Aus der Klinik für Herzchirurgie

der Heinrich-Heine-Universität Düsseldorf

Direktor: Univ.-Prof. Dr. med. Artur Lichtenberg

„Chest tube selection in cardiac and thoracic surgery: a survey of chest tube-related complications and their management“

DISSERTATION

zur Erlangung des Grades eines Doktors der Medizin

der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf

vorgelegt von

Shanaz Shalli

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DEDICATION

To my man and children: Zara, San and Yara

Teile dieser Arbeit wurden veröffentlicht:

Shalli S, Saeed D, Fukamachi K, Gillinov M, Cohn WE, Perrault LP, Boyle EM. Chest Tube Selection in Cardiac and Thoracic Surgery: A Survey of Chest Tube-Related Complications and Their Management. J Card Surg 2009;503-509.

Shalli S, Boyle EM, Saeed D, Fukamachi K, Cohn WE, Gillinov AM.The Active Tube Clearance System:A Novel Bedside Chest-Tube Clearance Device. Innovations 2010; 42-47.

Zusammenfassung

Blutansammlungen in den Thoraxhöhlen können zu schwerwiegenden Komplikationen führen, sofern sie nicht adäquat drainiert werden. Da verstopfte und verschlossene Thoraxdrainagen postoperativ zu lebensbedrohlichen Komplikationen führen können, werden grundsätzlich möglichst großkalibrige Drainagen verwendet, um einen bestmöglichen Abfluss zu gewährleisten.

Um die Probleme in der derzeitigen Anwendung von Thoraxdrainagen besser abzubilden, wurde eine Umfrage unter nordamerikanischen Herz- und Thoraxchirurgen und einschlägig spezialisierten Krankenschwestern erhoben. Insgesamt antworteten 108 Chirurgen sowie 108 Krankenschwestern. Diese Studie zeigte, dass eine verstopfungsbedingte Fehlfunktion der Drainage in direktem Zusammenhang mit der Wahl des Drainagekalibers steht. 106 von 106 der antwortenden Chirurgen konnten über die Erfahrung von verstopften Thoraxdrainagen berichten. 103 von 106 (87 %) Chirurgen berichteten über unerwünschte therapeutische Konsequenzen, hervorgerufen durch eine verstopfte Drainage. Bis zu 51 % der befragten Chirurgen gaben an, mit den derzeitigen Drainagekonzepten und Methoden zur Verstopfungsvermeidung nicht zufrieden zu sein. Zudem berichteten die Befragten über ein gesteigertes Unbehagen der Patienten mit zunehmender Kalibergröße der Drainage. Die Ergebnisse dieser Studie betonen die gängigen Probleme mit den derzeitigen postoperativen Drainagesystemen und implizieren gleichzeitig den Bedarf an innovativen Lösungen, die sowohl den Komplikationsraten, den klinischen Erfordernissen, sowie dem Schmerzempfinden der Patienten gerecht werden.

Basierend auf dieser Erhebung wurde eine neuartige Vorrichtung zur Gewährleistung der Durchgängigkeit der Drainagen entwickelt. In dieser wird ein Reinigungselement innerhalb der Drainage unter sterilen Bedingungen vor- und zurückgeschoben, um Koagel zu zerkleinern und in den Auffangbehälter der Drainage zu befördern. Somit kann das Innere der Drainage frei von verstopfendem Material gehalten werden.

Schlussfolgernd lässt sich sagen, das sich mit erhaltener Offenheit der Drainage ein besserer Abfluss aus dem Thorax gewährleisten lässt. Die beschriebene Vorrichtung kann möglicherweise kleinere Thoraxdrainagen und weniger invasive Applikationen ermöglichen.

ABSTRACT

Blood accumulating inside chest cavities can lead to serious complications if it is not drained properly. Because life-threatening conditions can result from chest-tube occlusion after thoracic surgery, large-bore tubes are generally employed to optimize patency. To better define problems with current paradigms for chest drainage, a survey of North American cardiothoracic surgeons and specialty cardiac surgery nurses was conducted. A total of 108 surgeons and 108 nurses responded. The survey revealed that clogging leading to chest-tube dysfunction is a major concern when choosing tube size. Of surgeons responding, 106/106 (100%) had observed chest-tube clogging, and 93/106 (87%) reported adverse patient outcomes from a clogged tube. Up to 51% of surveyed surgeons stated they are not satisfied with currently available tubes and procedures to avoid tube occlusion. In addition, respondents noted that patients experience increasing discomfort with increasing drain size. Results of this survey highlight the frequent problems with current postsurgical chest drainage systems and suggest the need for innovative solutions to avoid complications and overcome clinician concern and patient pain. Based on this survey, a novel chest tube clearance apparatus was developed to maintain chest tube patency. Using this novel system, chest tube clearance is achieved by advancing the specially designed clearance member back and forth within the chest tube under sterile conditions, breaking down and pulling clots back toward the drainage receptacle, thereby leaving the inner portion of the chest tube clear of any obstructing material. In conclusion, by maintaining chest tube patency, chest tube drainage can be performed more safely, and this apparatus may possibly lead to the use of smaller chest tubes and less invasive insertion techniques.

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1. INTRODUCTION

Postoperative drainage of surgical sites is a standard component of many operations and is employed routinely after cardiac and thoracic surgery. Chest tubes are inserted in patients after heart, lung, and trauma surgery. In the setting of pneumothorax, hemothorax, or pericardial tamponade, chest tubes facilitate removal of blood, serous fluid, or air and prevent heart and lung compression. Chest tubes commonly become partially or completely occluded with blood clots or other fibrinous material, which can impair their function. To achieve optimal outcomes in the setting of ongoing production of blood, effusions, or air, maintaining an adequately functioning chest tube is, therefore, critical.[1]

Occlusion of drain tubes can lead to life-threatening complications, including tamponade, tension pneumothorax, and sepsis.[2, 3] Additional surgery may be necessary if occluded tubes lead to development of empyema, pericardial tamponade, or a hemothorax that is large enough to cause loss of lung volume. [1, 4, 5] To avoid the aforementioned complications, surgeons typically use large-bore chest tubes after thoracic surgery.[6] However, large-bore tubes are associated with significant patient discomfort; furthermore, even larger tubes frequently become clogged or occluded. In certain settings, the use of small-diameter tubes provides several advantages over standard-sized chest tubes, as smaller tubes facilitate safer insertion with a lower rate of infection-related complications and are considered to be more comfortable for the patient. [7, 8]

Patent drainage tubes are necessary not only to drain air and fluid but also to alert caregivers to internal bleeding, air leaks, and anastomotic leaks. To keep a chest tube patent, healthcare personnel often perform numerous maneuvers to clear the clog; however, none of these actions are uniformly effective, and all have significant drawbacks clinically.[9-13] These

procedures include stripping, milking (squeezing the chest tube over an area of visible clot to break it up and facilitate clot removal), and fan folding (folding and bending the chest tube to break up visible clot), all of which require manipulations of the outside of tube to try to break up thick material located inside the tube. A number of clinicians have highlighted their concerns with the high negative pressures generated inside the thorax by chest tube stripping.[9, 14, 15] In extreme circumstances, the surgeon will disconnect the chest tube from the tubing connector and advance a suction catheter into the tube to suction it out and reopen a clogged chest tube.[16] This technique of open suction of a chest tube, although effective, has the distinct disadvantage of requiring a break in the sterile environment of the chest tube system, as well as the creation of a pneumothorax once the occluded tube is reopened. Thus, these measures are carried out only in dire situations when no other alternatives are available. [17, 18] In addition to being of questionable efficacy, all of the aforementioned techniques are time consuming and can distract caregivers from other important care-related tasks.

Although the aforementioned issues with chest tube drainage are well recognized, there has been little innovation in this area of patient care. To identify the most important unmet needs, we conducted a survey to gather and quantify concerns of cardiothoracic surgeons and nurses related to chest tube drainage. [19] The results of this survey point to unmet needs and opportunities to improve patient care and safety by addressing patency issues with chest tubes.

Further, to address unmet clinical needs related to chest tube clogging, the active tube clearance system (Clear Catheter Systems, Bend, OR) was developed to mechanically break up clot and prevent clogging in chest tubes in the setting of heart, lung, or trauma surgery.[20] This system is designed to specifically clear any occluding material that develops within a chest tube

via an easy-to-operate mechanism that can be used in nearly any clinical setting without breaking the sterile environment within the tube. It is anticipated that this technology will allow surgeons to use chest tubes of smaller diameter with more confidence that clogging will not occur. It is also anticipated that this technique will allow nurses to focus on other critical patient care tasks that using make shift methods to keep a chest tube open.

Novel Device Description

The device is configured in such a way that a guidewire with a loop at the end rests within the chest tube.[20] When the guidewire is moved within the chest tube, it mechanically breaksup clot and solid debris. The guidewire is moved back and forth by the nurse or doctor by sliding a magnetic shuttle guide that resides outside of the chest tube. The magnetic shuttle guide is coupled magnetically to the guidewire in the tube. As the shuttle guide is advanced or retracted, it causes the guidewire to move within the tube, breaking up obstructing material.

The active tube clearance system is a disposable, single-use system that includes a chest tube and a guide tube (Fig. 1). Set on the guide tube is the shuttle guide, which consists of a polycarbonate housing that provides the mechanism to advance and retract a tube clearance member back and forth within the chest tube to keep the internal passage way free of any clogging or obstructing debris. The chest tube is 20 inches in length, similar to other standard chest tubes. It is inserted and secured in place in the usual fashion. When trimming the catheter, the proximal end of the PleuraFlow Thoracic drainage catheter is cut precisely where indicated by the labeling that indicates “cut.” This is to assure that the clearance apparatus is properly

sized in terms of length (Fig. 2). The guide tube is made of polyvinyl chloride and has a proximal (toward the patient) and a distal (toward the chest tube canister) barbed adapter. The proximal-barbed adapter is fit to the chest tube, in place of the usual tubing connector, and the distal-barbed adapter is fit to the drainage tubing to the drainage receptacle, such as the Pleurevac Chest-Drainage-Systems (Teleflex Medical, Research Triangle Park, NC) or the Atrium water seal or dry suction chest-drains (Atrium Medical, Corp., Hudson, NH; Fig. 3). The drainage receptacle is then set to the desired amount of suction (usually 20 cm H_2O) or to water seal. Encased in the main shuttle guide housing, external to the guide tube, is an external magnet that is fit over the outside diameter of the guide tube (Fig. 4). Within the guide tube, there is a 0.035-mm guidewire set on an internal magnet (Fig. 4). The internal magnet is sized, so that it does not block the inside passage of fluid from the chest tube to the drainage tubing and drainage canister. On the distal end of the guidewire is a clearance member shaped as a loop set at a 90-degree angle, which is sized to be slightly less than the internal diameter of the chest tube. This loop set on the wire is used to clear the internal portion of the chest tube of any occluding debris.

