South Central U.S.	Gauze and Tape	Daily and prn	No	Vaseline, gauze, tape, remove 24hours
South Central U.S.	Gauze and Tape	Daily and prn	No	Not specified
Eastern U.S.	Bio-occlusive	Not specified	May use	Not specified
South Central U.S.	Gauze and Tape	As needed	May use	Not specified
Midwest U.S.	Gauze and Micropore tape	Q72 & prn	May use, phys discretion	Vaseline gauze, gauze, micropore tape, remove 48 hours
Northeast U.S.	Gauze and tape	48 hours	Yes	Not specified
Central U.S.	Gauze and tape	As ordered	Yes	Petroleum gauze, gauze and tape, remove 24-48 hours
Central U.S.	Gauze and Tape	Not specified	Yes	Vaseline, gauze and tape, remove 24-48 hours
Midwest US	Gauze and Tape	24-48 hours and prn	Yes	Vaseline gauze, gauze and tape, remove 48-72 hours
Southeast US	Gauze and tape	24 hours	Yes	Vaseline gauze, gauze and tape.

The results of this survey revealed that 93 percent (13/14 respondents) of the respondents use gauze and tape to cover chest tube insertion sites in their adult patients. The review of policies revealed a great deal of variability in the frequency with which chest tube dressings are to be changed. The largest segment of respondents (35.7%, 5/14) did not specify a standard frequency for chest tube dressing change within the policy. Daily dressing changes and every other day dressing changes were each specified by 28.6% (4/14) respondents. Only one policy (7%) described a frequency greater than two days. The use of petroleum gauze was found to be a common practice among respondents. Only two of the policies submitted specifically declined the use of petroleum gauze beneath the gauze chest tube dressing.

Central Venous Catheters and their Dressings

A review of the literature for chest tube care revealed no clear best practice for the care and maintenance of chest tubes. Chest tubes and central venous catheters (CVC) differ in the purpose of their use for patients and the size of the tubes/catheters used for each purpose. However, they share similarities. Both are place through the skin into the chest and are covered by dressings for the duration of their use. It is because of these similarities that the central venous catheter literature was searched to identify the evidence supporting the use of transparent adhesive dressings to cover CVC insertion sites.

During the early 1980's, the method used for dressing central venous catheters was similar to that described for dressing chest tubes. The primary difference was that antimicrobial ointment was recommended for use under CVC dressings and petroleum gauze was recommended for use around the chest tube under the gauze chest tube dressings (Dison, 1979; Holloway, 1984; Keen, 1975; Kim, 1978; Luckman, 1980; Sweet & Arroyo, 1954; von Hippel, 1970; Woods & Grose, 1982). Nursing texts of the time suggested that catheters be taped in

place with a dry sterile dressing applied, and recommended daily site inspection for signs of infection (Dison, 1979; Kim, 1978; Woods & Grose, 1982). Roach, Larsen and Bartlett (1996) documented the continued use of gauze dressings alone by up to 20% of surveyed critical care nurses. They also documented the use of gauze and transparent dressings by approximately 30% and transparent dressings alone in 35% of the surveyed nurses. Since this time, other published studies have significantly impacted CVC care (Maki, Stolz, Wheeler, & Mermel, 1997).

In 2002, the Centers for Disease Control and Prevention published research based recommendations for the care and dressing of central venous catheters to decrease the number of catheter associated blood stream infections. These recommendations have been endorsed and adopted by numerous national and international organizations including the Society for Critical Care Medicine, American College of Chest Physicians, the Association for Professionals in Infection Control and Epidemiology and the Infusion Nurses Society (O'Grady, et al., 2011). The prescribed methods and recommendations for CVC placement, skin cleaning around the catheter insertion site, type of dressings that should be used and dressing change frequency were included in these recommendations.

Recommendations for precautions used during CVC placement are led by the use of maximum barrier precautions. These precautions include the use of sterile gowns and gloves, caps and masks for the practitioner placing the central venous line providing the spontaneously breathing patient and any assistants with a mask, and using a full length drape to cover the patient. Further recommendations include preparing the skin prior to puncture with 2% chlorhexidine gluconate as an antiseptic agent. The guidelines also specifically discuss the frequency and manner for changing the protective dressings. Transparent, semi-permeable dressings when used should be changed every seven days or when loose, soiled or damp. Gauze

dressings may be used to cover the CVC site, in which case the dressings should be changed every two days.(O'Grady, et al., 2011) Gauze dressings are recommended for the diaphoretic patient and when the site is bleeding or oozing. The use of antibiotic ointment is not recommended as it has been shown to increase the likelihood of fungal infections. Recommendations for care of the line after placement include the use of chlorhexidine gluconate 2% to clean the skin around the insertion site when the protective dressings are changed (O'Grady, et al., 2011; N. O'Grady, M. Alexander, & E. P. Dellinger, 2002b).

The evidence supporting the recommendations for CVC care may have led to the widespread use of transparent adhesive dressings for covering other wound and catheter sites. Transparent adhesive dressings have been used to cover skin transplant donor sites, to protect neonatal skin, and as an integral component of negative pressure wound therapy (Darmstadt & Dinulos, 2000; Persson & Salemark, 2000; Scherer, et al., 2008). Mcle, Petitte, Pride, Leeper & Ostrow (2009) evaluated the use of the transparent adhesive dressings as compared to pressure dressings after removal of arterio-venous sheaths following coronary angiography. In their study, they evaluated the ease of site assessment and the comfort to the patient associated with different types of dressings. They determined that there was no increase in bleeding complications and nurses reported greater ease in assessing the groin site. Patients reported positive comments about the transparent dressings used in the study and frequently complained about pain and removal of the pressure dressings (Mcle, Petitte, Pride, Leeper, & Ostrow, 2009). Perrson (2000) also reported less pain and discomfort associated with transparent dressings and greater ease in removal than other dressings used on skin donor sites.

Conceptual Framework

The Haddon Phase Factor Matrix is one of the most common public health frameworks to describe the epidemiology of individual infectious disease and injury outcomes. William Haddon Jr. first described a framework for injury prevention in 1968 with his seminal work "The changing approach to the epidemiology, prevention and amelioration of trauma: Transition to approaches etiologically rather than descriptively based" (Haddon, 1968). This matrix model provides a framework that incorporates time with the numerous individual and highway factors that impact crash outcomes (Haddon, 1968). Haddon expanded the framework concepts in 1973 with an article that described ten strategies for decreasing the impact of energy on injuries (Haddon, 1973). This framework facilitates the consideration of the impact of multiple factors on prevention of injuries. Haddon suggested early in his work that these matrices have two dimensions, one related to time and one related to factors. Divided into three time frames and three factors the researcher is challenged to consider the aspects of time, the vehicle of injury, environmental and human factors that may lead to the development of an injury. Time is divided into pre-event, event and post-event timeframes. Environmental factors are also commonly divided into social/cultural environment and physical environment categories (Haddon, 1980a; Runyan, 2003).

In later writings, Haddon applied his theory to more than traffic events and the Haddon Matrix is a well established public health framework (Haddon, 1980a, 1980b; Runyan, 1998). Authors have used this framework to describe a variety of injuries and injury patterns. Conroy and Fowler (2000) used Haddon's framework as a framework for forensic investigations. The authors presented the use of this tool to investigate traumatic deaths by considering host, environmental and vector/vehicle factors that play a role in these types of deaths. (Conroy &

Fowler, 2000). Barnett and colleagues used Haddon's matrix to describe preparation strategies needed by hospitals and communities faced with the possibilities of pandemic infections and or bioterrorism (Barnett, et al., 2005).

Matrix Format

A table layout is used to represent the matrix. The rows of the table/matrix are used to represent the passage of time from pre-event to event and post event. The columns are used to represent both the person impacted by the injury (host/human), the means by which the energy is transferred to the person (vector/agent), and the physical surroundings that may be contributing factors to the injury (environment) (Runyan, 1998, 2003).

Table 2. Haddon Matrix Format

Time Factors	**Human Factors**	**Vehicle/Vector/ Agent Factors**	**Environmental Factors**
Pre event			
Event			
Post event			

Time Factors

Event time factors are considered in relation to their impact on the host, the causal agent of the injury and the physical and environmental factors. Some factors may remain a constant influence across all time frames such as the age of the person impacted by the injury. Other factors may impact only one time frame such as the environmental factor of where the injury occurred.

Pre-Event Factors

Pre-event factors include the prevention of the injury causing agent, prevention of release of the injury causing agent, barriers that prevent the injury causing agent from reaching the host

and barriers that protect the host from injury. This may include processes that have been put in place to limit individual or group injury. The pre-event factors that influence the potential for injury in this study include the reason the participant needs the chest tube, the age and overall health of the patient.

Event Factors

Event factors include those actions or barriers that minimize the amount of injury causing agent applied to the host. These factors include those that disperse the energy of the agent or disperse the pattern of injury and minimize the impact of the force, and factors that increase the ability of the host to resist injury at the time of the event occurrence (Haddon, 1980c; Runyan, 1998, 2003). Chest tube injury event factors include the location of the chest tube within the patient's thorax. The nutritional and hydration status of the patient impacts the overall condition of the tissue at the time of surgery and may impact the resistance to skin injury and wound healing.

Post-Event Factors

Post-event factors supply rapid treatment and rehabilitation to and for the host (Haddon, 1980c; Runyan, 1998, 2003). These factors describe the relationship of time on the prevention of injury in this model. The post-event time period may be complicated by uncontrolled hyperglycemia, tissue oxygenation and altered perfusion.

Human Factors

Human factors include the state of health and resilience to injury of the individual. These human factors are not limited to the individual upon whom the action is applied, but may also include the actions of others made on the behalf of the person at risk for injury. Human participant factors are those factors that vary by individual but may influence the impact of the

injury on the person involved. When considered in relationship to potential chest tube associated complications these factors include age associated skin changes, overall health of the individual, co-morbidities and the reason the individual requires the chest tube. Health factors known to impact the development of wounds and skin injury include but are not limited to hyperglycemia, infection, and immobility, nutritional status and hydration (Bergstrom, et al., 1987; Bochicchio, Salzano, Joshi, Bochicchio, & Scalea, 2005; Ousey, 2009; Tuggle, Kuhn, Jones, Garza, & Skinner, 2008). In addition, the reason for the chest tube placement – air removal, fluid/blood removal or both determines the location of the chest tube and potentially the likelihood that the dressing may require changing due to fluid contamination.

Vehicle Factors

Vehicle factors are the agents that result in the injury. It may be the speed of the car in the case of a motor vehicle crash or the force used to deliver a blow. Vehicle factors associated with chest tubes and their dressings include the adhesives used in the individual dressings, the force applied when removing the dressing, and the ability of the observer to detect complications associated with these dressings in a timely manner (Cutting, 2008a; Dykes & Heggie, 2003; Glenn, 2006; Mcle, et al., 2009; Meuleneire; J. O'Brien & Reilly, 1995; Persson & Salemark, 2000; Thomas, et al., 1999).

Environmental Factors

Environmental factors are those external factors that may play a role in the development of an injury. When considered in association with traffic injuries, environmental factors would include the condition of the road and the quality of lighting at the site of the crash, presence or absence of rain etc. When considered in relationship to the development of complications associated with chest tubes, these factors include the location within the hospital or pre hospital

environment where chest tube placement occurred, whether or not the chest tube was placed emergently, the type of dressing used and the frequency of dressing changes (Aguilar, et al., 1997; Ball, et al., 2007; Cutting, 2008a; Dykes & Heggie, 2003; Etoch, 1995; Mcle, et al., 2009; Spanjersberg, et al., 2005; Thomas, et al., 1999).

The use of the Haddon phase factor matrix to describe the associated with injury to the individual with a chest tube are presented in Table 3. The events of interest in this study are the development of a chest tube associated infection and or the development of skin irritation or a skin tear. The location within the matrix of the patient, the surgery and dressing application and removal are described here as they relate to these events.

Table 3. Application of Haddon Phase Factor Matrix – chest tube associated injuries.

	Human/Host	**Agent/Vector**	**Environment**
Pre-event	Reason for chest tube placement	Method of skin preparation prior to chest tube placement	Physical location where chest tube placement occurred (surgery, emergency department, intensive care unit)
	Hydration	Pre-existing pneumonia	
	Age		
	Overall health factors		
	Preexisting medical conditions/physical condition		
	Adhesive sensitivity		
	Medications		
Event	Age	Maintenance of Sterile Technique	Method of chest tube placement (percutaneous or open)
	Location of chest tube	Adhesive strength	Type of dressing used
	Nutrition	Method of dressing removal	Number of dressing changes required
	Medications		
	Hydration		
Post-event	Age	Site infection	

	Preexisting medical conditions/physical condition	Skin tear	
	Ability of observer to detect complications	Skin irritation	
	Participant hyperglycemia	Empyema development	

Application of Phase Factor Matrix to Chest Tube Associated Injury

Pre-event, host factors that influence the likelihood that an individual might develop either a chest tube associated infection or injury include the patient's age, and hydration status, the reason the chest tube is needed and adhesive sensitivity. Pre-event agent factors include the method of skin preparation and the presence of a pre-existing pneumonia. The environmental factors that may impact the development of one of these complications include the physical location within or outside of the hospital where the patient receives the chest tube. Chest tubes placed in a surgical suite would be expected to have a lower incidence of site infections than those that are placed in a less controlled environment such as in the emergency department or during cardio-pulmonary resuscitation in the pre-hospital setting. Event related factors for each the host, agent and environmental factors include those mentioned previously and the location within the chest of the chest tube (host), maintenance of sterile technique throughout the procedure, adhesive strength and the method used to remove the dressing (agent), and the type of dressing used, and the number of dressing changes required (environment). Post-event factors are the development of a chest tube associated site infection and/or empyema, development of chest tube dressing associated skin irritation or skin tear. This framework also serves as a method to identify the factors that might further influence study outcomes.

In his landmark paper, *Advances in the epidemiology of injuries as a basis for public health policy,* Haddon, provided additional structure for injury prevention with ten strategies for

decreasing the impact of energy on the development of injuries (Haddon, 1980a). These energy minimization strategies provide countermeasures to minimize the risk of individual injury. Haddon begins with preventing the injury from occurring through preventing or decreasing the frequency with which the host receives the energy. In this study, one of the types of injury to be prevented is damage to the skin associated with the use of chest tube dressings. This injury may occur secondary to the type of dressing adhesive or the manner in which the dressing is removed. This type of injury can be minimized by decreasing the number of times the dressings are required to be changed. Prevention of infection is the second type of injury to be prevented. Attention to appropriate pre-procedural skin preparation and strict adherence to sterile technique is important to minimize this risk. All of the patients included in this study had their chest tubes placed in the operating room as part of their prescribed surgical procedure. Table 4 summarizes each of Haddon's ten strategies for injury prevention. These strategies were then applied to the potential mechanisms of injury associated with the use of chest tube dressings in the post cardio-thoracic surgery patient.

Table 4. Haddon's Energy damage and countermeasure strategies and application to chest tube dressings.