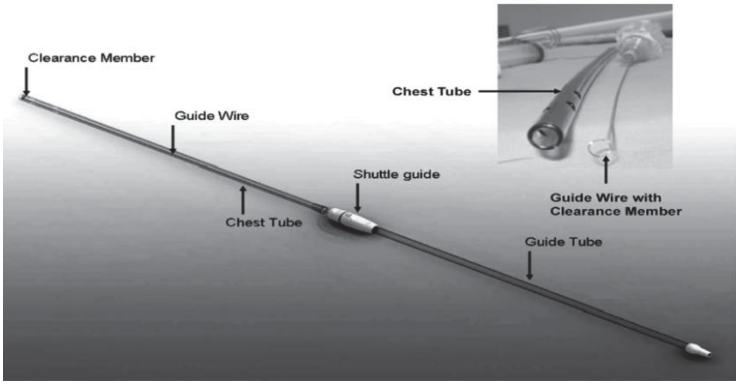

Figure 1: Active tube clearance system, descriptive illustration with a picture of the device

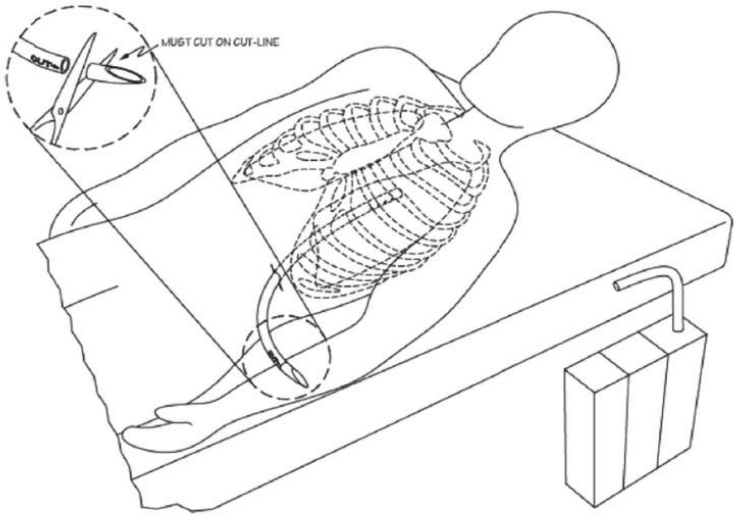

Figure 2: Illustration of the chest tube inserted and secured in place in the usual fashion

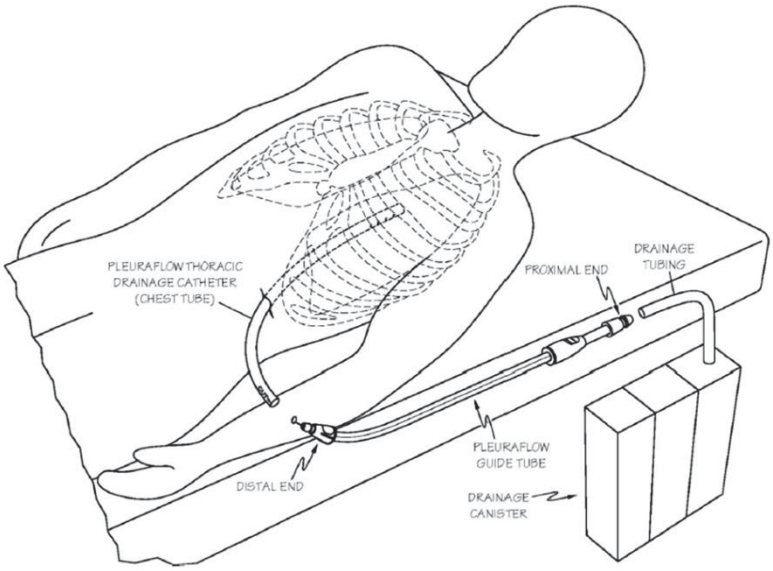

Figure 3: Illustration of the guide tube placed between the chest tube and the drainage receptacle

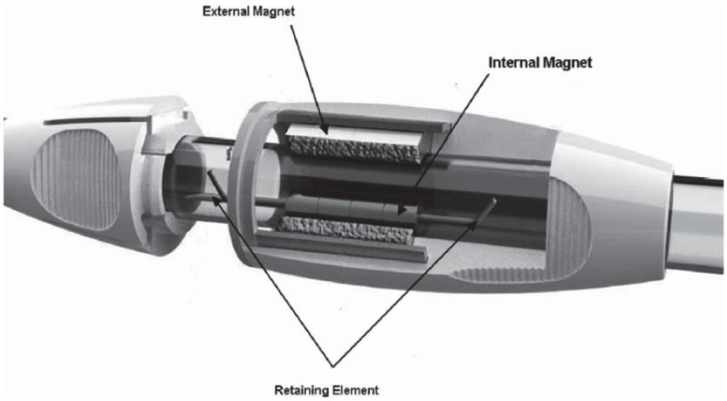

Figure 4: Tube clearance mechanism of active tube clearance system, descriptive illustration

Depending on the chest tube diameter size (ie, 20 Fr to 36 Fr), the loop is fashioned to be precisely sized to clear that size of tube. The external/internal magnet system allows the clearance loop to be advanced and retracted without breaking the sterile environment within the tube or creating internal pressure shifts (as seen with chest tube stripping). The proximal portion of the shuttle guide and the main shuttle guide housing are held together by a snap fitting that can be opened with gentle finger pressure on the proximal portion (Fig. 5). Once the snap fit is opened and pulled away from the proximal housing, the main shuttle guide housing can be slid along the guide tube, away from the patient (Fig. 6). The external and internal magnets are coupled such that movement by the external magnet via advancement and retraction of the shuttle guide housing results in movement of the internal magnet and, thus, the guidewire that is advanced into the chest tube. Retaining elements are set on the internal magnets to retain them

within the guide tube (Fig. 4). This keeps the internal guidewire from extending beyond the end of the chest tube or falling back uncoupled. Clinicians or other personnel can advance the wire loop back and forth within the catheter by advancing and retracting the external shuttle. As the wire loop is advanced and retracted within the tube, the internal portion of the tube is cleared by the clearance member. In this fashion, the clot is broken down and scooped back toward the drainage receptacle (Fig. 7), leaving the chest tube entirely clear of clots or other obstructing material.

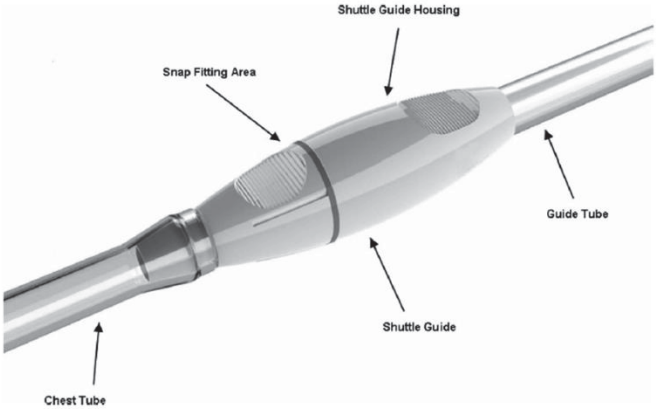

Figure 5: External appearance of shuttle guide part, active tube clearance system

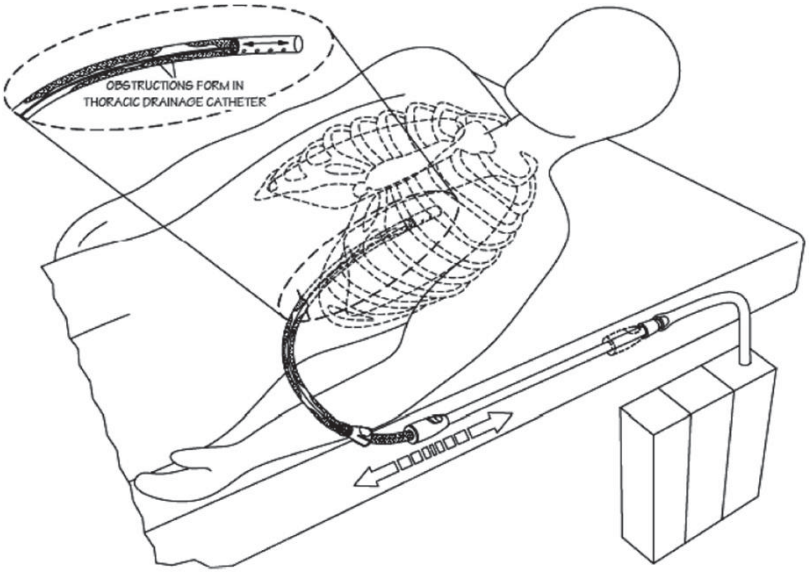

Figure 6: Illustration of the active tube clearance system's clearance member, which scoops back clot and debris from the distal end of the chest tube toward the drainage tube

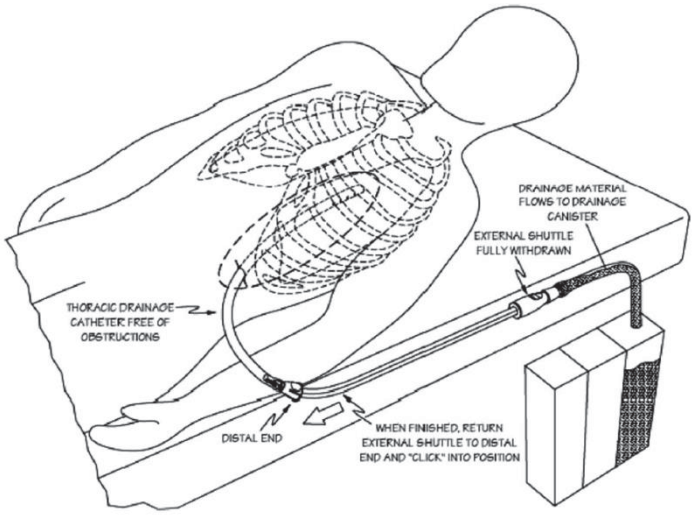

Figure 7: Illustration of the clot broken down and scooped back toward the drainage receptacle, leaving the chest tube entirely clear of clots or other obstructing material

The clearance mechanism is, therefore, a combination of both a mechanical clot-pulling action and a morcellation effect that occur when the loop breaks up clots and occluding material into progressively smaller and less occlusive pieces. The suction maintained in the drainage receptacle then pulls the morcellated clot and debris from the shuttle guide tube to the drainage tubing to be carried to the drainage receptacle. This is facilitated as the patient moves, coughs, and ambulates. However, when the patient is on a ventilator and sedated, the caregivers can be assured the tube is patent. The external and internal magnet coupling is the key to maintaining the sterile environment within the tube. The length of the guidewire, coupled with the retaining elements that keep it fixed in the guide tube, prevents the wire from being extended beyond the

tip of the chest tube. The wire loop is sized such that it cannot fit outside the side holes. When not in use, the wire and end loop are parked in the distal end of the tube, such that any new occluding material that builds up between uses will be scooped back toward the drainage receptacle, outside of the patient, rather than pushed back into the patient. Because guidewires can be made in very small sizes and of varying degrees of stiffness and flexibility, this novel technology lends itself well to facilitating clearance of the internal space of even the smallest-diameter tubes.

2. AIM OF THE STUDY

Blood accumulating inside chest cavities can lead to serious complications if it is not drained properly. Because life-threatening conditions can result from chest-tube occlusion after thoracic surgery, large-bore tubes are generally employed to optimize patency. To better define problems with current paradigms for chest drainage, we aimed in this study to conduct a survey to gather and quantify concerns of cardiothoracic surgeons and nurses related to chest tube drainage. The survey was constructed in two variant forms, one to surgeons (20 questions; Table 1) and another to nurses (10 questions; Table 2). The majority of participating nurses worked in an intensive care unit for postoperative heart surgery patients and had experience in managing patients with chest tubes.

The survey focused on the impact of particular factors (bleeding, clogging and patient discomfort) on surgeon's choice of chest tube and on the effectiveness of currently employed clearance methods, including milking, tapping, squeezing, folding and stripping of the chest tube, applied by nurses to minimize the potential of chest tube-related complications. Additionally, the surgeon's survey assessed the doctors' experience with alternative methods of chest drainage, including heparin-coated tubes and Blake drains. Finally, some questions were specifically focused on the impact of chest-tube size and methods of management on patient pain and discomfort.

Based on this survey, the design and function of a proprietary active tube clearance system, which is a novel device that clears clots and debris from chest tubes, was developed and described in a different publication.

3. DISSERTATION RELATED ORIGINAL PUBLICATIONS

Chest Tube Selection in Cardiac and Thoracic Surgery: A Survey of Chest Tube-Related Complications and Their Management

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ABSTRACT ***Background:*** **Blood accumulating inside chest cavities can lead to serious complications if it is not drained properly. Because life-threatening conditions can result from chest tube occlusion after thoracic surgery, large-bore tubes are generally employed to optimize patency.** ***Aims:*** **The aim of this study was to better define problems with current paradigms for chest drainage.** ***Materials and Methods:*** **A survey was conducted of North American cardiothoracic surgeons and specialty cardiac surgery nurses. A total of 108 surgeons and 108 nurses responded.** ***Results:*** **The survey revealed that clogging leading to chest-tube dysfunction is a major concern when choosing tube size. Of surgeons responding, 106 of 106 (100%) had observed chest tube clogging, and 93 of 106 (87%) reported adverse patient outcomes from a clogged tube. Despite techniques such as tube stripping, tapping, and squeezing, up to 51% of surveyed surgeons stated they are not satisfied with currently available tubes and procedures to avoid tube occlusion and some even forbid the stripping maneuver for fear of causing more bleeding by the negative pressures generated. In addition, respondents noted that patients experience increasing discomfort with increasing drain size.** ***Discussion:*** **The major reason surgeons choose large-diameter chest tubes is linked to concern about the suboptimal available methods to avoid and treat chest-tube clogging. Even though larger tubes are thought to be associated with more pain, physicians generally err on the side of caution to avoid clogging and insert tubes with larger diameters.** ***Conclusion:*** **Results of this survey highlight the frequent problems with clogging with current postsurgical chest drainage systems and suggest the need for innovative solutions to avoid clogging complications and overcome clinician concern and patient pain.**
doi: 10.1111/j.1540-8191.2009.00905.x *(J Card Surg 2009;24:503-509)*

Postoperative drainage of surgical sites is a standard component of many operations and is employed routinely after cardiac and thoracic surgery. Patent drainage tubes are necessary to alert caregivers to internal bleeding, air leaks, and anastomotic leaks. Occlusion of drain tubes can lead to life-threatening complications, including tamponade, tension pneumothorax, and sepsis.[1,2] Additional surgery may be necessary if occluded tubes lead to development of empyema, pericardial tamponade, or a hemothorax that is large enough to cause loss of lung volume.[3-5] To avoid the aforementioned complications, surgeons typically employ larger-bore chest tubes after cardiac and thoracic surgery.[6] However, large-bore tubes are associated with significant patient discomfort; furthermore, even larger tubes frequently become clogged or occluded. In certain settings, the use of small-diameter tubes provides several advantages over standard-sized chest tubes, as smaller tubes facilitate safer insertion with a lower rate of infection-related complications and are considered to be more comfortable for the patient.[7,8] Although the aforementioned issues with chest tube drainage are well recognized, there has been little

Dr. Boyle is a founder, shareholder, and CEO of Clear Catheter Systems (Bend, OR); Dr. Gillinov is a founder, consultant, shareholder, and member of the Scientific Advisory Board of Clear Catheter Systems; Dr. Cohn is a consultant and member of the Scientific Advisory Board for Clear Catheter Systems.

Source of funding: Clear Catheter Systems Company.

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J CARD SURG
2009;24:503-509

innovation in this area of patient care. To identify the most important unmet needs, we conducted a survey to gather and quantify concerns of cardiothoracic surgeons and nurses related to chest tube drainage. The results of this survey point to unmet needs and opportunities to improve patient care and safety by addressing patency issues with chest tubes.

MATERIALS AND METHODS

Cardiac and/or thoracic surgeons (n = 108) and cardiothoracic nurses (n = 108) responded to our survey. A total of 772 surgeons' surveys were sent out by electronic mail. A total of 150 nurses' surveys were distributed in the cardiac surgery intensive care unit setting. Surveys were completed by 108 of 772 (14%) surgeons and 108 of 150 (72%) nurses. The survey was constructed in two variant forms, one to surgeons (20 questions; Table 1) and another to nurses (10 questions; Table 2). Not all questions were answered by any given responder. The majority of participating nurses worked in an intensive care unit for postoperative heart surgery patients and had experience in managing patients with chest tubes.

The survey focused on the impact of particular factors (bleeding, clogging, and patient discomfort) on surgeon's choice of chest tube and on the effectiveness of currently employed clearance methods, including milking, tapping, squeezing, folding, and stripping of the chest tube, applied by nurses to minimize the potential of chest tube-related complications. Additionally, the surgeon's survey assessed the clinicians experience with alternative methods of chest drainage, including heparin-coated tubes and Blake drains. Finally, some questions were specifically focused on the impact of chest tube size and methods of management on patient pain and discomfort.

Most questions were answered with one of four percentage ranges (from 0% to 24%, 25% to 49%, 50% to 74%, and 75% to 99%) and finally 100%. For some questions, the answers were divided into any of four answers for ease of selection: completely negative, partially negative, totally positive, and partially positive. Some questions needed simply a "yes" or "no" answer. The survey questionnaires were prepared by a group of surgeons and nurses with extensive experience related to all aspects of chest tube-related care.

RESULTS

Chest tube selection

Clogging of chest tubes was observed by 106 of 106 responding surgeons (100%) and 98 of 104 nurses (94.2%). Adverse patient outcome related to clogging was experienced by 93 of 106 (87.7%) surgeons and 87 of 107 (81.3%) nurses. This experience influenced the surgeon's choice of chest tube size. Ninety-two of 106 (86.8%) surgeons reported that concern for the potential clogging within a chest tube affects their choice of chest tube diameter (e.g., 36 F vs. 20 F).

TABLE 1
Cardiothoracic Surgeon Chest Tube Survey

Question	Response (%)	Response (n)
1. Primary specialty?		
Cardiac surgery only	33.3	36
Cardiac and thoracic surgery	38.9	42
Thoracic surgery only	20.4	22
Pediatric heart surgery only	2.8	3
Adult and pediatric heart surgery and thoracic surgery	2.8	3
Other	1.9	2
Answered Question		108
Skipped question		0
2. Region of your practice?		
North America	98.1	106
South America	0.9	1
Asia	0.9	1
Answered question		108
Skipped question		0
3. Do you insert chest tubes and/or manage patients with chest tubes in your practice?		
Yes	100.0	108
No	0.0	0
Answered question		108
Skipped question		0
4. Does the concern for the potential for clogging within a chest tube impact your choice of chest tube diameter size to be inserted into a patient (e.g., 36 F vs. 20 F)?		
Yes	86.8	92
No	13.2	14
Answered question		106
Skipped question		2
5. If you have a case in which you expect bleeding, are you more likely to insert large-diameter chest tube (e.g., 36 F vs. 20 F)?		
0% to 24% of time	20.8	22
25% and 49% of time	3.7	4
50% and 74% of time	12.3	13
75% and 99% of time	18.8	20
100% of time	44.3	47
Answered question		106
Skipped question		2
6. Does your concern for the potential for clogging in a particular case impact your choice of the number of chest tubes to be inserted?		
0% to 24% of time	24.5	26
25% to 49% of time	8.4	9
50% to 74% of time	18.8	20
75% to 99% of time	17.9	19
100% of time	30.2	32
Answered question		106
Skipped question		2
7. Have you ever observed an adverse patient outcome related to chest tube clogging?		
Yes	87.7	93
No	12.3	13
Answered question		106
Skipped question		2

Continued.