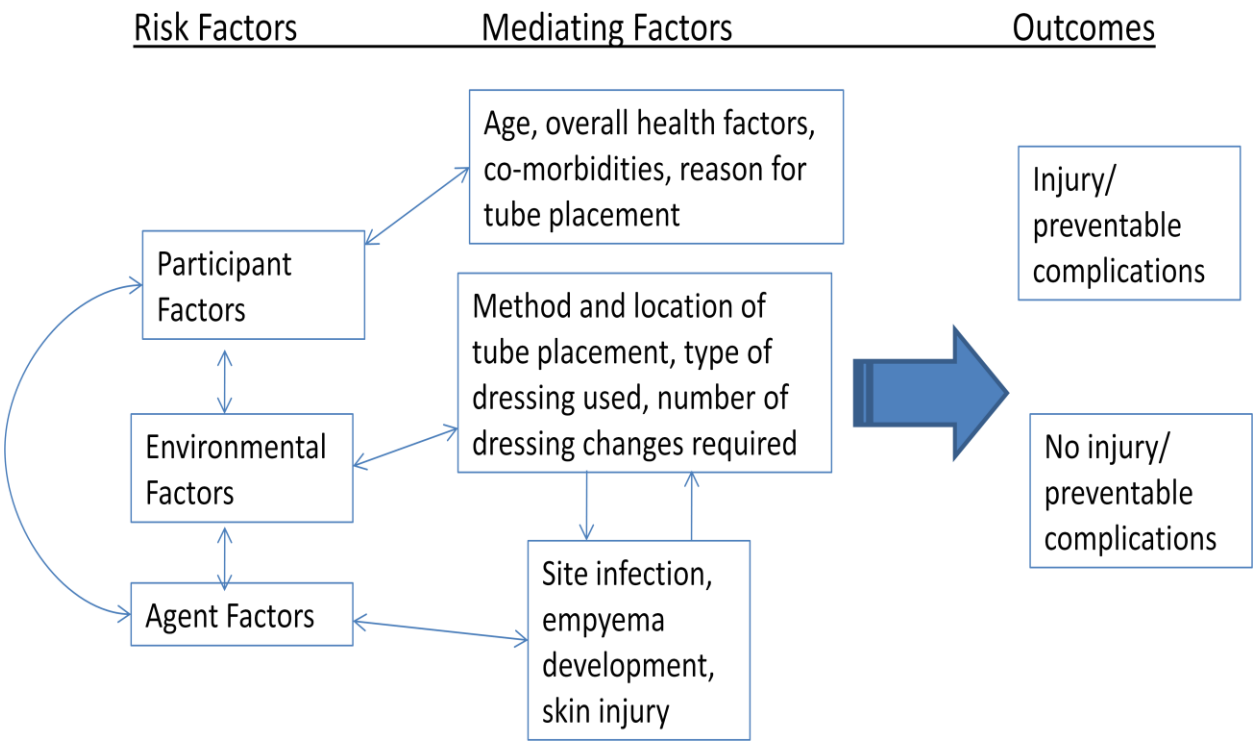
Strategy number	**Haddon's description**	**Application to chest tubes and dressings**
First	Prevent the form of injury from being applied	Reduce frequency of dressing changes. Prepare skin with antimicrobial prior to placement of chest tube. Provide controlled environment for chest tube placement.
Second	Reduce the amount of energy applied	Do not use dressings that increase the tension placed on skin (pressure type dressings). Stabilize chest tube to decrease movement of tube.
Third	Prevent release of energy	Reduce frequency of dressing changes. Clean skin around chest tube insertion site with each dressing change.
Fourth	Modify rate of energy release from source	Remove transparent dressings by pulling on edges as described by manufacturer. Clean skin around chest tube insertion site with each

		dressing change.
Fifth	Separate in space and time the release of energy from object	Reduce frequency of dressing changes.
Sixth	Separation by barrier material	Clean skin around chest tube insertion site with each dressing change.
Seventh	Modify contact surface to minimize contact	Use only as much tape as necessary. Use consistent dressing size.
Eighth	Strengthen structure that might be damaged by energy	Minimize complicating factors associated with loss of skin integrity. Clean skin around chest tube insertion site with each dressing change.
Ninth	Rapid detection and evaluation of damage	Assess the skin underneath the dressing and the surface in contact with the adhesive with each dressing change and with assessment in the case of the transparent dressing.
Tenth	Evaluation of return to pre-event status	Evaluations of the skin impacted by the dressing after dressings are no longer required.

The Study's Conceptual Framework

This study's conceptual framework was developed to help explain the types of catheters that are placed percutaneously into the chest cavity. Catheters are placed either, to remove fluid and air from areas within the chest cavity, and/or to administer fluids, as is the case with central intravenous catheters (CVC). Dressings are placed over both of these types of catheters with the primary objective being to provide barrier coverage over the area of the skin that has been breached by the catheter. The types of dressings used varies depending upon whether the tube was placed for administration of fluid (as with CVCs) or for removal of fluid or air (chest tubes). A historic review of dressing recommendations for chest tubes and CVCs demonstrated similarities in how both were cared for when they gained increased use in the 1970's and 1980's (Dison, 1979; Holloway, 1984; Keen, 1975; Kim, 1978; Luckman, 1980; Stacy, 1994; Sweet & Arroyo, 1954; von Hippel, 1970; Woods & Grose, 1982).

Figure 1. Conceptual framework for the understanding of chest tube complications.



Volumes of literature have been published since the turn of the last century that relate to the care of central venous catheters, owing in part to increased use of CVCs and the availability of new dressing products. Reasons suggested for changing dressings include the need to assess the site for signs of infection, injury to underlying tissue and presence of fluid or air in the underlying tissue. The need to assess for these problems leads to the difference in frequency of dressing changes with each type. Gauze dressings do not allow direct observation of the insertion site while transparent adhesive dressings do. Research using transparent adhesive dressings recommends that these dressings need not be changed more often than every seven days if they are not loose, soiled or damp and they do not have gauze beneath them. Those transparent adhesive dressings with gauze beneath them should be changed at least every two days or when loose soiled or damp (O'Grady, et al., 2011; O'Grady, et al., 2002b).

Superiority, Equivalence and Non-Inferiority Trials

An extensive review of the literature was performed related to non-inferiority sampling. Methodology for equivalence trials and non-inferiority trials were reviewed. Equivalence trials are used to establish that the effects of two treatments are identical (Christensen, 2007). This type of trial is used when an established therapy has known effectiveness but a new therapy potentially offers greater ease of use, less cost and/or fewer side effects (Christensen, 2007; Piaggio, et al., 2006; Wiens, 2006; Zee, 2006). Non-inferiority trials (NIT) are not the same as equivalence trials (ET), although the terms are frequently used interchangeably. Non-inferiority trials do not seek to establish sameness as seen in ETs, but conversely they are designed to demonstrate that one therapy is not worse than another therapy when evaluating a prescribed outcome (Christensen, 2007; Wiens, 2006; Zee, 2006). NIT design differs from superiority and equivalency designs in several other ways.

Table 5 summarizes the similarities and differences between these three methodological designs. Non-inferiority margin is established by identifying the minimal acceptable difference between the two measures. Although there is no accepted standard for the acceptable differences between treatments in non-inferiority studies, Kaul and colleagues suggest using a proportional difference (non-inferiority margin) of 15-20 percent.

Table 5. Similarities and differences in randomized control trial study design. (Christensen, 2007; Kaul & Diamond, 2006; Kaul, Diamond, & Weintraub, 2005; Piaggio, et al., 2006; Wiens, 2006)

	Superiority Trials	Equivalence Trials	Non-Inferiority Trials
Goal	Determine superiority of a new intervention as compared to a placebo or established therapy.	Establish that there is no difference between two studied treatments/interventions.	Establish that the new treatment/intervention is no worse than (is not inferior to) the established treatment.

Parallel Samples (Randomization Possible)	Yes	Yes	Yes
Confidence Intervals	95% 2-tailed	95% 2-tailed	97.25% 1-tailed (equivalent to 95% 2-tailed)
Alpha	.05	.05	.05
Beta	.8	.8	.8
Standard Deviation	Yes	Yes	Not usually
Non-Inferiority Margin	No	No	Yes – No accepted standard, 15-20% commonly accepted.

Cost-effectiveness

The seminal work in this area was published by O'Brien, Drummond, Labelle and Willan (1994). The authors discuss what was at the time, a relatively new method of concurrently conducting cost-effectiveness analyses in conjunction with prospective randomized controlled trials. O'Brien et al., outline concerns and solutions that shape the recommendations for economic evaluations methodology today (Chiou, et al., 2003; Evers, Goossens, de Vet, van Tulder, & Ament, 2005; B. J. O'Brien, Drummond, Labelle, & Willan, 1994; Ramsey, McIntosh, & Sullivan, 2001; Soares & Dumville, 2008; Stearns & Drummond, 2003).

Ramsey, McIntosh and Sullivan (2001) support O'Brien et al.,'s (1994) recommendations that cost-effectiveness studies have hypotheses, and that the null hypothesis should be that there is no difference in cost of the two treatments being studied. Cohen & Reynolds (2008) took these concepts further by outlining three types of health economic studies and key principles for the interpretation of cost-effectiveness studies.

Table 6 describes the similarities and differences in different cost-effectiveness study designs. Trial based studies provide the opportunity to incorporate randomization and establish measureable endpoints for comparison. This type of study design may be limited in inclusion

criteria as to make it difficult to reproduce and apply in wider patient populations. Mathematical models are used when the measures being study may not be performed using experimental design. The results obtained using these models reflect the appropriateness of the model and the accuracy of the data used in the model's calculations. Hybrid studies attempt to extend the results obtained through various study methods to populations not previously studied.

Table 6. Types of Cost-effectiveness studies(Cohen & Reynolds, 2008).

Type of study	Strengths	Limitations
Trial Based Studies	Randomization minimizes bias; established, measurable endpoints	Limited reproducibility in wider populations; limited time studies
Mathematical Models	May include data from multiple studies in analysis. May be used to estimate outcomes when randomized and clinical trials cannot be performed.	Reflect accuracy of data used; Results dependent upon well designed mathematical model.
Hybrid Studies	Uses the strengths associated with randomization and the ability to extend results beyond the time limits outlined in the initial study through use of mathematical modeling.	Same limitations outlined in each study design above.

Cohen and Reynolds (2008) described five key principles that should be considered when designing and reviewing cost-effectiveness studies (Table 7). The first principle is the analytic perspective. Information should be presented in a manner that stakeholders are able to identify the impact of the treatment or therapy. Stakeholders may include healthcare organizations, third-party payers and individuals receiving the therapy. These authors suggest that it is important to present the cost data in such a way that stakeholders are able to compare these costs across settings and timeframes. Incremental comparisons, (third principle) are possible through clear

reporting of each component used in determining the cost of individual treatments. It is also important to consider the principle of time-horizons (third principle) when evaluating the cost of therapies. Assessing the cost of a treatment or therapy too soon may artificially deflate the cost associated with this care, while extending the assessment beyond the timeframe associated with the treatment may make the therapy appear more expensive. The fourth and fifth principles are uncertainty and limitations. The authors describe uncertainty as relate to the power of the study and cautions stakeholders not to use the study limitations as the sole source for decision making. Table 7 further describes each of these principles.

Table 7. Principles of Cost-effectiveness Studies (Cohen & Reynolds, 2008).

Analytic Perspective	Cost-effectiveness evaluation must include perspective of all stakeholders.
Incremental Comparison	Implies that cost of therapy may not be apparent in the final total cost analysis but may also need to be calculated on a per intervention basis. Evaluation of incremental costs may allow for treatment determination based on budgetary constraints and associated outcomes.
Time-horizons	The determination of follow-up time may significantly impact the cost-effectiveness of individual treatments. Time determinations that are set too short may inappropriately inflate the cost of therapy. Time determinations that are too long may deflate the cost of therapy. Short time frames should be used when expenditures and benefits occur in a finite time frame (i.e.) length of time of a chest tube being in place).
Uncertainty	Usually expressed as power, p values and confidence intervals. These parameters may be inadequately studied and have no basis for comparison in cost-effectiveness studies making these numbers difficult to determine.
Limitations	Should not be used as sole source for decision making (requires additional information about comparative effectiveness of treatments for consideration). Should be considered along with feasibility and meaningfulness of other obtained information.

Polsky, Glick, Willke and Schulman (1997) published a study comparing four methods of determining confidence intervals for cost-effectiveness ratios. The authors evaluated the use of

the box method (where cost and effect intervals are examined separately), the Taylor series method (incorporates correlations of effectiveness and cost into an equation of standard error), the non-parametric bootstrap method (involves calculation of confidence interval from repeated random samples from the measured population) and the Fieller theorem method (makes parametric assumptions applied to the ratios). The authors determined that the bootstrap and Fieller theorem methods were the most accurate of the four methods compared and recommend the use of one of these two methods when evaluating the value of an intervention based on cost (Polsky, Glick, Willke, & Schulman, 1997).

A review of the literature related to cost-effectiveness analysis also identified another controversy in calculating the cost of services when one of the factors of analysis includes products. Folland, Goodman and Stano (1997) discuss the numerous ways of calculating product costs including the charge of the product to the patient, the charge of the product that the third party payer has agreed to and the actual cost of the product to the organization providing the care (Folland, Goodman, & Stano, 1997a, 1997b). The authors make the case that because of the inflation of charges that the most appropriate number to use is the cost that the organization pays for the product.

Cardio-Thoracic Surgery

Despite the progress that has been made in identify contributing factors associated with coronary heart disease; millions of Americans continue to require medical and surgical treatment for these life threatening conditions. Coronary revascularization surgeries are performed in patients who have failed medical management and/or for whom percutaneous coronary intervention with stents is either not possible or inadequate to re-establish coronary perfusion. Coronary revascularization surgeries are among the most commonly performed surgical

procedures in the United States. It is estimated more than 1 million procedures are performed each year. The use of chest tubes is a routine part of the post-surgical care these patients require. Establishing a clear best practice for managing the dressings used to cover the chest tube insertion site would impact each of these patients and potentially those who require chest tubes for other reasons (Centers for Disease Control and Prevention, 2011; Charnock & Evans, 2001; Epstein, et al., 2011; Godden & Hiley, 1998).

CHAPTER III

METHODS

The purpose of this chapter is to describe the design of this research study, including the sample, setting, and conceptual and operational definitions. The chapter also includes the methods and procedures utilized in the data collection and analysis, and discussion of human subjects protection.

Purpose

The purpose of this non-inferiority, experimental study was to compare the use of this SGD with the use of a transparent adhesive dressing (TAD) related to several outcome measures. These outcome measures included the development of an infection at the insertion site, chest tube associated empyema, skin irritation and/or skin tears related to removal of the adhesive dressings, and documentation of the number of dressing changes required during the duration of chest tube intubation.

Research Questions

There is a dearth of research documenting the best practice relative to chest tube dressing and care. Millions of Americans receive chest tubes annually to treat acute and chronic medical and surgical conditions. As discussed in chapters one and two, there are significance morbidity, mortality and health care expenditures related to complications from chest tube insertion. Two of the most significant complications, skin tears and secondary infection, can be potentially life threatening for the patient and may result healthcare systems losing millions of dollars because of CMS regulations regarding non-payment of nosocomial infections. Therefore, it is essential to conduct research that validates or refutes the current care of chest tube dressings and that also

considers the financial implications of such a change. This study sought to answer the following research questions:

1. Is there a significant difference in the incidence of chest tube (CT) site infections in patients whose chest tubes are dressed with standard gauze dressing (SGD) and those who are dressed with transparent adhesive dressings (TAD)?
    a. Null hypothesis: There is no significant difference in the incidence of chest tube site infections in patients whose chest tubes are dressed with SGD and those whose chest tubes are dressed with TAD.
2. Is there a significant difference in the incidence of CT associated empyema development in patients whose CT is dressed with SGD and those whose chest tubes are dressed with TAD?
    a. Null hypothesis: There is no significant difference in the incidence of CT associated empyema development in patients whose CT is dressed with SGD and those whose chest tubes are dressed with TAD.
3. Is there a significant difference in the frequency of skin irritation in the area in contact with the chest tube dressing in patients whose CT are dressed with SGD and those who are dressed with TAD?
    a. Null hypothesis: There is no significant difference in the frequency of skin irritation in the area in contact with the CT dressing in patients whose CT are dressed with SGD and those who are dressed with TAD.
4. Is there a significant difference in the number of times dressing changes are required in patients whose CT are dressed with SGD and those who receive TAD?

   a. Null hypothesis: There is no significant difference in the number of times dressing changes are required in patients whose CT are dressed with SGD and those who receive TAD.

Secondary questions were asked related to cost of providing care with each type of dressing. These questions included:

1. Is there a significant difference in the cost of the two dressing types?
   a. Null hypothesis: There is no significant difference in the cost of the two dressing types.
2. How long does it take nurses to properly change each type of dressing?
3. What are the product costs for each type of dressing?
4. What are the mean nursing salaries for direct care nurses within the institution?

This information was used to determine the total cost to the organization per dressing change for each type of dressing used. Determination of cost for each dressing type plays an important role in the overall evaluation of which dressing type is most appropriate for patients with chest tubes. If there is no difference in the outcome measures related to infection and skin injury, but the SDG requires daily dressing changes in order to assess the site, requiring greater commitment of nursing time and greater product use, then the TAD dressing may prove to be the more efficient, effective dressing.

Sample and Setting

Participants were recruited from the population of adult patients of a 500 bed, private, not-for-profit, community tertiary care hospital in Oklahoma who had chest tubes placed during a cardio-thoracic surgical procedure and were admitted to one of two participating nursing care units. Approximately 500 patients undergo cardio-thoracic surgical procedures annually at the

study facility. These procedures are performed by four cardio-thoracic surgeons who have been in practice an average of 28 years. In addition to performing coronary artery bypass graft surgeries, heart valve replacement surgeries and thoracostomies, these surgeons also perform heart transplant surgeries and implant mechanical hearts in patients for whom this surgery is needed. These units were identified because they provide care for the majority of patients in this facility that require chest tubes as part of their care. Since this study compares a new method of dressing chest tubes (TAD) to the current standard practice (SGD), the study was conducted only in those areas that were likely to care for patients with chest tubes.