TABLE 1
Continued

Question	Response (%)	Response (n)
8. Have you ever observed a blood clot or other debris clogging a chest tube (e.g., when the tube is removed or when you take a patient back to the operating room)?		
Yes	100.0	106
No	0.0	0
Answered question		106
Skipped question		2
9. Do you have a standard protocol(s) for nurses managing tube blood clots or debris (assume you have decided that the patient does not need to go back to the operating room)?		
Yes	61.3	65
No	38.7	41
Answered question		106
Skipped question		2
10. Which statement best suits your attitude toward chest tube "stripping"?		
I allow it	73.6	78
I discourage it	22.6	24
I absolutely forbid it	3.8	4
Answered question		106
Skipped question		2
11. Do you believe that the currently available techniques for nurses to deal with active chest tube clogging (e.g., tapping, folding, squeezing, and milking the tube) in the setting of bleeding are:		
Completely unsatisfactory	1.8	2
Usually unsatisfactory	49.1	52
Usually satisfactory	49.1	52
Completely satisfactory	0.0	0
Answered question		106
Skipped question		2
12. Do you ever temporarily insert a suction catheter into a chest tube while you are closing the wound at the end of a case in the operating room?		
0% to 24% of time	36.8	39
25% to 49% of time	10.4	11
50% to 74% of time	11.3	12
75% to 99% of time	17.0	18
100% of time	24.5	26
Answered question		106
Skipped question		2
13. In your opinion does heparin coating a chest tube significantly prevent clogging or clotting?		
Yes	21.2	22
No	78.8	82
Answered question		104
Skipped question		4

Continued.

TABLE 1
Continued

Question	Response (%)	Response (n)
14. Which of the following best characterizes your use pattern for small diameter (e.g., 20 F) Blake drains in cardiothoracic cases?		
I have never put in one	12.6	13
I tried them, but no longer use them	20.4	21
I tried them, but rarely use them	34.0	35
I routinely use them	33.0	34
Answered question		103
Skipped question		5
15. Would you insert a small diameter Blake drain in a case where you expect significant bleeding or clogging?		
0% to 24% of time	69.6	71
25% to 49% of time	8.8	9
50% to 74% of time	7.8	8
75% to 99% of time	3.9	4
100% of time	9.8	10
Answered question		102
Skipped question		6
16. What is the perceived advantage of using a Blake drain rather than a standard chest tube in a cardiothoracic case?		
It causes less pain	76.7	79
Design of the drain tip	20.4	21
Flexibility of catheter	50.5	52
Resistance to clogging	18.4	19
Other	9.7	10
Answered question		103
Skipped question		5
17. What is the perceived disadvantage of using a Blake drain rather than a standard chest tube in a cardiothoracic case?		
Potential for clogging	54.4	56
Potential for kinking	17.5	18
Inability to clear needed volume of fluid due to tube diameter	47.6	49
Inability to reliably clear air in setting of an air leak	35.9	37
Other	9.7	10
Answered question		103
Skipped question		5
18. In your opinion, to what degree does chest tube pain impact a patient's overall comfort after a cardiothoracic procedure?		
Significant	83.3	85
Insignificant	16.7	17
Answered question		102
Skipped question		6
19. Is this discomfort impacted by the diameter size of the chest tube (e.g., 36 F vs. 20 F)?		
Yes	74.5	76
No	25.5	26
Answered question		102
Skipped question		6

Continued.

TABLE 1
Continued

Question	Response (%)	Response (n)
20. Do you find that your patients with chest tubes complain of pain related to the chest tube?		
0% to 24% of the time	15.7	16
25% and 49% of the time	15.7	16
50% and 74% of the time	34.3	35
75% and 99% of the time	26.5	27
100% of the time	7.8	8
Answered question		102
Skipped question		6

Concern about postoperative bleeding had an important impact on the decision of most appropriate chest tube size. In particular, 47 of 106 responding surgeons (44.3%) reported that they are more likely to insert a larger-diameter tube in the setting of anticipated bleeding. In contrast, 22 of 106 surgeons (20.8%) would not let bleeding influence their choice of the size of chest tube selected. In addition, 71 of 106 surgeons (67%) routinely placed more than one large chest tube when clogging was anticipated in more than 50% of times.

Pain and discomfort

Surgeons and nurses reported the potential for chest tubes to cause pain. Eighty-five of 102 responding surgeons (83%) considered the pain resulting from a chest tube to be significant after a cardiothoracic procedure. In addition, 76 of 102 surgeons (74%) reported that the level of patient discomfort is related to the diameter of the chest tube. Ninety-seven of 106 responding nurses (91%) reported that pain is moderate to severe in patients with chest tubes.

Conventional chest tube management

Sixty-five of 106 responding surgeons (61.3%) reported that they have standard protocols to manage chest tube clogging. These protocols include milking, tapping, squeezing, folding, and stripping the chest tube. Regarding stripping of the chest tube, this procedure is allowed by 78 of 106 surgeons (73.6%), discouraged by 24 of 106 (22.6%), and forbidden by four of 106 (3.8%) surgeons. In contrast, 76 of 106 responding nurses (71.7%) asserted that stripping the chest tube was not allowed as a means to manage the clogged chest tube at their institution. Over half of all surgeons responding were unsatisfied with available techniques to clear a clogged or clogging chest tube: 52 of 106 (49.1%) usually unsatisfied; two of 106 (1.8%) completely unsatisfied; none were completely satisfied. Correspondingly, only three of 105 responding nurses (2.9%) considered the currently available techniques including tapping, milking, squeezing, or bending the tube to be completely satisfactory. Furthermore, the majority of nurses, 80 of 107 (74.8%), stated that

TABLE 2
Nurses Chest Tube Survey

Question	Response (%)	Response (n)
1. Do you manage patients with chest tubes?		
Yes	100.0	108
No	0.0	0
Answered question		108
Skipped question		0
2. In what location(s) do you care for patients with chest tubes?		
In the ICU	88.6	93
On the wards	11.4	12
In the ER	1.0	1
In the operating room	2.9	3
Other	8.6	9
Answered question		105
Skipped question		3
3. What is the primary reason the patients for whom you provide care have chest tubes?		
After heart surgery	91.7	99
After thoracic surgery	7.4	8
After trauma	0.9	1
Medical ICU	0.0	0
Other	0.0	0
Answered question		108
Skipped question		0
4. Do you find that your patients with chest tubes complain of pain related to the chest tube?		
0% to 24% of the time	3.7	4
25% and 49% of the time	13.1	14
50% and 74% of the time	30.8	33
75% and 99% of the time	37.4	40
100% of the time	15.0	16
Answered question		107
Skipped question		1
5. To what degree would you say chest tube pain impacts a patient's comfort?		
None	0.0	0
Minimal	8.5	9
Moderate	67.0	71
Severe	24.5	26
Answered question		106
Skipped question		2
6. Have you ever noted a chest tube to be clogged or to contain material in the tube that impairs outflow?		
Yes	94.2	98
No	5.8	6
Answered question		104
Skipped question		4
7. Have you ever witnessed an adverse patient outcome from a clogged chest tube? (Examples include pericardial tamponade, the need to go back to the operating room to wash out a clot, or progressive subcutaneous emphysema from an air leak)		
Yes	81.3	87
No	18.7	20
Answered question		107
Skipped question		1

Continued.

TABLE 2
Continued

Question	Response (%)	Response (n)
8. Does your institution allow nurses to strip chest tubes and chest drainage tubing to remove clots?		
Yes	28.3	30
No	71.7	76
Answered question		106
Skipped question		2
9. Do you find the currently available techniques to manage chest tube clogging (i.e., tapping, milking, squeezing, or bending the tube) in the setting of bleeding are:		
Completely unsatisfactory	1.9	2
Usually unsatisfactory	48.6	51
Usually satisfactory	46.7	49
Completely satisfactory	2.9	3
Answered question		105
Skipped question		3
10. Does managing chest tube clogging take you away from other important tasks?		
Yes	74.8	80
No	25.2	27
Answered question		107
Skipped question		1

management of clogged chest tubes is a time-consuming procedure that takes them away from other important care-related tasks.

A potential alternative to prevent chest tube clogging is the use of heparin-coated tubes. This alternative was previously believed to be an effective method in prevention of clogs. However, 82 of 104 responding surgeons (78.8%) doubted the effectiveness of this method. Another alternative is the use of Blake drains. Surgeons had mixed opinions about their use of Blake-type fluted, small-caliber drains after cardiothoracic surgery. While 34 of 103 responding surgeons (33%) have routinely used them, 13 of 103 (12.6%) have never used them. The perceived advantage of using a Blake drain rather than a standard chest tube is that a smaller diameter results in less pain (reported by 79 of 103 [76.7%]) and increased flexibility of the catheter (reported by 52 of 103 [50.5%]). However, the greatest perceived disadvantage of using the Blake drain was the potential for clogging (56 and 103 [54.4%] of responding surgeons) and inability to clear the volume of fluid (49 of 103 [47.6%]) and air (37 of 103 [35.9%]) needed due to their small diameter. With regard to the use of a Blake drain in the setting of expected bleeding or clogging (i.e., a reoperation on a patient taking clopidogrel or who had an empyema), 80 of 102 responding surgeons (78.4%) would use them less than 50% of the time, and 22 of 102 (21.5%) 50% to 100% of the time.

DISCUSSION

Cardiothoracic surgeons currently face a dilemma when choosing a method of postsurgical chest tube drainage. They must balance their concerns for patient safety that is jeopardized by clogging and dysfunction of tubes with their desire to limit patient discomfort. At the bedside, nurses are challenged by and frustrated with the task of directly managing chest tube-related pain and clogging. Our survey was designed to assess attitudes of practicing cardiothoracic surgeons and specialty cardiac surgery nurses related to chest tube clogging and pain to determine the factors these surgeons consider when choosing chest tubes and managing these patients.

The potential for clogging is one of the most important considerations in the selection of chest tubes in cardiothoracic surgery and trauma patients. Any tube used to drain a body space after surgery can become clogged. Tube clogging usually occurs in the setting of bleeding, as a thick clot can obstruct the lumen of the tube and prevent it from functioning properly. Chest tube clogging can be life threatening in cardiac surgery for two reasons.[9,10] First, inadequate drainage can cause internal bleeding to go unrecognized, leading to hemodynamic compromise and death. Second, undrained blood can pool in the pericardial space, creating cardiac tamponade. In addition, with air leaks after pulmonary surgery, a clogged tube can lead to pneumothorax (lung collapse), which can be another life-threatening condition if left untreated.[5]

All the 106 surgeons responding had seen chest tube clogging and nearly all reported adverse patient outcomes from clogging. Nurses caring for patients with chest tubes reported a similar experience. For the surgeon, the potential for clogging is a major consideration. When a surgeon selects a chest tube, the main question to address is the tube's internal diameter. This survey revealed that the choice of tube size nearly always involves the surgeon's perception of the risk of clogging. It is generally thought that the higher the perceived risk, the bigger the diameter of the tube chosen. If a surgeon is simply draining a small amount of air or fluid, a small-diameter tube is often chosen (20 F). Ongoing production of more viscous fluids such as blood or pus, particularly if being generated rapidly, requires a larger bore tube (32 or 36 F) to try to limit the potential for clogging. Even these tubes, however, frequently become occluded with clotted blood, fibrinous debris, or in the case of an empyema, pus.[11] Nearly all surgeons responding reported that the potential for a patient to experience clogging within the chest tube influences the size (internal diameter) of the drainage tube selected. Furthermore, nearly two-thirds of the time, the surgeon will place more than one tube when there is concern that the clinical scenario suggests increased potential for clogging.

When clinicians caring for patients in the perioperative period following chest trauma and surgery notice that clots are forming in the visible portion of the tube external to the patient, they often undertake measures to try to remove the clot. There are several

commonly used techniques for nurses to manage chest tube drainage when bleeding and clogging occur, including milking, stripping, tapping, and, in some circumstances, open suction.[12] Protocols exist in many institutions to direct how nurses manage clogging of a chest tube. However, none of these methods are considered totally reliable, and none of them is without risk of further complications. In addition, these manipulations can be painful for the patient.

One of the most controversial methods of clearing a chest tube is stripping. Stripping the connecting tubing between the chest tube and the collection canister was once one of the most commonly used techniques for trying to maintain chest tube patency. The "stripping" technique generates short bursts of extremely negative pressure at the ends of the tube. The safety of this method has been questioned, as pressures exceeding −400 cm of water can be generated adjacent to suture lines, leading some to think that this technique actually makes bleeding worse.[12] Nevertheless, because there are currently limited options to try to maintain tube patency, most surgeons allow chest tube stripping. In contrast to the surgeon's willingness to allow chest tube stripping, most nurses are under the impression that they are not allowed to strip a chest tube to keep it clear of clogging and clot.

Surgeons responding to the survey were split on their perception of current methods available to clear a clogging tube. Half felt the current methods are usually or completely unsatisfactory, and none of the surgeons surveyed felt they are completely satisfactory. Likewise, nurses were split on the effectiveness of current techniques to clear chest tubes once they become occluded or clogged, with over half stating that the current techniques are usually or completely unsatisfactory. Furthermore, 75% of nurses felt that managing chest tube clogging takes them away from other important tasks.

Attempts at technological improvement have failed to solve the clinical problem of maintaining drain patency. Heparin-coated chest tubes were introduced with the thought that the treatment would retard clot formation. This approach seemed promising theoretically, but has not proved useful, as clot and thick material formation still occur, debris still accumulates, and the clinical benefit is generally marginal.[13,14] To date, specialty coating of the tubes has done little to ameliorate the clogging issue, likely because when blood encounters the foreign surfaces of any tube, it coagulates. The surgeons who responded to our survey clearly do not believe that tube coating is the answer.

In recent years, there has been increasing interest in minimally invasive surgery and the use of smaller diameter chest tubes to limit incision size and pain after cardiothoracic interventions. Chest tubes, however, are generally considered painful to the patient by surgeons and nurses. More than 80% of surgeons responding felt that the chest tube contributed significantly to patient pain in the postoperative period. Similarly, a high percentage of nurses caring for patients with chest tubes reported that chest tubes are associated with significant pain. It has been suggested that chest tube-related pain increases the demand for postoperative analgesia[15] and also negatively affects respiratory mechanism, consequently increasing the risk of postoperative respiratory complications.[16] In addition, pain from chest tubes could impair patients' early ambulation after surgery, increasing the risk for a thromboembolic event.[17] In this survey, the majority of surgeons and nurses stated that the diameter size of the chest tube contributed to the degree of pain experienced by the patient. Thus, the concern for clogging competes with the concern for pain for the patient when choosing a chest tube diameter, suggesting that the surgeons are more likely to choose a larger diameter tube even though it will result in more pain for the patient.

Some surgeons have turned to the Blake-type fluted drain as a small-diameter alternative to the more commonly used polyvinyl chloride chest drains. Only 33% of surgeons responding routinely use Blake-type fluted drains, while two-thirds have tried them and rarely use them or have not tried them at all. Surgeons cited the small diameter and increased flexibility as having less potential for pain, as well as the increased flexibility of the drains as perceived advantages of the Blake drain. An overwhelming majority of surgeons responding would not use this type of drain when bleeding or thick secretions are expected, citing the potential for clogging and the inability to adequately drain a sufficient amount of air or blood as reasons to avoid these types of drains in this setting.

In conclusion, this survey showed the issues associated with current postsurgical chest drainage systems and necessitates innovative approaches to prevent or treat chest tube clogging when it occurs, as well as to miniaturize tube size to improve patient comfort. Innovation techniques may include adding suction systems or clearance apparatus to the chest tube that clears the tubes safely, effectively, and reliably from clogging and may facilitate downsizing the currently available chest tube to minimize the patient's pain and discomfort. We are currently investigating several approaches in animal experiments that will be published in a separate paper.

REFERENCES

1. Watkins JA, Spain DA, Richardson JD, et al: Empyema and restrictive pleural processes after blunt trauma: An under-recognized cause of respiratory failure. Am Surg 2000;66:210-214.
2. Meyer DM, Jessen ME, Wait MA, et al: Early evacuation of traumatic retained hemothoraces using thoracoscopy: A prospective, randomized trial. Ann Thorac Surg 1997;64:1396-1400; discussion 1391-1400.
3. Velmahos GC, Demetriades D, Chan L, et al: Predicting the need for thoracoscopic evacuation of residual traumatic hemothorax: Chest radiograph is insufficient. J Trauma 1999;46:65-70.
4. McGillicuddy D, Rosen P: Diagnostic dilemmas and current controversies in blunt chest trauma. Emerg Med Clin North Am 2007;25:695-711, viii-ix.
5. Jones PM, Hewer RD, Wolfenden HD, et al: Subcutaneous emphysema associated with chest tube drainage. Respirology 2001;6:87-89.

6. Baumann MH: What size chest tube? What drainage system is ideal? And other chest tube management questions. Curr Opin Pulm Med 2003;9:276-281.
7. Horsley A, Jones L, White J, et al: Efficacy and complications of small-bore, wire-guided chest drains. Chest 2006;130:1857-1863.
8. Davies HE, Merchant S, McGown A: A study of the complications of small bore "Seldinger" intercostal chest drains. Respirology 2008;13:603-607.
9. Milas BL, Jobes DR, Gorman RC: Management of bleeding and coagulopathy after heart surgery. Semin Thorac Cardiovasc Surg 2000;12:326-336.
10. Clark G, Licker M, Bertin D, et al: Small size new silastic drains: Life-threatening hypovolemic shock after thoracic surgery associated with a non-functioning chest tube. Eur J Cardiothorac Surg 2007;31:566-568.
11. Wallen M, Morrison A, Gillies D, et al: Mediastinal chest drain clearance for cardiac surgery. Cochrane Database Syst Rev 2004;CD003042.
12. Day TG, Perring RR, Gofton K: Is manipulation of mediastinal chest drains useful or harmful after cardiac surgery? Interact Cardiovasc Thorac Surg 2008;7:888-890.
13. Salzman EW: Surface effects in haemostasis and thrombosis. The Chemistry of the Biosurfaces. Marcel Dekker, New York, 1972.
14. Carroll P: New developments in chest tube technology. Atrium Clinical Update 1998;1.
15. Milgrom LB, Brooks JA, Qi R, et al: Pain levels experienced with activities after cardiac surgery. Am J Crit Care 2004;13:116-125.
16. Craig DB: Postoperative recovery of pulmonary function. Anesth Analg 1981;60:46-52.
17. Dean E, Ross J: Discordance between cardiopulmonary physiology and physical therapy. Toward a rational basis for practice. Chest 1992;101:1694-1698.

The Active Tube Clearance System

A Novel Bedside Chest-Tube Clearance Device

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Objective: Chest-tube clogging can lead to complications after heart and lung surgery. Surgeons often choose large-diameter chest tubes or place more than one chest tube when concerned about the potential for clogging. The purpose of this report is to describe the design and function of a proprietary active tube clearance system, a novel device that clears clots and debris from chest tubes.

Device Description: The active tube clearance system is a novel chest tube clearance apparatus developed to maintain chest tube patency. Chest tube clearance is achieved by advancing the specially designed clearance member back and forth within the chest tube under sterile conditions, breaking down and pulling clots back toward the drainage receptacle, thereby leaving the inner portion of the chest tube clear of any obstructing material.