Inclusion Criteria

Individuals were considered eligible for study participation if they were age 21 years or older, consented to study participation, were admitted to participating units at INTEGRIS Baptist Medical Center (Oklahoma City, OK), and required a single or multiple pleural or mediastinal chest tubes as part of their medical/surgical management. Protected groups, including the elderly (age greater than 65 years), who met these criteria, were eligible for inclusion in the study.

Exclusion Criteria

Individuals with the following characteristics were excluded from the study: less than 21 years of age, patients with pleural and mediastinal chest tubes in place less than 24 hours, known dressing or tape allergy, non-intact skin around the chest tube insertion site, inability to adhere dressing at chest tube insertion site, inability to maintain dressing in place. Other exclusion criteria included: individuals who were cognitively impaired, persons over the age of 65 who were deemed legally incompetent at the time of their procedure, and patients whose physician's orders conflict with the protocol were excluded from the study.

Conceptual and Operational Definitions

Table 8 represents the key concepts and associated operational definitions used in this study.

Table 8. Concepts and operational definitions associated with chest tubes and their dressings.

Concept	***Operational Definition***
Chest tube	May also be known as a chest drain and/or thoracostomy drain or tube. It is a hollow flexible drainage tube placed into the pleural or mediastinal space to remove fluid or air from the space.
Gauze	Gauze is bleached cotton cloth made of plain weave used for bandages and dressings.
Standard gauze dressing (SGD)	The standard gauze dressing is composed of 4X4 gauze, without petroleum gauze, placed around the chest tube insertion site and covered with tape. This dressing is one of the two types of dressings that will be compared during this study.
Transparent adhesive dressing (TAD)	Transparent adhesive dressings are waterproof, elastic polyurethane film dressings. These dressings are permeable to gases and water vapor and allow skin to breathe. Transparent adhesive dressings also allow direct visualization of insertion site and skin that they cover.
Chest tube insertion site infection	The presence of pus or cloudy fluid draining from the chest tube insertion site is criterion for suspicion of chest tube insertion site infection.
Chest tube associated empyema	A chest tube associated empyema was defined as infected fluid within the pleural space not associated with a concurrent pneumonia and not present at the time of chest tube placement.
Skin irritation	Skin irritation is a change in the color of skin that was in contact with the adhesive component of the dressing used (either SGD or TAD). A 3 point scale was used to delineate the severity of skin irritation. 0 = skin in contact with the adhesive is unchanged from the surrounding skin not in contact with the adhesive component of the dressing. 1 = A pink coloration of the skin in contact with the adhesive as compared to the surrounding skin not in contact with the adhesive 2 = Red discoloration of the skin in contact with the adhesive surface of the dressing. 3 = Purple discoloration of the skin in contact with the adhesive surface of the dressing
Skin tear	A skin tear is the separation of the layers of the skin as a result of shearing, tearing, or friction (E. A. Ayello, 2003; Baranoski, 2001, 2003; Baranoski, et al., 2007; Payne & Martin, 1990; Payne & Martin, 1993). The revised Payne-Martin Classification of Skin Tears tool was used to delineate the severity of skin tears observed. See Instruments

	below.
Loose dressing	A dressing was considered loose if an occlusive coverage of the area around the chest tube insertion site cannot be maintained without adding to or modifying the existing dressing.
Soiled dressing	A soiled dressing is a dressing with suspected or visible drainage of fluid from underneath the confines of the dressing.
Damp dressing	A dressing was considered damp if there is suspected or visible moisture within the confines of the dressing.
Time required for dressing change	The time required for a dressing change was determined by using the mean amount of time required to change each type of dressing as determined by observing 3 dressing changes for each type of dressing and taking the average of the 3 times.
Suboptimal dressing	A suboptimal dressing is a dressing that may be required if neither the gauze dressing nor the transparent adhesive dressing can be maintained as described in the procedures for each dressing. This type of dressing may include, but is not limited to, a non adhesive securing device as might be required with a burn patient or with a patient who has significant skin injury or irritation precluding the use of an adhesive dressing. No dressings of this type were required during the study.
Cost of nursing time	Cost of nursing time was determined by obtaining the midpoint salary for direct care nurses providing care for patients with chest tubes at hospital from which the sample is derived.
Product Costs per dressing change	Product cost per dressing change was determined by summing the costs of the individual products for each type of dressing. A product cost per dressing will be determined for the standard gauze dressing (SGD) and for the transparent adhesive dressing (TAD).
Inadvertent tube removal	Inadvertent tube removal was determined to have occurred if there was displacement of the chest tube to a position other than where it was intentionally placed. This did not occur during the study.
Subcutaneous emphysema	The presence of air in the subcutaneous tissue. This presents as crepitus that is palpated under the skin in the area in proximity to the chest tube. The assessment of the presence of subcutaneous emphysema or subcutaneous air as it is also called is one of the reasons reported for changing chest tube dressings. This air may be present at the time of tube placement or develop at any time subsequent to the placement of the tube.

Instruments

The revised Payne-Martin Classification of Skin Tears tool *(Payne & Martin, 1993)* was used to categorize severity of observed skin tears. The Payne-Martin Classification System for

skin tears was developed in 1990 and revised in 1993. This system provides a description of the unique characteristics for each category of skin tear.

Table 9. Payne-Martin Classification of Skin Tears (Payne & Martin, 1990; Payne & Martin, 1993).	
Category I	Skin tears may be linear or flap in nature but occur without tissue loss.
Category II	Demonstrate partial tissue loss. The scant tissue loss is tissue loss of approximately 25% of the associated tissue. Moderate tissue loss is present if greater than 25% of associated tissue has been lost.
Category III	Complete tissue loss is unique to Category III skin tears.

Payne and Martin's classification (1993) did not include measures of internal or external validity and there are no kappa or alpha statistics for this instrument in the literature. However, the content validity of this instrument is established by consensus and through widespread use of this measurement scale in skin tear research. In fact, this instrument is used as part of standard practice in much of the wound care literature (Ball, 2002; Baranoski, 2001, 2003; Brillhart, 2006; Fleck, 2007; McGough-Csarny & Kopac, 1998; Milne & Corbett, 2005; Payne & Martin, 1993; Reddy, 2008; Roberts, 2007; Thomas, et al., 1999).

Research Assumptions

There were a number of research assumptions made during data collection and analysis. These are:

1. Dressing changes were performed as assigned and per procedure
2. The patient was randomized to a particular dressing not the individual tube.
3. Patients with multiple chest tubes present had data collected on each tube separately.

4. When chest tubes are sufficiently close in proximity that one dressing can be effectively applied, only one dressing was used.
5. Nurses in each participating unit will be provided training related to both types of dressing change procedures. Enduring educational materials were made available for both dressing types for reference.
6. Procedure for care and maintenance of each dressing was included in the randomization envelopes.

Procedure

Individuals admitted to one of the two participating nursing units who met criterion for inclusion and who consented to participate in the study were randomly assigned to receive either the standard treatment (standard gauze dressing) or intervention treatment (transparent adhesive dressing) over their chest tube site.

The standard treatment procedure and intervention treatment procedure are found in Tables 8 and 9 below. The standard gauze dressing procedure included cleaning around the insertion site with chlorhexidine gluconate (CHG) and covering the insertion site with a gauze dressing. The gauze dressing was then secured with tape. The SGD dressings was changed daily to allow assessment of the insertion site for signs and symptoms of infection and to assess for the development of subcutaneous emphysema. Standard gauze dressings were also changed when they became loose, soiled or damp. The procedure for the transparent adhesive dressing also included cleaning around the insertion site with CHG. When the skin was dry, the transparent adhesive dressing was applied covering the insertion site and a minimum amount of skin around the site. These dressings were changed every seven days or when loose, soiled or damp.

Table 10. Standard Gauze Dressing Change Procedure

	Step	Key Point	Reason

1	Gather supplies	**Sterile Gauze 4X4s**; Sterile Gloves, Tape, Masks, Chlorhexidine Germicidal wipe, Bedside data collection sheet	Additional mask needed for patient if not on ventilator or has respiratory compromise requiring supportive therapy via mask.
2	Wipe bedside table with germicidal wipe.	Supplies should be placed on surface that is clean and dry.	
3	Identify patient	2 patient identifiers - name, DOB	To ensure patient safety - right patient - right procedure
4	Explain procedure (ongoing through entire process)	Explain all key points to patient during procedure	To stay consciously aware of all steps and why they are important. Improves patient satisfaction.
5	Open Supplies		
6	Don mask	Sequence important	Donning mask on self prior to patient prevents cross contamination of germs from patient to self.
7	Don mask on patient	Mask before cleaning hands.	Prevents breaking aseptic technique.
8	Wash hands	Minimum of 15 seconds.	Per IHI, 2006
	A. Alcohol-based hand sanitizer	Enough sanitizer in hand to cover all surfaces of hands and fingers.	Hand hygiene is number one thing we can do to prevent hospital acquired infections.
		Alcohol is not effective against *C. difficile.*	
	B. Soap and Water	Enough soap and water to generate a lather covering all sides of hands and fingers for a minimum of 15 seconds.	
9	Don clean gloves	Consider latex allergy.	To keep hands and site clean.
10	Remove old dressing and discard	Pull slowly, towards insertion site. Consider use of adhesive remover.	To not dislodge the catheter.
		Dressing to be changed daily or sooner if soiled or loose.	
11	Assess site	Redness, edema, drainage (purulent, bloody), or soreness. Notify physician immediately of any changes	Indicators that site may be infected.
12	Remove and discard unclean gloves.		
13	Re-wash hands per step 4.		
14	Open Sterile supplies		
15	Don sterile gloves	Sequence important	Chest tube dressing change is

			an aseptic procedure.
17	Clean chest tube insertion site with chlorhexidine gluconate	Pinch wings on the chlorhexidine applicator to break open the ampule.	
18		Hold the applicator down to allow the solution to saturate the pad.	
19		Press sponge against patient skin; apply chlorhexidine solution using a back-and-forth friction scrub for at least 30 seconds. Do not wipe or blot.	Friction gets into the crevices of the skin.
		Allow antiseptic solution time to dry	
	Center and place gauze dressing over chest tube insertion site.		
	Apply tape over gauze dressing	**May use additional tape outside confines of dressing as needed to secure chest tube.** Attempt to place minimum amount of tape needed to cover dressing.	
20	Remove patient's mask	Remove patients mask first and wrap in gloves	Keeps mask contained
	Remove gloves		
21	Remove own mask	Remove own mask	
22	Re-wash hands per step 4.		
23	Label dressing	Date and time that dressing was changed.	So nurses assessing the chest tube will know when the dressing needs to be changed.
24		Initials of person who changed dressing.	In case there are questions about chest tube.
25		It is the nurse’s responsibility to date and time dressings at the time of insertion.	
	May use additional tape to secure tubing of drainage collection device.		
	Document	Document dressing change on nursing flow sheet	Provides a standardized location for identifying when dressing was changed.
Centers for Disease Control and Prevention, (2002). Guidelines for the prevention of			

intravascular catheter-related infections. *Morbidity and Mortality Weekly Report*, 51, 1-32.
Infusion Nurses Society, (2006). *Infusion nursing standards of practice*, s25-s79.

Table 11. Transparent Adhesive Dressing Change Procedure

	Step	Key Point	Reason
1	Gather supplies	Sterile Gloves, Masks, Chloroprep, germicidal wipe, **Transparent adhesive dressing,** bedside data collection sheet. (Sterile Gauze 4X4s if drainage present).	
			Additional mask needed for patient if not on ventilator or has respiratory compromise requiring supportive therapy via mask.
2	Wipe bedside table with germicidal wipe.	Supplies should be placed on surface that is clean and dry.	
3	Identify patient	2 patient identifiers - name, DOB	To ensure patient safety - right patient - right procedure
4	Explain procedure (ongoing through entire process)	Explain all key points to patient during procedure	To stay consciously aware of all steps and why they are important. Improves patient satisfaction.
5	Open Supplies		
6	Don mask	Sequence important	Donning mask on self prior to patient prevents cross contamination of germs from patient to self.
7	Don mask on patient	Mask before cleaning hands.	Prevents breaking aseptic technique.
8	Wash hands	Minimum of 15 seconds.	Per IHI, 2006
	A. Alcohol-based hand sanitizer	Enough sanitizer in hand to cover all surfaces of hands and fingers.	Hand hygiene is number one thing we can do to prevent hospital acquired infections.
		Alcohol is not effective against *C. difficile.*	
	B. Soap and Water	Enough soap and water to generate a lather covering all sides of hands and fingers for a minimum of 15 seconds.	
9	Don clean gloves	Consider latex allergy.	To keep hands and site clean.
10	Remove old dressing and discard	Pull slowly, towards insertion site. Consider use of adhesive remover.	To not dislodge the catheter.
		Dressing to be changed	

		every 7 days or sooner if soiled or loose.	
11	Assess site	Redness, edema, drainage (purulent, bloody), or soreness. Notify physician immediately of any changes	Indicators that site may be infected.
12	Remove and discard unclean gloves.		
13	Re-wash hands per step 4.		
14	Open Sterile supplies		
15	Don sterile gloves	Sequence important	Chest tube dressing change is a sterile procedure.
17	Clean chest tube insertion site with chlorhexidine gluconate	Pinch wings on the chlorhexidine applicator to break open the ampule.	
18		Hold the applicator down to allow the solution to saturate the pad.	
19		Press sponge against patient skin; apply chlorhexidine solution using a back-and-forth friction scrub for at least 30 seconds. Do not wipe or blot.	Friction gets into the crevices of the skin.
		Allow antiseptic solution time to dry	
	If gauze placed under transparent dressing, gauze should be placed between skin and tube, not over insertion site	This allows continuous visualization of site. **If gauze placed under transparent dressing, dressing changes should occur every 72 hours.**	
	Center and place transparent adhesive dressing over chest tube insertion site.	Attempt to use transparent dressing that provides adequate coverage of site with minimum adhesive surface contact with patient skin (appx 4-6 inches) **May use additional tape outside confines of dressing as needed to secure chest tube.**	
26	Remove patient's mask	Remove patients mask first and wrap in gloves	Keeps mask contained
	Remove gloves		

27	Remove own mask	Remove own mask	
28	Re-wash hands per step 4.		
29	Label dressing	Date and time that dressing was changed.	So nurses assessing the chest tube will know when the dressing needs to be changed.
30		Initials of person who changed dressing.	In case there are questions about catheter.
31		It is the nurse's responsibility to date and time dressings at the time of insertion.	
32	May use additional tape to secure tubing of drainage collection device.		
33	Document	Document dressing change on nursing flow sheet & bedside data collection sheet	Provides a standardized location for identifying when dressing
Centers for Disease Control and Prevention, (2002). Guidelines for the prevention of intravascular catheter-related infections. *Morbidity and Mortality Weekly Report*, 51, 1-32. Infusion Nurses Society, (2006). *Infusion nursing standards of practice,* s25-s79.			

Randomization

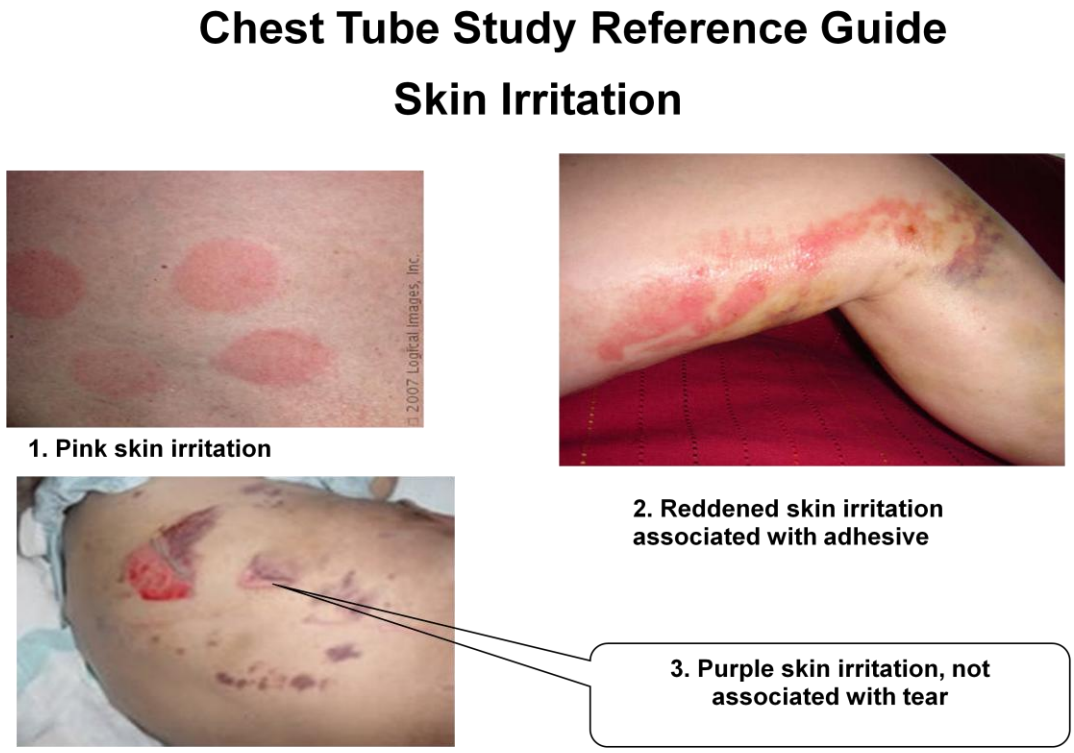
Randomization was performed using a computer randomization table. All participants were randomized from the same table. Numbered allocation folders were prepared based on the randomization table. These folders were secured by the study coordinator on the participating units and kept in sequence. When an individual agreed to participate in the study, the next sequential allocation folder was provided to the nurse caring for the patient. The contents of the folder included the study arm, a printed copy of the assigned dressing change procedure, a list of frequently asked questions and answers, and a bedside nursing dressing change record. An identifier log record was maintained by the unit-based coordinator on each nursing unit. This record contained space for the patient medical record number and the folder number. Each unit-based study coordinator completed human subject research protection training prior to the initiation of the study.

The principal investigator maintained a list of the randomization scheme and the associated folder numbers. This list was used to determine whether the randomization scheme was maintained. The principal investigator made weekly rounds on each participating unit to evaluate the accuracy of randomization maintenance.

Study Protocol

Unit based education was performed to train nurses in the proper method of performing both types of dressing changes and how to use the Payne-Martin skin assessment tool and skin irritation assessment. Education was performed several times on each of three shifts for each unit by the principal investigator and/or the unit based study coordinators. A pictorial reference for Payne-Martin Assessment and for skin irritation assessment was provided as a reference for staging skin tears and irritation (Figure 1). A resource book containing the instructions for carrying out both the standard gauze dressing change procedure (Table 10) and the transparent adhesive dressing change procedure (Table 11) were provided for each unit. These procedures were based on standard institutional protocols and all nurses who worked on the participating patient care units were educated about these procedures prior to study initiation. In addition to these documents a blank copy of the bedside dressing change record (Table 12), a blank copy of the chest tube dressing data collection sheet (Table 13) and a copy of the research protocol were included in this notebook as a resource for the nurses and physicians caring for participants in the study. This allowed for standardizations of data collection and aimed to decrease the risk of variation and inaccuracies in data collected. A unit based study coordinator was identified and trained for each nursing unit and served as an additional resource to the nursing staff.

Figure 1. Skin Irritation and Payne-Martin Classification Guide



When possible, participants were approached for consent for study inclusion prior to their surgery. When discussion with the subject prior to surgery was not possible, the individual identified as medical decision maker for the potential participant was approached for consent by the principle investigator or the unit based coordinator. After obtaining consent, the next allocation folder in the randomization sequence was pulled to determine the study arm designation. The patient's medical record number was entered by the study coordinator/investigator on the study log sheet and the participant's unique identifier number that was noted on the bedside data collection sheet (Figure 6) and the chest tube dressing data collection sheet (Figure 7). The number of the allocation folder assigned to that patient was used as the unique identifier and was recorded on the log. This provided a means by which maintenance of the randomization scheme could be verified. Each allocation folder was labeled with either the word "Standard" or "Transparent" written on the cover. Included in the folder was the written procedure for application and changing of the assigned dressing type, the bedside data collection sheet to be completed by the direct care nurse, and a copy of frequently asked questions and answers.

After random assignment the appropriate dressing either the standard gauze dressing (SGD) or the transparent adhesive dressing (TAD) was applied. If, upon arrival to the nursing unit, the patient's chest tube had been in place less than 24 hours and there was drainage around insertion site, gauze was placed under either dressing. If gauze was used under TAD the dressing, the dressing was changed after approximately 24 hours and a new TAD without gauze was placed.

Pilot Study

A pilot was conducted at the study hospital prior to this study and used the same instruments, procedures and study documents The purpose of this pilot was to identify challenges in the process of patient identification, group assignment, and staff education not originally anticipated by the investigator. This pilot study was conducted during the month of December 2008.

One of the issues of particular interest during the pilot study was whether or not the transparent adhesive dressing procedure could be used effectively in providing an occlusive dressing for tubes that are placed in the mediastinum as well as for tubes placed in the pleural space. The investigator and unit coordinators had concerns that the increased angle that mediastinal tubes protrude through the chest would prevent transparent adhesive dressings from provide sufficient cover for this type of tube This concern was refuted during the pilot and any difficulties with the study procedures were addressed prior to initiating this study.

Dressing Changes

Dressing change procedures were the same for both dressing types. First the old dressing was removed and appropriately disposed of. The skin around the insertion site of the chest tube was cleaned with a 2% CHG solution using sterile technique. Figure 4 for describes the dressing change procedure for the SGD and in Figure 5 describes the procedure for the TAD.

Dressing Change Frequency

Dressing change frequency was different for the SGD arm of the study and the TAD arm of the study. Standard gauze dressings were changed daily and when loose, soiled or damp. Transparent adhesive dressings were changed every seven days or when loose, soiled or damp. Exceptions to this rule with TAD included if gauze was placed under the dressing during the

initial application. In this instance the dressing was changed after approximately 24 hours. Fluid drainage around the insertion site of the chest tube necessitated the placement of gauze under the transparent dressing. These dressings were changed as needed when soiled or damp. Gauze placed under transparent dressing was placed between the skin and chest tube, not over the insertion site to allow forthe opportunity for site observation and fluid collection simultaneously. TAD dressings with gauze beneath them were changed every 72 hours or when soiled, damp or loose.

Dressing Placed at Time of Tube Removal

The type of dressing applied to the insertion site after removal of the chest tube was the same for both study arms. Upon removal of the chest tube the insertion site was covered with petroleum gauze, covered with gauze squares and secured in place using tape. The entire dressing; petroleum gauze, gauze squares and tape, was removed after 24 hours.

Data Collection

Demographic data collected included age, gender, race, primary diagnosis and secondary diagnosis. In addition to this information, data addressing the reason for the chest tube, the duration of intubation, need for mechanical ventilation, and length of stay in the intensive care unit and hospital length of stay was also collected. Information regarding the development of complications related to the chest tube was recorded on the bedside dressing change sheet. The chest tube data collection sheet (Table 13) contains a complete accounting of the information collected.

Table 12 is the dressing change record completed by the direct care nurses responsible for daily care of the patient. This documentation tool allowed the nurse to document in a single

location for each dressing change and served as a communication tool between nurses for easy review of any chest tube related issues associated with previous dressing changes.

Table 12. Bedside Dressing change record

Unique Identifier			**Individual Chest tube number (if > 1 dressing required)**		
Type of Dressing Used	1. Standard Gauze Dressing				
		a. Micro foam tape			
		b. Silk tape			
		c. Paper tape			
		d. Soft surgical cloth tape(Medipore)			
		e. Other – Specify			
	2. Transparent Adhesive Dressing				
		1. Without gauze 2. 2- with gauze (number of 4X4s used)			

Date Dressing Changed & Time		**(If problem identified, confirm with second care provider)**		
	Reason for Dressing Change/Removal	**Skin irritation**		**Skin Tear**
1	Due according to protocol	0 none		None
2	Dressing loose	1 pink		Category I
3	Dressing soiled	2 red		Category II skin tear with partial tissue loss
4	Dressing damp	3 purple		Category III Skin tear with complete tissue loss
5	Intentional removal of chest tube	Petroleum gauze used at time of removal 1 - Yes 2 - No		
Date Dressing Changed & Time		**(If problem identified, confirm with second care provider)**		
	Reason for Dressing Change	**Skin irritation**		**Skin Tear**
1	Due according to protocol	0 none		None
2	Dressing loose	1 pink		Category I Skin tear without tissue loss
3	Dressing soiled	2 red		Category II skin tear with partial tissue loss
4	Dressing damp	3 purple		Category III Skin tear

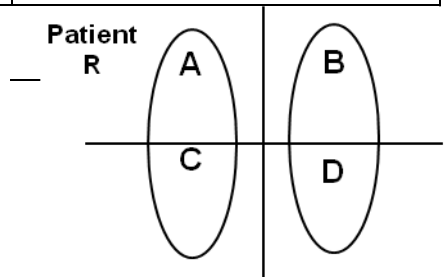
				with complete tissue loss
5	Intentional removal of chest tube			
Date Dressing Changed & Time		**(If problem identified, confirm with second care provider)**		
	Reason for Dressing Change	**Skin irritation**		**Skin Tear**
1	Due according to protocol	0 none		None
2	Dressing loose	1 pink		Category I Skin tear without tissue loss
3	Dressing soiled	2 red		Category II skin tear with partial tissue loss
4	Dressing damp	3 purple		Category III Skin tear with complete tissue loss
5	Intentional removal of chest tube			
Date Dressing Changed		**(If problem identified, confirm with second care provider)**		
	Reason for Dressing Change	**Skin irritation**		**Skin Tear**
1	Due according to protocol	0 none		None
2	Dressing loose	1 pink		Category I Skin tear without tissue loss
3	Dressing soiled	2 red		Category II skin tear with partial tissue loss
4	Dressing damp	3 purple		Category III Skin tear with complete tissue loss
5	Intentional removal of chest tube			

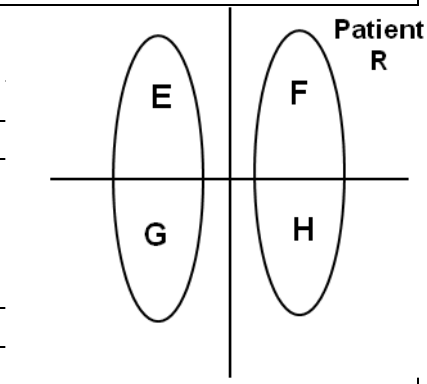
Table 13 is the complete data collection tool that was used for each participant in the study. In addition to demographic data, primary diagnosis, time on mechanical ventilation, length of stay, development of infection, and hospital mortality were collected. Number of days each participant required a chest tube, number of chest tube dressing changes that were required, and the development of chest tube associated complications were also collected.

Table 13. Chest tube dressing data collection sheet		
Unique Identifier		Folder number
(To include chest tube number as identified in drawing)		
Multiple Tubes	1. Yes	
	2. No	
Additional tube placed after initial enrollment (See associated data collection tool for that tube	1. Yes	
	2. No	
Age (years)		
Gender	1. Male	
	2. Female	
Race	1. African American	
	2. Caucasian	
	3. American Indian	
	4. Hispanic	
	5. Asian	
	6. Other	
Weight (kg)		
Height		
BMI (Calculate by computer)		
Has patient ever had previous chest tubes	1. Yes	
	2. No	
	3. Unknown	
Date Chest tube Placed		
Date study started		
Date Data Collection Terminated		
Reason for termination of data collection	1. Skin irritation requiring other than randomized dressing type	

	2. 48 hours after transfer to non-participating unit 3. Unable to maintain dressing 4. 48 hours after Chest tube removed or upon hospital discharge 5. Discharge from hospital. 6. Death	
Setting in which tube placed	1. Emergent	Placed during cardio-pulmonary arrest or unsure sterile technique maintained
	2. Non-emergent	Sterile technique likely maintained
	3. Unknown	
Chest tube placed by whom:		
	1. MD/DO	
	2. PA	
Reason for Chest tube placement (Circle all that apply)	1. Pneumothorax	
	2. Hemothorax	
	3. Pleural effusion	
	4. Post operative	
	5. Empyema	
	6. Other	
Primary Diagnosis	Cardiac/Cardiac Surgery	
Secondary Pneumonia	1. Yes	Pneumonia diagnosed more than 48 hours after admission.
	2. No	If yes, include: WBC, Tmax, chest x-ray findings
Type of Tube	1. Rigid Thoracostomy tube (ex. Argyle)	
	2. Pliable tube (ex. Pigtail, Pleurex).	
	3. Other - write in	
Size (French)		

Location of tube(s)



Anterior Chest View		
Clearly mark area on diagram where chest tube is located. (Place tube number also if more than one tube present).		
Location of tube(s)		
Posterior Chest View		
Clearly mark area on diagram where chest tube is located. (Place tube number also if more than one tube present).		
Dressing type	1. Transparent Adhesive Dressing	
	2. Standard Gauze Dressing	
	a. Micro foam tape	
	b. Silk tape	
	c. Paper tape	
	d. Soft Surgical Cloth tape (Medipore)	
	e. Other – Specify	

Dressing Change	Date:	Gauze Y	Date:	Gauze Y
(Specify gauze under dressing only if transparent dressing used)	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y
	Date:	Gauze Y	Date:	Gauze Y

On Mechanical Ventilation at	1. Yes

enrollment	2. No	
Days on Mechanical Ventilation		
Hospital Length of Stay		
Developed Tract infection	1. Yes	
	2. No	
Treatment Required	1. Yes	
	2. No	
Type of Treatment required:		
	1. Antibiotics	
	2. Tube Removal	
	3. Surgery	
	4. Other	
Specify organism if available		
Developed Empyema	1. Yes	
	2. No	
Chest tube associated empyema	1. Yes	Chest tube associated empyema – infected fluid within the pleural space not associated with a concurrent pneumonia
	2. No	
Treatment Required	1. Yes	
	2. No	
Type of treatment required:		
	1. Antibiotics	
	2. Tube Removal	
	3. Surgery	
	4. Additional tube placement	
	5. Other	
Antibiotics (Any time while tube in place)		
	1. Yes	
	2. No	
If yes:	1. Surgical Prophylaxis	
	2. Other than Surgical Prophylaxis	
Skin Irritation r/t chest tube dressing (associated with adhesive exposed area).	1. Yes	Refer to bedside data collection sheet
	2. No	
Type:	0. None	Skin Color

	1. Pink	
	2. Red	
	3. Purple	
Skin tears r/t chest tube dressing - (associated with adhesive exposed area).	1. Yes	Refer to bedside data collection sheet
	2. No	
Type: Payne Martin Scale	0. None	
	1. Category 1	Category I Skin tear without tissue loss
	2. Category 2	Category II skin tear with partial tissue loss
	3. Category 3	Category III Skin tear with complete tissue loss
Treatment Required	1. Yes	List treatment
	2. No	
Skin Irritation r/t chest tube dressing (associated with adhesive exposed area).	1. Yes	Refer to bedside data collection sheet
	2. No	
Type:	0. None	Skin Color
	1. Pink	
	2. Red	
	3. Purple	
Skin tears r/t chest tube dressing - (associated with adhesive exposed area).	1. Yes	Refer to bedside data collection sheet
	2. No	
Type: Payne Martin Scale	0. None	
	1. Category 1	Category I Skin tear without tissue loss
	2. Category 2	Category II skin tear with partial tissue loss
	3. Category 3	Category III Skin tear with complete tissue loss
Treatment Required	1. Yes	List treatment
	2. No	
Skin Irritation r/t chest tube dressing (associated with adhesive	1. Yes	Refer to bedside data collection sheet

exposed area).	2. No	
Type:	0. None	Skin Color
	1. Pink	
	2. Red	
	3. Purple	
Skin tears r/t chest tube dressing - (associated with adhesive exposed area).	1. Yes	Refer to bedside data collection sheet
	2. No	
Type: Payne Martin Scale	0. None	
	1. Category 1	Category I Skin tear without tissue loss
	2. Category 2	Category II skin tear with partial tissue loss
	3. Category 3	Category III Skin tear with complete tissue loss
Treatment Required	1. Yes	List treatment
	2. No	
Discharge by Death/Expired?	1. Yes	
	2. No	
Free text:		

Bedside dressing change sheets were maintained by the bedside nurse and kept with the documentation for each participant. Upon removal of the chest tube or transfer to a non-participating unit, the bedside data collection sheet was returned to the unit based study coordinator. Data collection sheets for individual participants were kept by the unit based study coordinator. All data collection sheets and bedside data collection sheets were returned to the principal investigator upon data collection completion. Data collection sheets remained secured when not in use. The identifier log record with associated unique identifiers was secured separately from the chest tube dressing data collection and bedside data collection sheets.