Conclusions: By maintaining chest tube patency, chest tube drainage can be performed more safely, and this apparatus may possibly lead to the use of smaller chest tubes and less invasive insertion techniques.

Key Words: Hemothorax, Clogging, Pneumothorax, Outcome, Chest tube, Drainage, Occlusion, Thoracostomy.

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Chest tubes are inserted in patients after heart, lung, and trauma surgery. In the setting of pneumothorax, hemothorax, or pericardial tamponade, chest tubes facilitate removal of blood, serous fluid, or air and prevent heart and lung compression. Chest tubes commonly become partially or completely occluded with blood clots or other fibrinous material, which can impair their function. To achieve optimal outcomes in the setting of ongoing production of blood, effusions, or air, maintaining an adequately functioning chest tube is, therefore, critical.[1]

Occlusion of drain tubes can lead to life-threatening complications, including tamponade, tension pneumothorax, and sepsis.[2,3] Additional surgery may be necessary if occluded tubes lead to development of empyema or a hemothorax that is large enough to cause loss of lung volume.[1,4,5] To avoid the aforementioned complications, surgeons typically use large-bore chest tubes after thoracic surgery.[6] However, large-bore tubes are associated with significant patient discomfort; furthermore, even larger tubes frequently become clogged or occluded.

Patent drainage tubes are necessary not only to drain air and fluid but also to alert caregivers to internal bleeding, air leaks, and anastomotic leaks. To keep a chest tube patent, healthcare personnel often perform numerous maneuvers to clear the clog; however, none of these actions are uniformly effective, and all have significant drawbacks clinically.[7–11] These procedures include stripping, milking (squeezing the chest tube over an area of visible clot to break it up and facilitate clot removal), and fan folding (folding and bending the chest tube to break up visible clot), all of which require manipulations of the outside of tube to try to break up thick material located inside the tube. A number of clinicians have highlighted their concerns with the high negative pressures generated inside the thorax by chest tube stripping.[7,12,13] In extreme circumstances, the surgeon will disconnect the chest tube from the tubing connector and advance a suction catheter into the tube to suction it out and reopen a clogged chest tube.[14] This technique of open suction of a chest tube, although effective, has the distinct disadvantage of requiring a break in the sterile environment of the chest tube system, as well as the creation of a pneumothorax once the occluded tube is reopened. Thus, these measures are carried out only in dire situations when no other alternatives are available.[15,16] In addition to being of questionable efficacy, all of the aforementioned techniques are time consuming and can distract caregivers from other important care-related tasks. A recent survey of cardiothoracic surgeons revealed that 100% of surgeons have seen clogged chest tubes, and a majority have seen adverse patient outcomes related to chest tube clogging.[17] This survey also found that surgeons often choose to use large-

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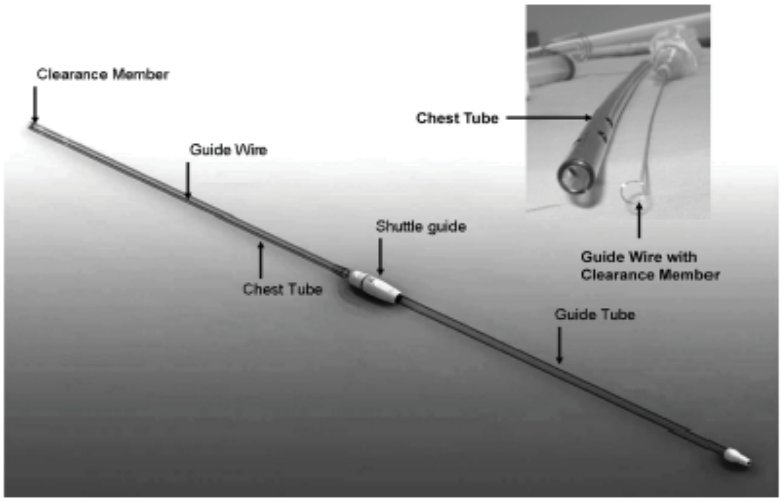

FIGURE 1. Active tube clearance system, descriptive illustration with a picture of the device.

diameter tubes, more than one tube, or both when the concern for clogging exists.

To address unmet clinical needs related to chest tube clogging, the active tube clearance system (Clear Catheter Systems, Bend, OR) was developed to mechanically break up clot and prevent clogging in chest tubes in the setting of heart, lung, or trauma surgery. This system is designed to specifically clear any occluding material that develops within a chest tube via an easy-to-operate mechanism that can be used in nearly any clinical setting without breaking the sterile environment within the tube. It is anticipated that this technology will allow surgeons to use chest tubes of smaller diameter with more confidence that clogging will not occur. It is also anticipated that this technique will allow nurses to focus on other critical patient care tasks that using make shift methods to keep a chest tube open. This report constitutes a description of the design and function of this novel technology.

Device Description

The device is configured in such a way that a guidewire with a loop at the end rests within the chest tube. When the guidewire is moved within the chest tube, it mechanically breaks up clot and solid debris. The guidewire is moved back and forth by the nurse or doctor by sliding a magnetic shuttle guide that resides outside of the chest tube. The magnetic shuttle guide is coupled magnetically to the guidewire in the tube. As the shuttle guide is advanced or retracted, it causes the guidewire to move within the tube, breaking up obstructing material.

The active tube clearance system is a disposable, single-use system that includes a chest tube and a guide tube (Fig. 1). Set on the guide tube is the shuttle guide, which consists of a polycarbonate housing that provides the mechanism to advance and retract a tube clearance member back and forth within the chest tube to keep the internal passage way free of any clogging or obstructing debris.

The chest tube is 20 inches in length, similar to other standard chest tubes. It is inserted and secured in place in the usual fashion. When trimming the catheter, the proximal end of the PleuraFlow Thoracic drainage catheter is cut precisely where indicated by the labeling that indicates "cut." This is to assure that the clearance apparatus is properly sized in terms of length (Fig. 2). The guide tube is made of polyvinyl chloride and has a proximal (toward the patient) and a distal (toward the chest tube canister) barbed adapter. The proximal-barbed adapter is fit to the chest tube, in place of the usual tubing connector, and the distal-barbed adapter is fit to the drainage tubing to the drainage receptacle, such as the Pleurevac Chest-Drainage-Systems (Teleflex Medical, Research Triangle Park, NC) or the Atrium water seal or dry suction chest-drains (Atrium Medical, Corp., Hudson, NH; Fig. 3). The drainage receptacle is then set to the desired amount of suction (usually 20 cm · H_2O) or to water seal.

Encased in the main shuttle guide housing, external to the guide tube, is an external magnet that is fit over the outside diameter of the guide tube (Fig. 4). Within the guide tube, there is a 0.035-mm guidewire set on an internal magnet (Fig. 4). The internal magnet is sized, so that it does not block the inside passage of fluid from the chest tube to the drainage tubing and drainage canister. On the distal end of the guidewire is a clearance member shaped as a loop set at a 90-degree angle, which is sized to be slightly less than the internal diameter of the chest tube. This loop set on the wire is used to clear the internal portion of the chest tube of any occluding debris. Depending on the chest tube diameter size (ie, 20 Fr to 36 Fr), the loop is fashioned to be precisely sized to clear that size of tube. The external/internal magnet system allows the clearance loop to be advanced and retracted without breaking the sterile environment within the tube or creating internal pressure shifts (as seen with chest tube stripping).

The proximal portion of the shuttle guide and the main shuttle guide housing are held together by a snap fitting that can be opened with gentle finger pressure on the proximal portion (Fig. 5). Once the snap fit is opened and pulled away from the proximal housing, the main shuttle guide housing can be slid

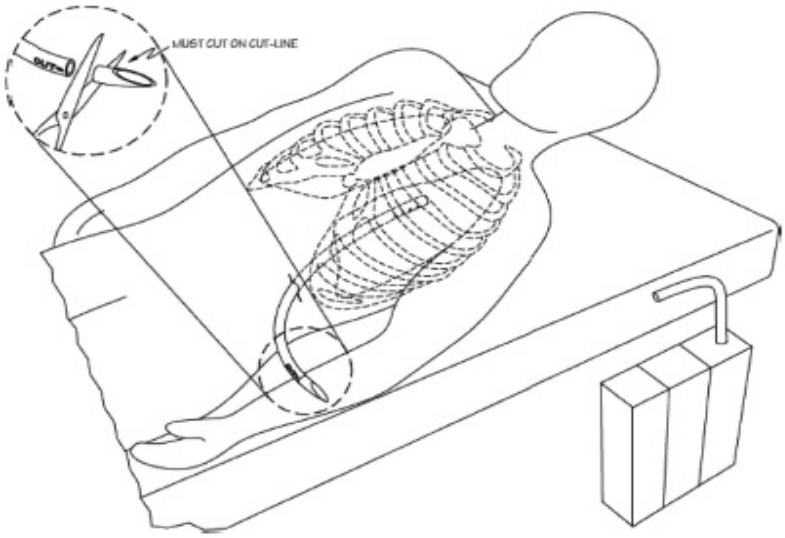

FIGURE 2. Illustration of the chest tube inserted and secured in place in the usual fashion.

along the guide tube, away from the patient (Fig. 6). The external and internal magnets are coupled such that movement by the external magnet via advancement and retraction of the shuttle guide housing results in movement of the internal magnet and, thus, the guidewire that is advanced into the chest tube. Retaining elements are set on the internal magnets to retain them within the guide tube (Fig. 4). This keeps the internal guidewire from extending beyond the end of the chest tube or falling back toward the chest drainage canister, if it became temporarily uncoupled.

Clinicians or other personnel can advance the wire loop back and forth within the catheter by advancing and retracting the external shuttle. As the wire loop is advanced and retracted within the tube, the internal portion of the tube is cleared by the clearance member. In this fashion, the clot is broken down and scooped back toward the drainage recepta-

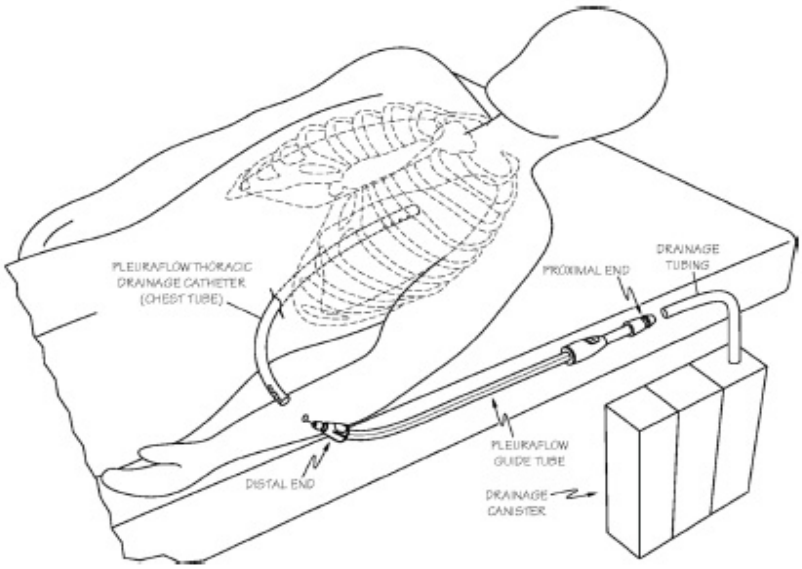

FIGURE 3. Illustration of the guide tube placed between the chest tube and the drainage receptacle.

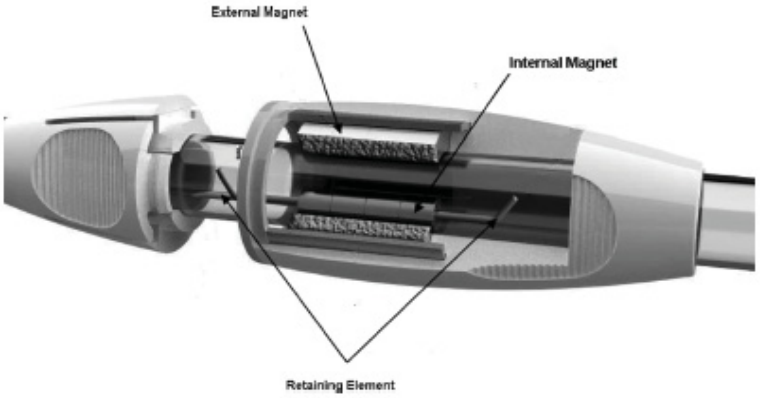

FIGURE 4. Tube clearance mechanism of active tube clearance system, descriptive illustration.

cle (Fig. 7), leaving the chest tube entirely clear of clots or other obstructing material.

The clearance mechanism is, therefore, a combination of both a mechanical clot-pulling action and a morcellation effect that occur when the loop breaks up clots and occluding material into progressively smaller and less occlusive pieces. The suction maintained in the drainage receptacle then pulls the morcellated clot and debris from the shuttle guide tube to the drainage tubing to be carried to the drainage receptacle. This is facilitated as the patient moves, coughs, and ambulates. However, when the patient is on a ventilator and sedated, the caregivers can be assured the tube is patent.

The external and internal magnet coupling is the key to maintaining the sterile environment within the tube. The length of the guidewire, coupled with the retaining elements that keep it fixed in the guide tube, prevents the wire from being extended beyond the tip of the chest tube. The wire loop is sized such that it cannot fit outside the side holes. When not in use, the wire and end loop are parked in the distal end of the tube, such that any new occluding material that builds up between uses will be scooped back toward the drainage receptacle, outside of the patient, rather than pushed back into the patient.

Because guidewires can be made in very small sizes and of varying degrees of stiffness and flexibility, this novel technology lends itself well to facilitating clearance of the internal space of even the smallest-diameter tubes.

DISCUSSION

When chest tube clogging occurs in the setting of continued drainage requirements, this can impact recovery, leading to retained hemothorax, pleural effusion, empyema, pneumothorax, subcutaneous emphasema, and, more rarely, tension pneumothorax, pericardial tamponade, and even death. When clot is noticed forming in the tubes, efforts are undertaken to break up, strip out, or mechanically clear the clot by opening the chest tube and using a suction device to clear the internal diameter. Although these efforts are usually initiated when chest tube clot is noticed in the visible portion of the tube, chest tube occlusion from clot and other fibrinous material can occur in the proximal

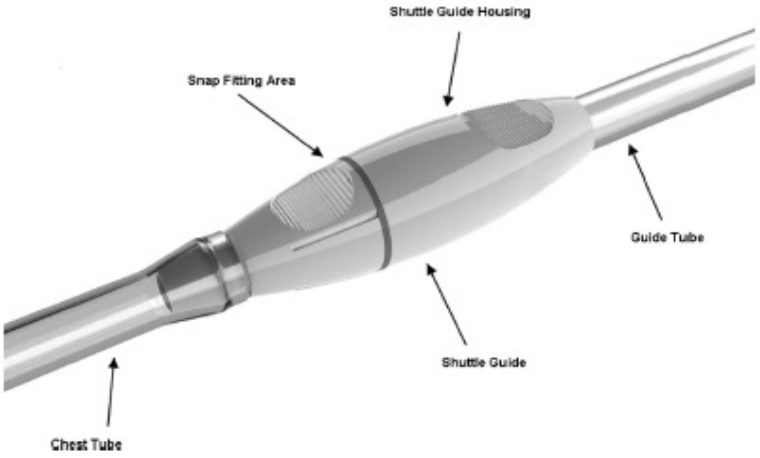

FIGURE 5. External appearance of shuttle guide part, active tube clearance system.

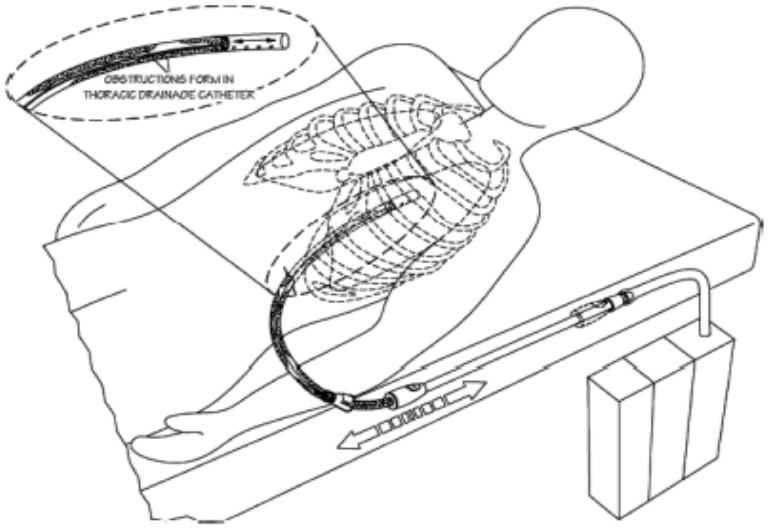

FIGURE 6. Illustration of the active tube clearance system's clearance member, which scoops back clot and debris from the distal end of the chest tube toward the drainage tube.

portion of the tube, that is, inside the patient, where it is not visible to those caring for the patient. When drainage ceases, it is usually assumed that there are no further drainage needs, and the tubes are removed, facilitating the patients continued post-operative recovery. Chest tubes, however, can become clogged while there is still fluid or air to be drained. Thus, the absence of drainage can in some cases be a false indication that adequate drainage has been achieved, especially when the chest tubes are occluded. Once the chest tubes are removed, fluid retained in the chest is common after cardiothoracic surgery. In a study by Light et al,[18] the prevalence of pleural effusions in the patients undergoing cardiac surgery was >60%, and the prevalence of effusions occupying >25% of the hemithorax nearly 10%.

In an era when maximizing optimal outcomes in the setting of more challenging cases is coupled with a clinical interest in minimizing the invasiveness of surgery, there is considerable room for improvement in the chest tubes that are commonly used in nearly all heart and lung surgery cases. This is the first reported description of the novel active tube clearance system, which was developed to provide a simple mechanical

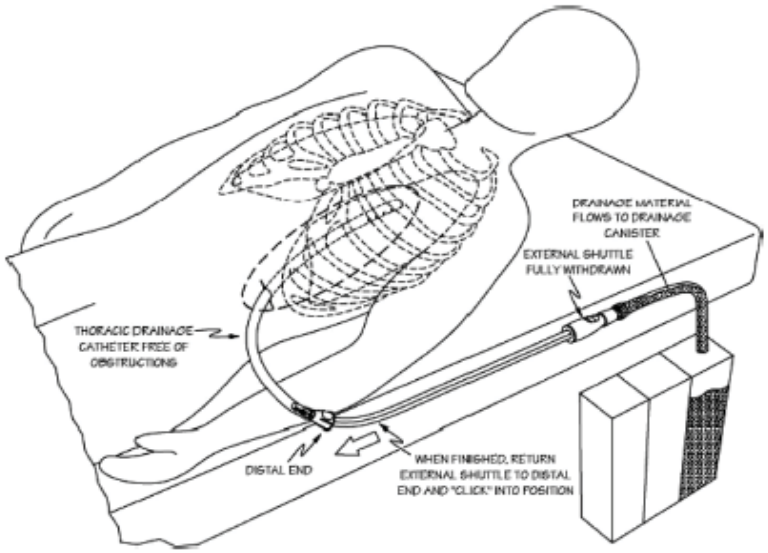

FIGURE 7. Illustration of the clot broken down and scooped back toward the drainage receptacle, leaving the chest tube entirely clear of clots or other obstructing material.

mechanism to maintain patency of the chest tube without introducing harmful pressure changes in the system or compromising sterile conditions within the system. This system addresses the safety concerns that arise when chest tubes become clogged in the setting of bleeding or the production of other thick fibrous materials, for example, empyema. With this system, caregivers such as nurses can simply run the shuttle back on a periodic basis, for example, when they check and record chest tube output, and be assured that there is no clot obstructing the tube in the visible and nonvisible portion of the tube. When bleeding is noted to be brisk and thick clots are forming, the system can be used more frequently.