Outcome Variables

Skin Injury

There were several outcome variables of specific interest to the investigator. Two of the outcomes of interest were related to the development of skin irritation or skin tears. Skin irritation was classified by color of the irritated skin. Scores of 0 for no irritation, 1 for pink colored skin, 2 for red skin and 3 for purple discoloration of the skin will be recorded at each dressing change. Also recorded at each dressing change was the presence or absence of skin tears.

A single digital photo was taken of the involved area when skin tears were identified. A paper measuring tape was placed next to the area for reference. The date, time and unique identifier assigned to that patient was written on a piece of paper and included in the photo. No other identifying information was included in the picture. A group of three nurses trained in the Payne-Martin Classification Scale for Skin Tears independently scored each picture. Interator reliability was established prior to initiation of the study through scoring of sample photographs. Skin tears were categorized using the Payne-Martin Classification Scale for Skin Tears. The scores from the three reviewers were recorded. The two skin tears that occurred received the same Payne-Martin Skin Tear score from all reviewers.

Infection

Skin injury types were not the only outcome measures of interest. Additional outcomes related to insertion site infection and or the development of a chest tube associated empyema. Chest tube insertion site infection was defined as presence of pus or cloudy fluid draining from the insertion site. A chest tube associated empyema was defined as infected fluid within the pleural space not associated with a concurrent pneumonia and not present at the time of chest

tube placement. Determination of chest tube site infection and chest tube associated empyema would have been made in consultation with an infection control professional blinded to the type of dressing being used. This would have been accomplished by removal of the dressing prior to assessment of the patient and the site of the chest tube.

Dressing Changes

Finally, the number of dressing changes required during the duration of intubation was evaluated. The total number of dressing changes was divided by the number of days the chest tube was in place. This number was determined for each participant and was evaluated for each dressing type. These numbers are expressed as the number of dressing changes/ number of days and the number of dressing changes required during the duration of insertion.

Secondary Analysis of Cost

Nursing time required to change each type of dressing was determined by observing nurses change each type of dressing and recording the time required. A novice nurse with less than 2 years experience and a nurse with more than two years experience were observed 3 times each for each dressing type. The average time required for the six observations was used to determine the length of time required to change each type of dressing. This average was multiplied by the midpoint salary for direct care nurses at the organization to determine the cost for the nursing time. The cost of the nurses' time in dollars per hour served as a constant between the two groups.

Cost of products to the hospital was used to calculate the product costs. The use of this cost seemed most appropriate for this study since the product costs used in changing chest tube dressings are not directly itemized and billed to the patient who has a chest tube, but are part of the bundled room charge.

The cost of each type of dressing change was calculated by adding the hospital cost of the products used for each dressing change to the cost of the nursing time needed to change the dressing. This yielded a cost per dressing change for both the SGD and the TAD. The amount of time required to change each type of dressing and the cost of the supplies for each dressing type were calculated and used consistently for each type of dressing.

Cost-effectiveness

The following formula was used to determine the incremental costs of providing the two different types of chest tube dressings for patients requiring chest tubes as part of their medical care. Incremental cost-effectiveness = $(Cost_a – Cost_b) / (Effectiveness_a – Effectiveness_b)$. Where (a) is the TAD group and (b) is the SGD group. This formula takes into account not only the cost of the products and the man hours, but also the effectiveness of each therapy as well. Though this formula helps to establish the calculation, it does not help with determination of confidence intervals for cost-effectiveness studies. Fieller's theorem was used to determine confidence intervals and incremental cost-effectiveness.

Threats to Validity

Threats to the internal validity of this study include the variability in the individual nurses who performed the dressing changes. Additional threats to internal validity include the variability of tape that was available for use and the lack of a standard definition for what constituted a damp dressing. Pre-study education of all of the staff was performed and frequent evaluation of the dressings was performed by the principle investigator or the unit-based coordinators. Individual questions were answered and the procedures were reviewed regularly with the nurses performing the dressing changes in an attempt to minimize the impact of these threats. The variability in technique of the surgeons performing the procedure, the type of

procedure performed and the urgency of the surgery must also be considered in review of the results. Co-morbid conditions, such as pre-existing diabetes might have been a threat if chest tube associated infections had developed.

As previously described, content validity of the Payne Martin classification is established but there are no published calculations of internal consistency or reliability for this instrument. The lack of research-based validity and reliability for this instrument poses a small threat to this study. However, as this instrument is widely used within the literature, it is assumed that this threat is minimal.

Threats to the external validity are related to the homogenous population in which the study was conducted. Patients who undergo cardio-thoracic surgery require chest tubes for a shorter period of time than do patients who require chest tubes for other reasons. These patients may also be on different medications, have a different nutritional status than other patient populations who require chest tubes.

The threats to internal and external validity for the cost components of the study are predominately addressed by use of random assignment of participants. Additionally, the threat to external validity of the cost of dressing changes is directly proportionate to the cost of the nursing time and the product costs. The amount of time per dressing change was recorded and will be reported in the subsequent publication of study results. This allows replication of this study. Additionally the product costs used for computing each of the dressing costs were recorded and are reported so that a cost comparison could be performed in different facilities. By reporting all of the costs used for these calculations, the external validity concerns related to historic effects and setting bias should be mitigated, although differences in institutional labor

and products costs may vary from institution to institution so direct application may not be possible.

Data Collection Termination

Data collection was terminated if a participant developed skin irritation or a skin tear requiring a dressing other than the assigned randomized dressing type. Data collection was also stopped 24 hours after participant transferred to a non-participating unit. This was done because non-participating units continued to follow the procedure for gauze dressings as outlined in current hospital policy and required daily dressing changes. No patients died during the time frame of the study or requested to be removed from the study and therefore no early study termination was required. Participants were followed for 24 hours following removal of the chest tube.

Power Analysis

Accurate a priori power analyses require research established base occurrence rates of phenomenon of interest. Previous publications cite that approximately 6% of all patients with chest tubes develop secondary infections, although there is no research to support this claim (Ball, et al., 2007). Therefore, power analysis for this study did not include research supported means or standard deviations.

A power analysis was performed and it was determined that using a moderate effect size an alpha of 0.05 and a beta of 0.8, data would need to be collected from a total of 168 patients, 84 in each arm of the study. Based on these assumptions, the original intent was to enroll up to 200 participants (100 in each arm of the study). This oversampling was to accommodate a participant attrition rate of approximately 30%.

Because of the limited evidence establishing the incidence of chest tube infection, data collected from the first 30 participants were reviewed by the investigator, and in consultation with a statistician, it was determined that the original power analysis may have been flawed. That analysis used the assumption that 6% of patients with chest tubes would develop a chest tube associated infection and/or empyema. Neither issue was identified among these 30 participants. The principle investigator had additional conversations with the three cardio-thoracic surgeons at the study institution and two cardio-thoracic surgeons at another facility to determine the frequency with which patients in their practice develop chest tube associated infections and/or empyemas. These surgeons have been in practice for an average of 10 years and perform a combined average of approximately 500 cardio-thoracic surgeries annually. Neither group of physicians recalled ever having these issues occur in their surgical patients. The investigator also queried physicians who specialize in pulmonary and infectious disease practices (n=5). Physicians from both of these groups did not recall any cases of chest tube site infection or empyema in their patients.

Further review of this sample (SGD N=17, TAD N=13) demonstrated that the randomization was maintained for all participants and that 96% of the time the expected number of dressing changes were required. Given these findings, power analysis was recalculated to determine an appropriate sample size. A non-inferiority sampling framework was used for these calculations.

Based on the non-inferiority framework the new sample size was calculated using the following assumptions: Alpha = 0.05, Power of .8, expected successful for each group of 95% and a non-inferiority margin of 15%. A sample of 36 per group (N=72) would be required using these assumptions (Sealed Envelope, 2011).

Human Subject Protection

The principal investigator and all study personnel completed human subject protection training. This study was approved by the Institutional Review Boards (IRB) of both INTEGRIS Baptist Medical Center and the University of Missouri–St. Louis.

Data Analysis

Statistical analysis was performed using the Software Package for the Social Sciences (SPSS) for Windows version 19 (IBM 2011 Armonk, New York).

Demographic data was evaluated using frequency tables. The nominal level data – development of site infection, development of chest tube related empyema, was intended to be evaluated by use of Chi Square statistic, however, none of these events occurred. Ordinal level data – skin irritation, skin tear, were evaluated using Mann Whitney test. Kendall's tau was used to evaluate correlations related to type of dressing used and other measured variables. This method was used instead of Spearman's rho due to the small sample size and the large number of measures of the same rank throughout the samples (Field, 2005).

Economic evaluations were evaluated utilizing the information regarding product cost, nursing time for each dressing change and mean nursing salaries. Fieller's theorem was used to calculate confidence intervals and incremental cost-effectiveness ratio (ICER).

The following formulas were used in Fieller's theorem.

$$ICER = \frac{\mu_{c_1} - \mu_{c_0}}{\mu_{e_1} - \mu_{e_0}}$$

μ_{c_1} = avg. cost of treatment 1

μ_{c_0} = avg. cost of treatment 0

μ_{e_1} = avg. effect of treatment 1

μ_{c_0} = avg. effect of treatment 0

A cost-effectiveness plane was used for plotting the calculated ratio with the effectiveness of the intervention plotted on the x-axis and the cost of the intervention plotted on the y-axis.

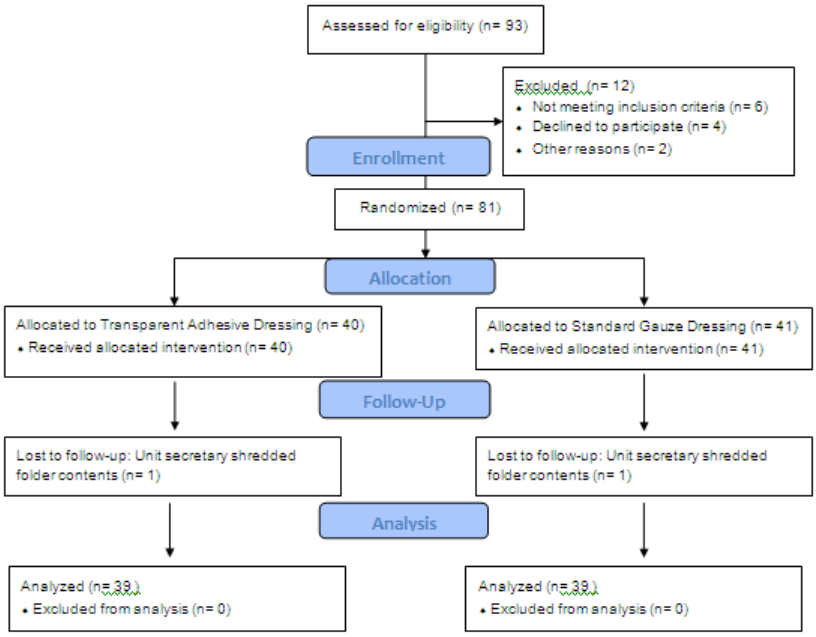
CHAPTER IV

RESULTS

Participants for this study were identified from the population of patients who presented to a large, tertiary care, not-for-profit hospital in the south central Midwest United States between October 2010 and September 2011. All participants underwent cardio-thoracic surgery and met the study inclusion criterion. Figure 3 shows the breakdown of numbers of participants enrolled as well as their allocation, follow-up and analysis.

A total of 93 participants were assessed for eligibility. Twelve were excluded prior to randomization, leaving 81 participants in the study. Forty participants received the transparent adhesive dressing and forty-one received the standard gauze dressing. Of the 81 individuals enrolled, two were lost to follow-up (one from each group).

Figure 3. Chest Tube Dressing Participant Flow Chart



Direct care nurses involved in the daily care of patients were responsible for documenting the dressing changes on the bedside dressing change data collection sheet. These sheets remained in the patient's allocated folder and were accompanied by the dressing change procedure sheet for each dressing type and the chest tube dressing data collection sheet for that participant. The investigator and/or the study coordinators completed the information on the chest tube dressing data collection sheet. Completed allocation folders were maintained by the study coordinator until collected by the researcher.

Demographic Data

The majority of participants in both arms of this study were Caucasian males. Hispanic and Native American participants were only found in the TAD allocation group. Age of patients ranged from 21 to 85 years. Participant weight and body mass index (BMI) ranged from a minimum of 50.7 kilograms (kg) to a maximum of 170.8 kg, and 18.9 meters squared (m^2) and 53 m^2 respectively. Table 14 contains the demographic data for all study participants.

Kendall's tau for independent sample was performed to compare mean ages and BMI between the two groups and the groups were not found to differ significantly (t (77) =-.506, p=.614 and t (77) p=.142 respectively).

Table 14. Demographic data

	All participants	**Standard gauze dressing (SGD)**	**Transparent adhesive dressing (TAD)**
Number of Participants	79	40	39
Age (years)	65.1 (SD=10.9)	64.5 (SD 12)	65.59 (SD 9.66)
Gender			
Male	73.4% (n=58)	77.5% (n=31)	69.2% (n=27)
Female	26.4% (n=21)	22.5% (n=9)	30.8% (n=12)
Race			
Caucasian	89.9% (n=71)	92.5% (n=37)	87.2% (n=34)
African American	6.3% (n=5)	7.5% (n=3)	5.1% (n=2)

Native American	1.3% (n=1)	0	2.6% (n=1)
Hispanic	2.5% (n=2)	0	5.1% (n=2)
BMI (m2)	29.38 (SD=6.7)	30.48 (SD 7.18)	28.25 (SD 6.14)
Previous chest tubes			
Yes	10.1% (n=8)	7.5% (n=3)	12.8% (n=5)
No	53.2% (n=42)	47.5% (n=19)	59% (n=23)
Unknown	36.7% (n=29)	45% (n=18)	28.2% (n=11)
Multiple chest tubes required	62% (n=49)	60% (n=24)	64.1% (n=25)
Mechanical Ventilation greater than 24 hours	8.9% (n=7)	10% (n=4)	7.7% (n=3)
Deaths	2.5% (n=2)	2.5% (n=1)	2.6% (n=1)

Chest Tube Placement

Patients had chest tubes inserted as part of the medical care required following surgical procedures. All chest tubes were placed by the operating surgeon in the operating room under sterile conditions. The initial chest tube dressing was applied in the operating room at the completion of the surgical procedure.

Previous and Multiple Chest Tubes

Little has been written about the impact of previous chest tubes on the development of chest tube associated complications. The researcher attempted to collect this information in an attempt to consider this variable in the event of complications. Few of the participants were able to say with certainty that they had previously required chest tubes (All 10.1%, n=8; SGD 7.5%, n=3; TAD 12.8% (n=5). An assessment of the skin of the chest was often not helpful in the determination because of the new surgical incisions and chest tube placement. Thirty-six percent of the participants (n=29) were unsure if they had required chest tubes in the past, eighteen (45%) were assigned to the SGD group and eleven (28.2%) were from the TAD group.

The number of chest tubes required by each participant was recorded. This information was gathered to determine if participants with multiple chest tubes were more likely to develop

infectious complications. Multiple chest tubes result in skin integrity breakage in a greater number of places. Multiple chest tubes were commonly required with 62% (n=49) overall requiring more than one tube. There were no chest tube associated infections in either the group that had a single chest tube or in the 62% of participants that had multiple chest tubes.

Chest Tube Associated Infections

This study was initially powered to identify a difference in chest tube associated infections. A review of the first 30 patients enrolled yielded no chest tube associated infections necessitating the recalculation of sample size. It is important to note that no infection occurred at the chest tube site nor did any chest tube associated empyemas develop in either group of patients.

Skin Injury

Seventy-nine participants were enrolled in this study, forty were randomized to the gauze dressing treatment SGD study arm and 39 were randomized to the transparent adhesive gauze TAD study arm. Eight percent (N=3) of participants receiving SGD developed pink skin irritation, no other skin irritation were noted in this group. Three percent (N=1) of the participants who received TAD developed pink skin irritation and 3% (N=1) developed red skin irritation. None of the participants had irritated skin that required additional treatment. Two participants who received SGD developed skin tears as a result of changing the chest tube dressings. One participant sustained a category 1 skin tear and one sustained a category 2 skin tear. Each skin tear occurred when the dressing was removed for discontinuation of the chest tube. The skin margins were approximated and gauze was applied over the tear areas to minimize the risk of further injury. One patient received the transparent adhesive dressing TAD developed a category 2 skin tear. This tear occurred at the time the dressing was being removed to remove

the chest tube and required no additional treatment. Mean and standard deviation was calculated using the following scales for skin irritation and skin tears for each dressing type.

Skin irritation	**Score**	**Payne Martin Skin Tear**	**Score**
None	0	None	0
Pink	1	Category I	1
Red	2	Category II	2
Purple	3	Category III	3

Kendall Tau correlation was performed and identified a positive correlation between presence of skin irritation and the presence of skin tears τ (79) = .767, p <.001.

Table 15. Skin Irritation and Skin Tear Rates and Types

	All participants	**Standard gauze dressing (SGD)**	**Transparent adhesive dressing (TAD)**
Number of Participants	79	40	39
Skin Irritation			
None	74 (94%)	37 (93%)	37 (95%)
Pink	4 (5%)	3 (8%)	1 (3%)
Red	1 (1%)	0	1 (3%)
Purple	0	0	0
Skin Tear			
None	76 (96%)	38 (95%)	38 (97%)
Payne Martin Category 1	1 (1%)	1 (3%)	0
Payne Martin Category 2	2 (3%)	1 (3%)	1 (3%)
Payne Martin Category 3	0	0	0

A Mann-Whitney test was used to evaluate differences in skin irritation and skin tears as described above. Participants who developed skin irritation did not seem to differ by dressing type, U = 763, p = .693. Participants who developed skin tears, as measured by the Payne-Martin skin tear scale, also did not seem to differ by dressing type, U = 761.5, p = .584. It is important to note that the skin tears that occurred (n=3) happened with the last dressing removal prior to discontinuing the chest tube. This suggests that further investigation to determine if there is a

correlation between the total number of dressing changes required and the development of skin tears might be valuable independent of the type of dressing used.

The proportional difference for establishing non-inferiority was set at 15% in the design of this study. The proportional presence for each item of interest was calculated with the number of events of interest/ the total observations for the sample. The proportion of skin irritation for SGD (3/40) was calculated to equal 0.075. The proportion of skin irritation for TAD (2/39) was calculated to equal 0.051. The skin irritation proportional difference was found to be (0.075 – 0.051) 0.024 (95% CI -0.1, 0.15), or approximately 2%. This is less than the 15% margin established for non-inferiority in this study. The TAD is not inferior to the SGD when skin irritation is the event of concern.

The proportion difference for skin tears was calculated using the same equation described above and with the same acceptable non-inferiority margin of 15%. The proportion of participants with SGD who developed skin tears was 0.05 (2/40). The proportion of participants who developed skin tears with TAD was 0.026. The proportional difference (0.05 - 0.026) for the development of skin tears was 0.024 (95% CI -0.08, 0.14). Based on this information, the TAD is not inferior to the SGD when the development of a skin tear is the event of concern.

Tube Days and Dressing Changes

Total number of tube days and dressing changes per patient were recorded for each group. The mean number of tube days for participants receiving SGD was 3.1 (SD 1.26). The mean number of tube days for participants receiving TAD was 3.69 days (SD 2.4). The mean number of dressing changes for SGD and TAD were 1.58(SD 0.99) and 1.13 (SD 0.41) respectively. This information was used to determine the number of dressing changes per tube days. Participants receiving SGD required 0.51 dressing changes per day the chest tube was in

place and participants who received TAD required 0.31 dressing changes per day the chest tube was in place. See Table 16 below for additional dressing change information. The proportional difference for dressing changes per chest tube day was calculated to evaluate non-inferiority between the two dressing types. This difference was found to approximately 20% (SGD 0.51-TAD 0.31). This falls outside the non-inferiority margin established. However, it is important to note that the TAD (experimental therapy) required fewer dressing changes per chest tube day than the SGD (control therapy). This marginal difference of 20% in favor of the use of the TAD requires greater research and a larger sample size to substantiate. This information suggests that the TAD would still not be considered inferior to the SGD.

Table 16. Dressing change Frequency and Type

	All participants	**Standard gauze dressing (SGD)**	**Transparent adhesive dressing (TAD)**	**Difference (Mann-Whitney)**
Hosp LOS	9.04 (SD 5.9)	8.6 (SD 4.38)	9.49 (SD 7.16)	U = 749, *p* = .759
Days chest tube in place	3.4 (SD 1.94)	3.1 (SD 1.267	3.69 (SD 2.4)	U =677.5, *p* = .296
Number dressing changes required	1.35 (SD 0.79)	1.58 (SD 0.99)	1.13 (SD 0.41)	U=601, *p* = .014
Dressing changes/tube days	0.39	0.51	0.31	

Nursing Care Costs

Nursing costs were determined by identifying the midpoint hourly salary for a registered nurse (RN) Level I and multiplying that salary times the mean fractional component of an hour that was required to change each dressing. The midpoint salary for these calculations was $24.60/hour. To obtain the mean time required to change each dressing, six different nurses were observed changing each type of dressing. Table 17 shows the results of those observations. The amount of time for each dressing change was then averaged and converted to a fraction of an hour. The time required for each dressing change performed by nurses at each experience level

is expected to be normally distributed. An independent sample t-test was performed to evaluate the difference in the amount of time required to change each dressing. The difference in time to change the dressing was not found to be significant (p =0.246).

Table 17. Time Required for Chest Tube Dressing Change (minutes)

	SGD Change	**TAD Change**	**Nursing Experience Level**	
RN1	17.75	17	Novice	
RN2	22.25	20	Novice	
RN3	24.5	21.25	Novice	
RN4	18.75	18.5	Proficient nurse	
RN5	19.5	19.25	Proficient nurse	
RN6	20.25	19.75	Proficient nurse	
Average	20.5	19.29		
Fraction of Hour	0.34	0.32	**t-test**	p=0.246

The fraction of the hour required per dressing change by type was then multiplied by the midpoint RN Level I salary to determine the nursing care costs per dressing change by type. TAD Nursing care costs per dressing change = $24.60/hour X 0.32 hours = $7.91/dressing change. SGD Nursing care costs per dressing change = $24.60/hour X 0.34 hours = $8.41/dressing change.

Product Costs

Product costs were calculated by summing the cost of the supplies required for each dressing change. Table 18 demonstrates the cost of each product used in the dressing change. Petroleum gauze was not used in this study, but the cost is included here for comparison by others. Included in the table is the cost of dressing change with each of the three types of tape that were possible to be used. The total dressing costs were computed using the type of tape specified for each participant. Foam tape was used for 95% (n=39) of SGD participants. The tape used for dressing changes remained consistent throughout the participant's enrollment in the

study. Dressing costs per participant were calculated using the cost figures appropriate for type of tape used. The total cost per dressing change was determined by adding the cost of nursing time to the sum of the products. This was done for each type of dressing and is reflected at the bottom of Table 18.

Table 18. Supply and Nursing Costs by Dressing Type

Supplies	**TAD**	**SGD/Foam**	**SGD/Paper**	**SGD/Pore**
Sterile Gloves	$ 0.19	$ 0.19	$ 0.19	$ 0.19
Mask	$ 0.12	$ 0.12	$ 0.12	$ 0.12
Chloraprep	$ 1.44	$ 1.44	$ 1.44	$ 1.44
TAD	$ 0.62	$ 0.62	$ 0.62	$ 0.62
Gauze (ea)	$ 0.11	$ 1.10	$ 1.10	$ 1.10
Germicidal wipe	$ 2.47	$ 2.47	$ 2.47	$ 2.47
Foam Tape		$ 3.03		
Paper Tape			$ 0.64	
Pore Tape				$ 1.90
	$ 4.95	**$ 8.97**	**$ 6.58**	**$ 7.84**
RN costs/dressing change	**$ 7.91**	**$ 8.41**	**$ 8.41**	**$ 8.41**
Total Cost/dressing change	**$ 12.86**	**$ 17.38**	**$ 14.99**	**$ 16.25**

Total Dressing Change Cost per Participant

The per participant dressing change costs were determined by multiplying the number of dressing changes required for each participant by the per dressing cost. The mean per dressing cost for participants who received TAD were $14.51 (SD $5.26). The mean per dressing costs for participants who received SGD were $26.20 (SD $16.41). The proportional difference for dressing costs per chest tube day was calculated using the method described above. The proportional cost of dressing change per chest tube day for TAD was 0.078 and the proportional cost for dressing change per chest tube day for SGD was 0.06. The proportional difference was 0.018 (95% CI -0.008, 0.046) or approximately 2%, well within the established non-inferiority margin of 15%. These results suggest that the TAD is non-inferior to the SGD when dressing change cost per chest tube day is the measure of interest.

The effectiveness measure for this study was established as proportional difference in the dressing changes required per chest tube day. The incremental cost-effectiveness (ICER), as calculated using Fieller's cost intervals incremental cost calculator, between the two dressings was calculated using the following calculation:

ICER = (mTAD cost – mSGD cost) / (mEffectiveness TAD – mEffectiveness SGD)

Fieller's cost intervals incremental cost calculator was used to calculate this information by dressing type.

TAD cost /dressing change = TAD supply cost + TAD nursing cost

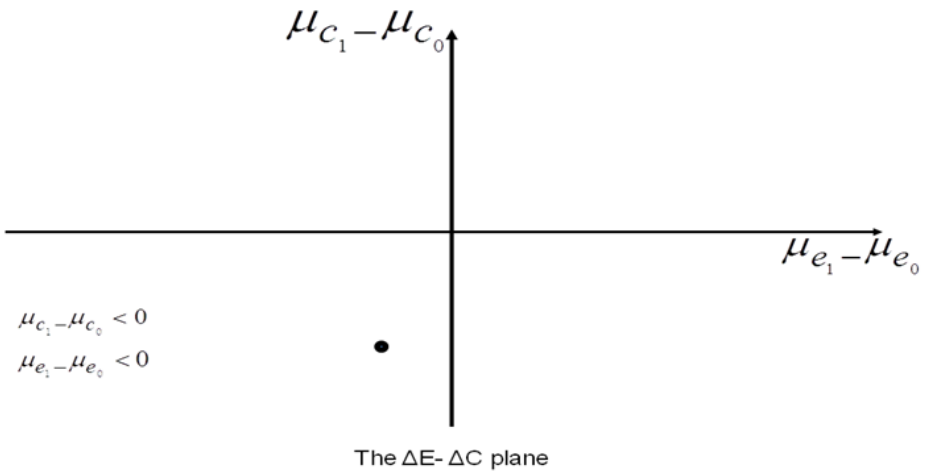
The same process was repeated for the SGD, SGD supply costs + SGD nursing cost = SGD cost/dressing change. The cost/dressing change was then multiplied times the number of dressing changes required for each participant. The product of that equation was the cost associated with dressing changes for that participant. Measures of central tendency were then calculated for each dressing type. The mean cost for the TAD was $14.51, median $12.86 and standard deviation (SD) $5.26. The mean cost for the SGD was $26.20, median $17.38 and SD $16.41. A Chi Square ($\chi^2$) test was performed comparing dressing change costs and number of dressing changes required per chest tube day. The results for dressing change cost were a χ^2 of 107.633, df 7, p <.001. The results for number of dressing changes required per chest tube day were $\chi 2$ of 124.557, df 12, p <.001. The incremental cost-effectiveness ratio for number of dressing changes per chest tube day between TAD and SGD is 77.93/dressing change (95% CI 44.86, 156.23). Tables 19 and 20 below reflect the calculations for ICER and confidence intervals using Fieller's confidence interval calculator (Health Decisions Strategies LLC, 2002).

Table 19. Dressing Changes per Chest Tube Day using Incremental Cost-effectiveness Ratio (ICER)			
Factors	**TAD**	**SGD**	**Incremental Analysis**
Cost-Inputs (mean)	$14.51	$26.20	($11.69)
Effectiveness - outcomes (mean)	0.37	0.52	(0.15)
			ICER
Cost-effectiveness Ratio Slope= (Cost/Effect)	39.21	16.58	77.93

Table 20**.** Fieller's Confidence Intervals: Dressing Changes per Chest Tube Day Confidence Intervals for Cost-Effectiveness Ratio)		
	TAD	**SGD**
Number of cases	39	40
Cost Standard Deviation	5.26	16.41
Effect Standard Deviation	0.17	0.21
Cost-Effect Correlation	(0.21)	0.67
	Upper 97.5% slope	**Lower 2.5% Slope**
Fieller's CI	156.23	44.86

Graphic representation of the change in effect and the change in cost with both values less than 0 is demonstrated in Figure 8. This symbolizes the lower cost of the TAD as compared to the SGD with little difference in effectiveness.

Figure 4. Graphic representation of cost-effectiveness ratio for TAD/SGD



Research Questions

Research question 1: Is there a significant difference in the incidence of chest tube (CT) site infections in patients whose chest tubes are dressed with standard gauze dressing (SGD) and those who are dressed with transparent adhesive dressings (TAD)?

No chest tube site infections were identified in any of the 79 participants in this study.

Research Question 2: Is there a significant difference in the incidence of CT associated empyema development in patients whose CT is dressed with SGD and those whose chest tubes are dressed with TAD?

No chest tube associated empyemas were identified in any of the 79 participants in this study.

Research Question 3: Is there a significant difference in the frequency of skin irritation in the area in contact with the chest tube dressing in patients whose CT are dressed with SGD and those who are dressed with TAD?

A total of five participants developed some form of skin irritation, three in the SGD allocation group and two in the transparent adhesive dressing group. Pink skin irritation accounted for all of the SGD group findings and one of the TAD dressing groups. The remaining TAD skin irritation was categorized as red. Neither group of participants was identified as having purple skin irritation. A Mann-Whitney test was used to evaluate differences in skin irritation and skin tears by dressing type. Participants who developed skin irritation did not seem to differ by dressing type, U = 763, p= .693. Participants who developed skin tears, as measured by the Payne-Martin skin tear scale, also did not seem to differ by dressing type, U = 761.5, p = .584.

Research Question 4: Is there a significant difference in the number of times dressing changes are required in patients whose CT are dressed with SGD and those who receive TAD?

The mean number of dressing changes for SGD and TAD were 1.41 (SD 0.91) and 1.13 (SD 0.41) respectively. A Mann-Whitney test was performed to evaluate differences in the number of dressing changes required by dressing type. Participants who received SGD required significantly more dressing changes than those that received TAD, U=601, p=.01.

Research Question 5: Is there a significant difference in the cost of the two dressing types?

The sum of product costs for each dressing type and nursing care costs for each type of dressing were used to calculate total costs per dressing change. The mean cost per SGD change was $26.20 (SD $16.41). The mean cost per TAD change was $14.51 (SD $5.26). Participants who received SGD required an average of 1.5 (SD .93) dressing changes during the study period. Participants who received TAD required on average 1.1 (SD .41) dressing changes during the

study period. A Mann-Whitney test to evaluate the differences in costs by dressing type was performed. The cost of the two dressings were found to be significantly different, U=118, *p* 001. Kendall's tau correlation was performed to determine the direction of the association. Chest tube dressing costs were significantly greater in participants who received SGD when compared to those who received TAD τ (79), $p<.001$.

Incidental Findings

No information exists regarding the frequency with which patients' chest tubes are removed unintentionally during the course of their medical and surgical care. One of the concerns expressed by nurses early in this study was that they feared without the substantial amounts of tape that was used to secure the SGD, that there would be a greater number of these unintentional dislodgements. There were no unintentional dislodgements of chest tubes in either group.

A total of 79 participants were enrolled in this study. None of the participants developed a chest tube associated infection. Only three of the 79 participants developed a skin tear of any type and each participant that developed a skin tear also demonstrated skin irritation as well. Each of the skin tears occurred during the final dressing removal before the chest tube was to be removed. No other chest tube associated complications were identified.

Nursing time required for each type of dressing change did not differ. The product costs for the standard gauze dressings were greater than the product costs for the transparent adhesive dressing. The most expensive gauze and tape dressings were those where the microfoam tape was used. The least expensive gauze and tape dressings were those that used paper tape. The expense of gauze and tape dressings were also greater overall, in part because these dressings

required daily changes whereas the transparent adhesive dressings could be left in place up to seven days.

CHAPTER V

This study provides an evidence base for the care and maintenance of chest tube dressings. The literature contains multiple opinion articles that date back to the mid 1950's when thoracostomy tubes first gained use and gauze and tape were the only barrier items available that suggest proper methods for chest tube care (Sweet & Arroyo, 1954). Much has changed in healthcare in the subsequent 60 years but the recommendations for the dressings have not changed since those early days of chest tube insertion. What is evident is that there is a dearth of scientific evidence to support current nursing care of patients with chest tubes.

Nurses routinely provide care for patients who require chest tubes to manage a variety of underlying medical conditions. The recommendations for chest tubes dressings have changed little in 50 years. This study is the first step towards establishing the best practice models for chest tube care that are based on scientific evidence and not solely expert opinion.

The theoretical and conceptual frameworks for this study were borrowed from public health and represent a novel approach to studying the phenomenon of adverse medical outcomes. The novel use of the frameworks opens up the possibility of using this model to study other unintended consequences of healthcare treatment.

Discussion of Results

Haddon's Injury Prevention Matrix

This study was designed to compare the standard method of dressing chest tubes in adult participants to a new method that follows the recommendation for central venous catheter dressing changes established by the CDC (O'Grady, et al., 2011; N. O'Grady, M. Alexander, & E. Dellinger, 2002a). Haddon's Matrix was used as the framework for this study. As described in Table 2. Haddon's energy damage and countermeasures strategies were applied to chest tube

associated injury prevention. Based on this framework, control of environmental factors should be made a priority in injury prevention strategies. Procedures performed under emergent situations and in environments where sterile procedures may be difficult to assure, have a greater risk of developing infection related complications. O'Grady et al., (2011), describe the importance of strict adherence to sterile procedure and the use of maximum barrier precautions to decrease the risk of central venous catheter associated infections. The risk of participant's developing a chest tube associated infection related to this type environmental factor was minimized in this study as all tubes were placed in the operating room following sterile procedures. Standards for surgical site preparation were followed prior to the beginning of and throughout the surgical procedures. Other study strategies to minimize the risk associated with these tubes included careful cleansing of the patient's skin around the chest tube insertion site with each dressing change, adherence to the procedure for frequency of dressing changes, and careful application and removal of the dressings.

The impact of a potential injury causing force, removal of adherent dressing, was assessed during each dressing change. Both groups were similar in the number of days the chest tubes remained in place and for hospital length of stay (chest tube days U=677, p = .296; hospital LOS U=749, p = .759). Participants who received TAD required fewer dressing changes than those who received SGD (U=601, p = .014). This is especially important when considered with the short time chest tubes were required in this patient population. The difference in number of chest tube dressing required has the potential to be magnified in patients who require chest tubes for longer time period.

Adverse Outcomes

Five participants (12%) were determined to have a total of eight unintended injuries related to the force associated with chest tube dressing removal. Three of these five participants developed a skin tear and skin irritation associated with the chest tube dressing. Further investigation is needed to establish the incidence of skin irritation and skin tears associated with adhesive dressings across a broad patient population.

None of the participants studied developed either chest tube site infections or empyemas. The previously reported prevalence for this type of infection was 5%-6%. No chest tubes were unintentionally dislodged during this study. This despite concerns verbalized by the nursing staff that the TAD would not provide enough support to hold the chest tube in place. No information could be found to document the incidence or prevalence of unintentional chest tube dislodgement. Further study to establish the prevalence of chest tube associated infections and unintentional dislodgement is warranted in order to adequately power future studies if this type of difference is to be used as an outcome variable of interest.

Skin Injury

Skin injury as measured by presence of skin irritation and/or skin tear at the time of dressing change occurred in 6% and 4% of participants respectively. There was no significant difference in the rate of occurrence of either type of injury between the two participant groups. The use of adhesive dressings has been associated with shear force injury to the skin; little has been written about the incidence and prevalence of these injuries in hospitalized adults. Further studies in this and other patient populations will help to establish the expected occurrence rates of these types of injuries. Greater understanding of the prevalence of adhesive associated injury provides opportunity for injury prevention planning.

Cost-effectiveness

A cost-effectiveness analysis was performed to evaluate the difference in dressing costs related to outcomes. Fieller's method was used to compare the incremental dressing costs of each dressing. The difference in cost between TAD ($14.51) and SGD ($26.20) was $-11.69/dressing. The incremental difference in number of dressing changes per chest tube day was -0.05 (TAD 0.17 – SGD 0.21). The TAD was found to be non-inferior to the SGD in all of the measured outcomes with the exception of dressing changes per chest tube day. In this instance the proportional differences between the two dressings was 20%, with SGD dressing changes per chest tube day 20% greater than those required in the TAD group.

Implications for Nursing Practice

The results of this study have the potential to change nursing practice across the world and to establish a research basis for a practice previously based on opinions. A survey of nursing practice from a variety of hospitals revealed that chest tube dressings in adult patients generally include gauze covered by tape, and the dressings are changed daily. This research study demonstrated that the use of a TAD was not inferior to the standard gauze, tape secured dressing in patients who required these tubes after cardio-thoracic surgery. Based on these results, recommendations can be made that TADs are a non-inferior alternative to gauze dressings in post cardio-thoracic surgery patients, and that daily dressing changes may no longer be necessary if TADs are used.

The population in this study was homogeneous and not representative of the entire population of patients who require chest tubes as treatment for an underlying condition. All of the chest tubes in this study were inserted under controlled, sterile conditions. Individuals with chest tubes placed in emergent situations or in less controlled environments might have higher

risk of contamination during insertion and this may result in increased chest tube infection rates. It is possible that individuals who have chest tubes placed following traumatic injury, for example, have unique characteristics that would result in different findings should this study be replicated. If these findings hold true across other populations, the change to use of TAD could become the standard practice, resulting in millions of dollars in savings to healthcare systems and greater time for nurses to spend providing other types of care to these patients.

Mounting healthcare costs and increasing demands for nursing time and attention necessitates that nurses question practices that have little or no research support. The frequency with which nurses perform a variety of tasks must be questioned and measured. Through this structured inquiry we have the opportunity to ensure that patients receive all the care they need and none that is unnecessary. Decreasing the number of unnecessary therapies, tests and treatments increases the availability of limited resources for a seemingly infinite number of patients in need of care.

Implications for Future Research

Although this study demonstrated that the transparent adhesive dressing was not inferior to standard gauze dressing with tape in post operative cardio-thoracic surgery patients, further study is needed to determine the effectiveness of this type of dressing in other patient populations. This type of study is especially needed in patients who require chest tubes to remain in place for longer periods of time, where the time and cost savings associated with a decrease in dressing change frequency would potentially have a greater impact. A replication study in non-surgical patients who require chest tubes would be beneficial in determining if the lack of device associated infections seen in this study true in the full spectrum of chest tube associated outcomes.

This study established that the transparent adhesive dressing is not inferior to the commonly used gauze and tape dressing in this sample. Further work is needed to establish equivalency and or superiority of the TAD in comparison to the standard gauze dressing. Results from this study also suggest that chest tube associated infections are lower than previously suggested. The low rate of occurrence established in this study can be used to improve power analysis precision in future studies.

Evaluation of the TAD dressing is also needed in pediatric and neonatal patients as there are unique physiologic differences between infants, children and adults that may significantly influence the safety and effectiveness of the TAD. Transparent adhesive dressings with and without gauze beneath them are commonly used in the pediatric and neonatal populations. However, no research could be found to establish this practice.

The Haddon Matrix framework has potential to for use in many other areas of healthcare research where there are unintended consequences to care and where the frequency with which care is provided lacks a research basis. Examples of areas where this framework could be used include evaluation of the frequency for endotracheal tube repositioning in patients requiring mechanical ventilation, pressure ulcer prevention strategies, fall prevention and prevention of catheter associated blood stream infections and catheter associated urinary tract infections. The matrix serves as a framework to consider unique patient, vehicle and environmental factors with regards to prevention and treatment.

Other areas for future inquiry include assessment of patient perceptions related to each dressing type. Patient perception of dressings relative to comfort, ease of movement, and pain are all areas that need to be explored further. Nurse and physician perceptions of the ease of dressing

application, removal, and ability to observe the skin around the chest tube insertion site should also be explored.

Little evidence could be found to substantiate the occurrence of chest tube related infections, skin tears and skin irritation. Incidence and prevalence studies are necessary to determine the frequency with which each of these complications occurs across a heterogeneous patient population.

Limitations

One of the limitations of this study is the homogenous population in which this study was conducted. Participants self-selected from those who presented for cardio-thoracic surgery in a single Mid-western non-academic tertiary care hospital. Participants were randomly assigned after agreeing to participate in the study in an attempt to control for unaccounted for variability in the population. The post-surgical patient population may not require chest tubes to remain in place as long as patients who require chest tubes for other reasons. The average number of days chest tubes were in place in this study was 3.4 days (SD 1.9 days). Only fifteen percent (n=12, SGD = 7, TAD = 5) of the participants in this study required chest tubes for five days or more. The average number of dressing changes required for this group was 2.25 (SD 1.29). This is a relatively short time period across which to measure all of the outcome variables of interest.

Conclusion

This cross sectional, study utilizing a 2 group experimental design demonstrates that the use of transparent adhesive dressings to cover chest tube insertion sites is not inferior to standard gauze dressing in post cardio-thoracic surgery patients. The cost associated with use of the transparent adhesive dressing was less than the cost of the standard gauze dressing ($U=-715$, τ (79), $p < .001$). The transparent adhesive dressing was associated with fewer dressing changes per

chest tube day (U = 440, τ (79), *p* = .001). The proportional difference of the incremental cost-effectiveness ratio (ICER) between these two dressings showed that despite the transparent adhesive dressing being non-inferior, it was less costly (ICER 77.93 (95% CI 44.86, 156.23). These findings support the use of transparent adhesive dressings to cover chest tube insertion sites in post operative cardio-thoracic surgery patients and possibly others.

Replication is necessary with other patient populations especially those who do not have chest tubes placed in the operating room and those who require chest tubes for longer periods of time. Caution should be used in generalizing these findings to other populations without further study.

BIBLIOGRAPHY

Aguilar, M., Battistella, F., Owings, J., & Su, T. (1997). Posttraumatic empyema: Risk factor analysis. *Archives of Surgery, 132*(6), 647-651.

Allibone, L. (2003). Nursing management of chest drains. *Nursing Standard, 17*(22), 45-54.

Allibone, L. (2005). Principles of inserting and managing chest drains. *Nursing Times, 101*(42), 45-49.

American Association of Acute and Critical Care Nurses. (2005). Chest Tubes. In D. Lynn-McHale Wiegand, Carlson, KK (Ed.), *AACN Procedure Manual for Critical Care* (5th Edition ed.). St. Louis: Elsevier/Saunders.

American Nurses Association. (2011). Nurse-Sensitive Indictors - defined. Retrieved December 3, 2011, from http://www.nursingworld.org/MainMenuCategories/ThePracticeofProfessionalNursing/PatientSafetyQuality/Research-Measurement/The-National-Database/Nursing-Sensitive-Indicators_1

Author, & Unknown. (1996). Dressing up for a change: Chest tube insertion site. *Nursing* (7), 44-46.

Avery, S. (2000). Insertion and management of chest drains. *Nursing Times Plus, 96*(37), 3-6.

Ayello, E., & Sibbald, R. (2008). Preventing pressure ulcers and skin tears. In E. Capezuti, D. Zwicker, M. Mezey & T. Fulmer (Eds.), *Evidence-based Geriatric Nursing Protocols for Best Practice* (3rd ed., pp. 403-429). New York: Springer Pbulishing Company.

Ayello, E. A. (2003). Preventing pressure ulcers and skin tears. In M. D. Mezney, Fulmer, T., & Abraham, I. (Ed.), *Geriatric Nursing Protocols for Best Practice* (pp. 165-184). New York: Springer Publising Company.

Ball, C. (2002). Management of pretibial lacerations in the community. *Journal of Community Nursing, 16*(6), 37-42.

Ball, C., Lord, J., Laupland, K., Gmora, S., Mulloy, R., Ng, A., et al. (2007). Chest tube complications: How well are we training our residents? *Canadian Journal of Surgery, 50*(6), 450-458.

Baranoski, S. (2001). Skin Tears: Guard against this enemy of frail skin. [Journal Article]. *Nursing Management, 32*(8), 25-32.

Baranoski, S. (2003). How to prevent and manage skin tears. *Adv Skin Wound Care, 16*(5), 268-270.

Baranoski, S., Ayello, E., & Tomic-Canic, M. (2007). Skin: An essential organ. In S. Baranoski & E. A. Ayello (Eds.), *Wound Care Essentials* (pp. 47-63): Lippincott Williams & Wilkins.

Barnett, D. J., Balicer, R. D., Blodgett, D., Fews, A. L., Parker, C. L., & Links, J. M. (2005). The Application of the Haddon Matrix to Public Health Readiness and Response Planning. [Article]. *Environmental Health Perspectives, 113*(5), 561-566.

Bauerhaus, P. I. (2010). Health care payment reform: Implications for nurses. *HNursing Economics, 28*(1), 49-54

Bergstrom, N., Braden, B., Laguzza, A., & Holman, V. (1987). The Braden Scale for Predicting Pressure Sore Risk. *Nursing Research, 36*(4), 205-210.

Bochicchio, G. V., Salzano, L., Joshi, M., Bochicchio, K., & Scalea, T. M. (2005). Admission preoperative glucose is predictive of morbidity and mortality in trauma patients who require immediate operative intervention. *The American Surgeon, 71*(2), 171-174.

Brillhart, B. (2006). Preventive Skin Care for Older Adults. [Journal Article]. *Geriatrics & Aging, 9*(5), 334-339.

Broaddus, V., & Light, R. (2005). Pleural Effusion. In R. Mason, J. Murray, V. Broaddus & N. JA (Eds.), *Murray and Nadel's textbook of respiratory medicine* (4th Edition ed., Vol. Murray and Nadel's textbook of respiratory medicine—4th ed. [edited by] Robert J. Mason, V. Courtney Broaddus, John F. Murray, Jay A. Nadel p). Philladelphia: Elsevier Saunders.

Bryant, R. (2000). Skin pathology and types of damage. In R. Bryant (Ed.), *Acute & Chronic Wounds: Nursing Management* (Second Edition ed.). St. Louis: Mosby.

Carroll, P. (2000). Exploring chest drain options. *RN, 63*(10), 50-54, 56.

Centers for Disease Control and Prevention. (2011). *Prevalence of Coronary Heart Disease - United States, 2006-2010*.

Centers for Medicare and Medicaid Services. (2008). MEDICARE AND MEDICAID MOVE AGGRESSIVELY TO ENCOURAGE GREATER PATIENT SAFETY IN HOSPITALS AND REDUCE NEVER EVENTS. Retrieved from http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863

Charnock, Y., & Evans, D. (2001). Nursning management of chest drains: a systematic review. *Australian Critical CAre, 14*(4), 156-160. .

Chiou, C. F., Hay, J. W., Wallace, J. F., Bloom, B. S., Neumann, P. J., Sullivan, S. D., et al. (2003). Development and validation of a grading system for the quality of cost-effectiveness studies. *Med Care, 41*(1), 32-44.

Christensen, E. (2007). Methodology of superiority vs. equivalence trials and non-inferiority trials. [doi: 10.1016/j.jhep.2007.02.015]. *Journal of Hepatology, 46*(5), 947-954.

Cohen, D. J., & Reynolds, M. R. (2008). Interpreting the Results of Cost-Effectiveness Studies. *J Am Coll Cardiol, 52*(25), 2119-2126.

Conroy, C., & Fowler, J. (2000). The Haddon matrix: applying an epidemiologic research tool as a framework for death investigation. *American Journal of Forensic Medicine & Pathology, 21*(4), 339-342.

Coughlin, A., & Parchinsky, C. (2006). Go with the flow of chest tube therapy. *Nursing 2006, 36*(3), 36-42.

Cutting, K. (2008a). Impact of adhesive surgical tape and wound dressings on the skin, with reference to skin stripping. *Journal of Wound Care, 17*(4), 157-162.

Cutting, K. (2008b). Impact of adhesive surgical tape and wound dressings on the skin, with reference to skin stripping. *Journal of Wound Care 17*(4), 157-162.

D'Haese, S., Bate, T., Claes, S., Boone, A., VanVoorden, V., & Efficace, F. (2005). Management of skin reactions during radiotherapy: a study of nursing practice. *European Journal of Cancer Care, 14*, 28-42.

Darmstadt, D., & Dinulos, J. G. (2000). NEONATAL SKIN CARE. [Journal Article]. *The Pediatric Clinics of North America,, 47*(4), 757-782.

Dison, N. (1979). Intravenous fluid therapy. In N. Dison (Ed.), *Clinical Nursing Techniques* (pp. 318-319). St. Louis: C.V. Mosby Company.

Dykes, P., & Heggie, R. (2003). The link between the peel force of adhesive dressings and subjective discomfort in volunteer subjects. *Journal of Wound Care, 12*(7), 260-262.

Epstein, A., Polsky, D., Yang, F., Yang, L., & Groeneveld, P. (2011). Coronary Revascularization Trends in the United States, 2001-2008. *JAMA: The Journal of the American Medical Association, 305*(17), 1769-1776.

Etoch, S., Bar-Natan MF, Miller FB & Richardson JD. (1995). Tube thoracostomy: Factors related to complications. *Archives of Surgery, 130*(5), 521-526.

Evers, S., Goossens, M., de Vet, H., van Tulder, M., & Ament, A. (2005). Criteria list for assessment of methodological quality of economic evaluations: Consensus on Health Economic Criteria. *Int J Technol Assess Health Care, 21*(2), 240-245.

Field, A. (2005). Correlations. In F. A (Ed.), *Discovering Statistics Using SPSS* (pp. 107-131). Thousand Oaks: Sage.

Fleck, C. A. (2007). Preventing and treating skin tears. *Adv Skin Wound Care, 20*(6), 315-320.

Folland, S., Goodman, A., & Stano, M. (1997a). Cost-benefit analysis and applications to health care. In S. Folland, A. Goodman & M. Stano (Eds.), *The Economics of Health and Healthcare* (Second ed., pp. 562-581). Saddle River, NJ: Prentice Hall.

Folland, S., Goodman, A., & Stano, M. (1997b). The production and cost of health care. In S. Folland, A. Goodman & M. Stano (Eds.), *The Economics of Health and Health Care* (Second ed., pp. 292-319). Saddle River, NJ: Prentice Hall.

Frisch, S., & Collins, E. (2004). Maintaining the chest tube and chest drainage system. In G. B. Altman (Ed.), *Delmar's Fundamental and Advanced Nursing Skills* (Second ed.): Delmar Learning.

Glenn, Y. (2006). When your patient is sensitive to tape. *Nursing 2006, January*, 17.

Godden, J., & Hiley, C. (1998). Managing the patient with a chest drain: a review. *Nursing Standard, 12*(32), 35-39.

Gross SB. (1993). Current challenges, concepts, and controversies in chest tube management. *AACN Clinical Issues, 4*(2), 60-275.

Haddon, W., Jr. (1968). The changing approach to the epidemiology, prevention, and amelioration of trauma: the transition to approaches etiologically rather than descriptively based. *American Journal of Public Health & the Nation's Health, 58*(8), 1431-1438.

Haddon, W., Jr. (1973). Energy damage and the ten countermeasure strategies. *Journal of Trauma-Injury Infection & Critical Care, 13*(4), 321-331.

Haddon, W., Jr. (1980a). Advances in the epidemiology of injuries as a basis for public policy. *Public Health Reports, 95*(5), 411-421.

Haddon, W., Jr. (1980b). Emergency medical services and highway safety. *JAMA, 244*(21), 2413-2414.

Haddon, W., Jr. (1980c). Options for the prevention of motor vehicle crash injury. *Israel Journal of Medical Sciences, 16*(1), 45-65.

Hamersten, R., Hamersten, J., & Jemsby, P. (2003). Preoperative skin testing of materials used in surgical procedures. *AORN American Operating Room Nurses Journal, 77*(4), 762-771.

Health Decisions Strategies LLC. (2002). Fieller's confidence intervals incremental calculator and plotter. Retrieved September 20, 2011

Holloway, N. (1984). Acute Aeration Disorders *Nursing the Critically Ill Adult: Applying Nursing Diagnosis*

(Second ed.). Menlow Park, CA: Addison-Wesley Publishing Company.

Institute of Medicine. (2000). *To Err is Human* Washington DC: National Academy Press.

Institute of Medicine. (2001). Executive Summary *Crossing the Quality Chasm*. Washington DC: National Academy Press.

Kaul, S., & Diamond, G. A. (2006). Good enough: a primer on the analysis and interpretation of noninferiority trials. *Annals of Internal Medicine, 145*(1), 62-69.

Kaul, S., Diamond, G. A., & Weintraub, W. S. (2005). Trials and Tribulations of Non-Inferiority: The Ximelagatran Experience. *J Am Coll Cardiol, 46*(11), 1986-1995.

Keen, G. (1975). Traumatic Pneumothorax and Haemothorax. In G. Keen (Ed.), *Chest Injuries: A Guide for the Accidental Department* (pp. 46-64). Chicago: John Wright & Sons, Ltd. .

Kim, M. J. (1978). Disturbances in blood pressure. In D. Jones, C. Dunbar & M. M. Jirovec (Eds.), *Medical-Surgical Nursing A Conceptual Approach* (pp. 964-965). New York: McGraw-Hill Book Company.

Lawrence, D. M., & Carlson, K.K. (2005). Chest tube Placement. In D. J. C. Lynn-McHale Wiegand, K.K. (Ed.), *AACN Procedure Manual for Critical Care, American Association of Critical Care Nurses* (Fifth Edition ed.). St. Louis Elsevier/Saunders.

Lazzara D. (2002). Eliminate the air of mystery from chest tubes. *Nursing 2002, 32*(6), 36-45.

LeBlanc K, Christensen, D., Orsted, H., & Keast, D. (2008). Preventing and treatment of skin tears. [Journal Article]. *Wound Care Canada, 6*(1), 14-30.

LeBlanc, K., Christensen, D., Orsted, H. L., Keast, D. H., . (2008). Preventing and treatment of skin tears. [Journal Article]. *Wound Care Canada, 6*(1), 14-30.

Lehwaldt, D., & Timmins, F. (2005). Nurses' knowledge of chest drain care: an exploratory descriptive survey. [Journal Article]. *Nurs Crit Care, 10*(4), 192-200.

Liu, L., Haddadin, H., Bodian, C., Siganl, S., Korman, J., Bodenheimer, H., et al. (2004). Outcome analysis of cirrhotic patients undergoing chest tube placement. *Chest, 126*(1), 142-148.

Luchette, F., Barrie, P., Oswanski, M., Spain, D., Mullins, C., Palumbo, F., et al. (2000). Practice management guidelines for prophylactic antibiotic use in tube throacostomy for traumatic

hemopneumothorax: The EAST practice management guidelines work group. *Journal of Trauma, Injury, Infection and Critical Care, 48*(4), 753-757.

Luckman, J. S., K.C. . (1980). Disturbances of Respiratory Function. In J. Luckman & K. C. Sorenson (Eds.), *Medical-Surgical Nursing: A Psychophysiologic Approach* (Second Edition ed., pp. 1368-1370). Philadelphia: W. B. Saunders.

Maki, D., Stolz, S., Wheeler, S., & Mermel, L. (1997). Prevention of central venous catheter related bloodstream infection by use of an antiseptic-impregnated catheter A randomized, controlled trial. *Annals of Internal Medicine, 127*(4), 257-266.

Mattison, L., Coppage, L., Alderman, D., Herlong, J., & Sahn, S. (1997). Pleural effusions in the medical ICU: Prevalence, causes and clinical implications. *CHEST, 111*(4), 1018-1023.

McGough-Csarny, J., & Kopac, C. A. (1998). Skin tears in institutionalized elderly: an epidemiological study. *Ostomy Wound Manage, 44*(3A Suppl), 14S-24S; discussion 25S.

Mcle, S., Petitte, T., Pride, L., Leeper, D., & Ostrow, L. (2009). Transparent film dressing vs. pressure dressing after percutaneous transluminal coronary angiography. *American Journal of Critical Care, 18*(1).

Mergaert, S. (1994). STOP and assess chest tubes the easy way. *Nursing 94*, 52-53.

Meuleneire, F. Using a soft silicone-coated net dressing to manage skin tears. [Journal Article].

Milne, C. T., & Corbett, L. Q. (2005). A new option in the treatment of skin tears for the institutionalized resident: formulated 2-octylcyanoacrylate topical bandage. *Geriatr Nurs, 26*(5), 321-325.

Noble-Adams, R. (1999). Radiatin-induced skin reactions 2: Development of a measurement tool. *British Journal of Nursing 8*(18), 1208-1211.

O'Brien, B. J., Drummond, M. F., Labelle, R. J., & Willan, A. (1994). In search of power and significance: Issues in the design and analysis of Stochastic cost-effectiveness studies in health care. *Med Care, 32*(2), 150-163.

O'Brien, J., & Reilly, N. (1995). Comparison of tape products on skin integrity. *Advances in Wound Care, 8*(6), 26, 28, 30.

O'Grady, N., Alexander, M., Burns, L., Dellinger, E., Garland, J., Heard, S., et al. (2011). *Guidelines for the prevention of intravascular catheter-related infections, 2011*. Retrieved from http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf.

O'Grady, N., Alexander, M., & Dellinger, E. (2002a). Guidelines for the prevention of intravascular catheter-related infections. [Journal Article]. *MMWR Recomm Rep. 2002 Aug 9;51(RR-10):1-29., 51*(RR-10), 1-29.

O'Grady, N., Alexander, M., & Dellinger, E. P. (2002b). Guidelines for the prevention of intravascular catheter-related infections. [Journal Article]. *MMWR Recomm Rep. 2002 Aug 9;51(RR-10):1-29., 51*(RR-10), 1-29.

O'Hanlon-Nichols, T. (1996). Commonly asked questions about chest tubes. *American Journal of Nursing, 96*(5), 60-64.

OCEBM Levels of Evidence Workgroup. (2011). *The Oxford 2011 Levels of Evidence*. London: Oxford Centre for Evidence-based Medicine

Ousey, K. (2009). Identifying, managing and treating skin tears. *Journal of Community Nursing, 23*(9), 18.

Parkin, C. (2002). A retrospective audit of chest drain practice in a specialist cardiothoracic centre and concurrent review of chest drain literature. *Nursing in Critical Care, 7*(1), 30-35.

Payne, R., & Martin, M. (1990). The epidemiology and management of skin tears in older adults. *Ostomy Wound Manage, 26*, 26-37.

Payne, R., & Martin, M. (1993). Defining and clsassifying skin tears: Need for a common language. *Ostomy/Wound Management, 39*(5), 16-26.

Persson, K., & Salemark, L. (2000). How to dress donor sites of split thickness skin grafts: a prospective, randomised study of four dressings. *Scand J Plast Reconstr Surg Hand Surg, 34*(1), 55-59.

Piaggio, G., Elbourne, D. R., Altman, D. G., Pocock, S. J., Evans, S. J. W., & Group, f. t. C. (2006). Reporting of Noninferiority and Equivalence Randomized Trials. *JAMA: The Journal of the American Medical Association, 295*(10), 1152-1160.

Polsky, D., Glick, H., Willke, R., & Schulman, K. (1997). Confidence intervals for cost-effectiveness ratios: A comparison of four methods. *Health Economics, 6*, 243-252.

Pruitt, W. C. (2002). Understanding chest tube use. *RT*, (April/May). Retrieved from http://www.rtmagazine.com/issues/articles/2002-04_10.asp

Ramsey, S. D., McIntosh, M., & Sullivan, S. D. (2001). Design issues for conducting cost-effectiveness analyses alongside clinical trials. *Annu Rev Public Health*, *22*, 129-141.

Reddy, M. (2008). CE Skin and Wound Care: Important Considerations in the Older Adult. *Advances in Skin and Wound Care, 21*

(9), 424-436.

Rhody, C. (2000). Bacterial infections of the skin. *Primary Care Clinics in Office Practice, 27*(2), 459-473.

Roberts, M. J. (2007). Preventing and managing skin tears: a review. *J Wound Ostomy Continence Nurs, 34*(3), 256-259.

Roman, M., & Mercado, D. (2006). Review of chest tube use. *Med Surg Nursing, 15*(1), 41-43.

Runyan, C. W. (1998). Using the Haddon matrix: introducing the third dimension. *Injury Prevention, 4*(4), 302-307.

Runyan, C. W. (2003). Introduction: Back to the future - Revisiting Haddon's conceptualization of injury epidemiology and prevention. *Epidemiology Review, 25*, 60-64.

Scherer, S., Pietramaggiori, G., Mathews, J., Prsa, M., Huang, S., & Orgill, D. (2008). The mechanism of action of the vacuum-assisted closure device. *Plast Reconstr Surg, 122*(3), 786-797.

Schiff, L. (2000). Chest drainage systems. *RN, 63*(19), 57-58.

Schmidt, U., Stalp, M., Gerich, T., Blauth, M., Maull, K., & Tscherne, H. (1998). Chest tube decompression of blunt chest injuries by physicians in the field: Effectiveness and complications. *Journal of Trauma, Injury, Infection and Critical Care, 44*(1), 98-100.

Sealed Envelope. (2011). Power (sample size) calculators Retrieved September 3, 2011, from http://www.sealedenvelope.com/power_binary_noninferior.php

Soares, M., & Dumville, J. (2008). Critical appraisal of cost-effectivness and cost-utility studies in health care. *Evidence-Based Nursing, 11*(4), 99-102.

Spanjersberg, W., Rignburg, A., Bergs, B., Krijen, P., Inger Schipper, S., Ringburg, A., et al. (2005). Prehospital chest tube throacostomy: Effective treatment or additional trauma? *Journal of Trauma, Injury, Infection and Critical Care, 59*(1), 96-101.

Stacy, K. (1994). Pulmonary Therapeutic Management. In D. Thelan LA, JK, Urden, LD, Lough, ME (Ed.), *Critical Care Nursing Diagnosis and Managment* (pp. 455-458). St. Louis: Mosby

Stearns, S., & Drummond, M. (2003). Grading systems for cost-effectiveness studies: Is the whole greater than the sum of the parts? *Med Care, 41*(1), 1-3.

Sweet, R., & Arroyo, J. R. (1954). Operations Concerning the Pleural Cavity *Thoracic Surgery* (Second Edition ed., pp. 135-153). Philadelphia: W. B. Saunders.

Tang, A., Velissaris, T., & Weeden, D. (2002). An evidence-based approach to drainage of the pleural cavity: evaluation of best practice. *Journal of Evaluation of Clinical Practice, 8*(3), 333-340.

Thomas, D. R., Goode, P. S., LaMaster, K., Tennyson, T., & Parnell, L. K. (1999). A comparison of an opaque foam dressing versus a transparent film dressing in the management of skin tears in institutionalized subjects. [Clinical Trial

Comparative Study

Journal Article

Randomized Controlled Trial

Research Support Non-U S Gov't]. *Ostomy Wound Manage, 45*(6), 22-24, 27-28.

Tuggle, D. W., Kuhn, M. A., Jones, S. K., Garza, J. J., & Skinner, S. (2008). Hyperglycemia and infections in pediatric trauma patients. *The American Surgeon, 74*(3), 195-198.

von Hippel, A. (1970). *Chest tubes and Chest Bottles*. Springfield, IL: Charles C Thomas.

Wanek, S., & Mayberry, J. (2004). Blunt thoracic trauma: flail chest, pulmonary contusion, and blast injury. *Critical Cre Clinics, 2004*(20), 71-81.

Watson, G., & Harbrecht, B. G. (2005). Chest tube placement, care and removal. In M. Fink, Abraham E, Vincent JL, Kochanek PM (Ed.), *Fink: Textbook of Critical Care* (5th Edition ed.). Philadelphia: Elsevier Saunders.

Welton, J. M. (2008). Implications of Medicare reimbursement changes related to inpatient nursing care quality. *Journal of Nursing Administration, 38*(7-8), 325-330.

Welton, J. M., & Harris, K. (2007). Hospital billing and reimbursement: charging for inpatient nursing care. *Journal of Nursing Administration, 37*(4), 164-166.

Welton, J. M., Meyer, A. A., Mandelkehr, L., Fakhry, S. M., & Jarr, S. (2002). Outcomes of and resource consumption by high-cost patients in the intensive care unit. *American Journal of Critical Care, 11*(5), 467-473.

Welton, J. M., Unruh, L., & Halloran, E. J. (2006). Nurse staffing, nursing intensity, staff mix, and direct nursing care costs across Massachusetts hospitals. *Journal of Nursing Administration, 36*(9), 416-425.

Welton, J. M., Zone-Smith, L., & Fischer, M. H. (2006). Adjustment of inpatient care reimbursement for nursing intensity. *Policy, Politics, & Nursing Practice, 7*(4), 270-280.

Wiens, B. L. (2006). Randomization as a basis for inference in noninferiority trials. *Pharmaceutical Statistics, 5*(4), 265-271.

Woods, S., & Grose, B. L. (1982). Hemodynamic monitoring in patiens with acute myocardial infarction. In S. Underhill, S. Woods, E. Sivarrajan & C. J. Halpenny (Eds.), *Cardiac Nursing* (pp. 288-289). Philadelphia: J.B. Lippincott Company

Wysocki, A. (2000). Anatomy and physiology of skin and soft tissue. In R. Bryant (Ed.), *Acute & Chronic Wounds: Nursing Management* St. Louis: Mosby.

Zee, B. C.-Y. (2006). Planned equivalence or noninferiority trials versus unplanned noninferiority claims: are they equal? *Journal of Clinical Oncology, 24*(7), 1026-1028.