It is anticipated that another advantageous byproduct of this solution will be that fewer and perhaps smaller-diameter chest tubes can be placed via less invasive procedures, because a common reason cited to use larger and sometimes multiple tubes is to facilitate evacuation of blood and clots, which tend to more easily obstruct the smaller tubes.[17] In addition to facilitating the improved function of larger-sized chest tubes (such as 32 Fr), this system will facilitate drainage in smaller diameter tubes. In recent years, surgeons have sought small-diameter alternatives to the standard chest tubes used after most heart and lung surgery procedures. The intent is that by using small-diameter tubes, the patient's pain will be lessened and recovery hastened. Small-diameter tubes, however, are more likely to become clogged, which can result in a poor outcome.[19] Thus, there is an unmet clinical need to facilitate adequate drainage in smaller diameter tubes, so that they can more safely be used in cases where a minimally invasive diameter of tube (eg, 20 Fr or smaller) is used. Thus, it is anticipated that this approach ultimately will help to reduce pain and facilitate recovery by allowing the use of fewer, smaller-diameter chest tubes and by minimizing the complications, such as pneumothorax, pleural effusions, or tamponade, which can delay or compromise the course of recovery.

Further studies are in progress to determine if this device will consistently result in improved drainage and lower the rate of retained hemothorax, pleural effusion, and pneumothorax compared with a standard chest tube. Additional studies are also planned to determine if this system will allow the use of smaller diameter chest tubes in the setting of bleeding and thick secretions while maintaining flow characteristics comparable with those of larger-diameter or multiple tubes.

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REFERENCES

1. Jones PM, Hewer RD, Wolfenden HD, et al. Subcutaneous emphysema associated with chest tube drainage. *Respirology*. 2001;6:87–89.
2. Watkins JA, Spain DA, Richardson JD, et al. Empyema and restrictive pleural processes after blunt trauma: an under-recognized cause of respiratory failure. *Am Surg*. 2000;66:210–214.
3. Meyer DM, Jessen ME, Wait MA, et al. Early evacuation of traumatic retained hemothoraces using thoracoscopy: a prospective, randomized trial. *Ann Thorac Surg*. 1997;64:1396–1400; discussion 1400–1401.
4. Velmahos GC, Demetriades D, Chan L, et al. Predicting the need for thoracoscopic evacuation of residual traumatic hemothorax: chest radiograph is insufficient. *J Trauma*. 1999;46:65–70.
5. McGillicuddy D, Rosen P. Diagnostic dilemmas and current controversies in blunt chest trauma. *Emerg Med Clin North Am*. 2007;25:695–711, viii–ix.
6. Baumann MH. What size chest tube? What drainage system is ideal? And other chest tube management questions. *Curr Opin Pulm Med*. 2003;9:276–281.
7. Duncan CR, Erickson RS, Weigel RM. Effect of chest tube management on drainage after cardiac surgery. *Heart Lung*. 1987;16:1–9.
8. Lim-Levy F, Babler SA, De Groot-Kosolcharoen J, et al. Is milking and stripping chest tubes really necessary? *Ann Thorac Surg*. 1986; 42:77–80.
9. Milas BL, Jobes DR, Gorman RC. Management of bleeding and coagulopathy after heart surgery. *Semin Thorac Cardiovasc Surg*. 2000;12: 326–336.
10. Knauss PJ. Chest tube stripping: is it necessary? *Focus Crit Care*. 1985;12:41–43.
11. Wallen M, Morrison A, Gillies D, et al. Mediastinal chest drain clearance for cardiac surgery. *Cochrane Database Syst Rev*. 2004:CD003042.
12. Pierce JD, Piazza D, Naftel DC. Effects of two chest tube clearance protocols on drainage in patients after myocardial revascularization surgery. *Heart Lung*. 1991;20:125–130.
13. Duncan C, Erickson R. Pressures associated with chest tube stripping. *Heart Lung*. 1982;11:166–171.
14. Halejian BA, Badach MJ, Trilles F. Maintaining chest tube patency. *Surg Gynecol Obstet*. 1988;167:521.
15. Day TG, Perring RR, Gofton K. Is manipulation of mediastinal chest drains useful or harmful after cardiac surgery? *Interact Cardiovasc Thorac Surg*. 2008;7:888–890.
16. Halm MA. To strip or not to strip? Physiological effects of chest tube manipulation. *Am J Crit Care*. 2007;16:609–612.
17. Shalli S, Saeed D, Fukamachi K, et al. Chest tube selection in cardiac and thoracic surgery: a survey of chest tube-related complications and their management. *J Card Surg*. 2009;24:503–509.
18. Light RW, Rogers JT, Moyers JP, et al. Prevalence and clinical course of pleural effusions at 30 days after coronary artery and cardiac surgery. *Am J Respir Crit Care Med*. 2002;166(12 Pt 1):1567–1571.
19. Clark G, Licker M, Bertin D, et al. Small size new silastic drains: life-threatening hypovolemic shock after thoracic surgery associated with a non-functioning chest tube. *Eur J Cardiothorac Surg*. 2007;31:566–568.

CLINICAL PERSPECTIVE

This is a novel device that assists in maintaining chest tube patency by clearing clots and debris. A guidewire with a loop rests within the chest tube and is used to mechanically break up debris. The guidewire is moved back and forth by the clinician by sliding a magnetic shuttle guide that is coupled to the end of the guidewire and resides outside the tube. It is a disposable single-use system. This type of device has the potential of providing a unique way to prevent of occluded drainage tubes and avoid complications such as tamponade, pneumothorax, and sepsis. It may also allow for the use of smaller chest tubes with less patient discomfort. However, the authors have presented no clinical data to support the clinical utility of this device, and thus its advantages remain hypothetical.

4. OTHER ORIGINAL PUBLICATIONS

1- Saeed D, Zahr R, **Shalli S**, Fumoto H, Horai T, Anzai T, Arakawa Y, Dessoffy R, Catanese J, Golding LAR, Fukamachi K. Median sternotomy approach for chronic bovine experiments. ASAIO J 2008;54:585-588.

2- Fukamachi K, Saeed D, Massiello AL, Horvath DJ, Fumoto H, Horai T, Zahr R, **Shalli S**, Anzai T, Dessoffy R, Catanese J, Chen JF, Zhou Q, Benefit S, Alfini S, Golding LA. Development of DexAide right ventricular assist device: Update II. ASAIO J 2008; 54:589-593.

3- Shalli S, Saeed D, Fukamachi K, Gillinov M, Cohn WE, Perrault LP, Boyle EM. Chest Tube Selection in Cardiac and Thoracic Surgery: A Survey of Chest Tube-Related Complications and Their Management. J Card Surg 2009;24:503-509.

4- Horai T, Fumoto H, Saeed D, Zahr R, Anzai T, Arakawa Y, **Shalli S**, Ootaki C, Catanese J, Dessoffy R, Tan CD, Rodriguez ER, Massiello A, Young JB, Fukamachi K.. Novel Implantable Device to Detect Allograft Rejection after Heart Transplantation. Circulation, 2009;120:S185-S190.

5- Shalli S, Boyle EM, Saeed D, Fukamachi K, Cohn WE, Gillinov AM. The Active Tube Clearance System: A Novel Bedside Chest-Tube Clearance Device. Innovations 2010; 5:42-47.

6- Saeed D, Massiello A, **Shalli S**, Fumoto H, Horai T, Anzai T, Golding LAR, Fukamachi K. Introduction of fixed-flow mode in the DexAide right ventricular assist device. J Heart Lung Transplant 2010;29:32-36.

7- Zahr R, Saeed D, Fumoto H, Horai T, **Shalli S**, Anzai T, Arakawa Y, Dessoffy R, Catanese J, Massiello A, Litwak KN, Fukamachi K. A pilot study for inducing chronic heart failure in calves by means of oral monensin. Int J Biomed Sci 2010; 6(1):1-7.

8- Saeed D, **Shalli S**, Fumoto H, Ootaki Y, Ootaki C, Horai H, Anzai T, Zahr R, Horvath D, Massiello A, Dessoffy R, Chen JF, Catanese J, Golding LAR, Fukamachi K. In Vivo Evaluation of Zirconia Ceramic in the DexAide Right Ventricular Assist Device Journal Bearing. Artificial Organs 2010;34:146-149.

9- Saeed D, Kidambi T, **Shalli** S, Lapin B, Malaisrie SC, Lee R, Cotts WG, McGee EC Jr. Tricuspid valve repair with left ventricular assist device implantation: is it warranted? J Heart Lung Transplant. 2011 May;30(5):530-5.

10- McCarthy PM, Kruse J, **Shalli S**, Ilkhanoff L, Goldberger JJ, Kadish AH, Arora R, Lee R. Where does atrial fibrillation surgery fail? Implications for increasing effectiveness of ablation. J Thorac Cardiovasc Surg. 2010 Apr;139(4):860-7.

4. DISSCUSSION

Cardiothoracic surgeons continuously face a dilemma when choosing a method of postsurgical chest-tube drainage. They must balance their concerns for patient safety that is jeopardized by clogging and dysfunction of tubes with their desire to limit patient discomfort. At the bedside, nurses are challenged by and frustrated with the task of directly managing chest-tube-related pain and clogging. This study was designed to assess attitudes of practicing cardiothoracic surgeons and specialty cardiac surgery nurses related to chest-tube clogging and pain to determine the factors these surgeons consider when choosing chest tubes and managing these patients. Further, based on the survey a novel device that clears clots and debris from chest tubes was developed.

The potential for clogging is one of the most important considerations in the selection of chest tubes in cardiothoracic surgery and trauma patients. Any tube used to drain a body space after surgery can become clogged. Tube clogging usually occurs in the setting of bleeding, as a thick clot can obstruct the lumen of the tube and prevent it from functioning properly. Chest-tube clogging can be life threatening in cardiac surgery for two reasons. [12, 21] First, inadequate drainage can cause internal bleeding to go unrecognized, leading to hemodynamic compromise and death. Second, undrained blood can pool in the pericardial space, creating cardiac tamponade. In addition, with air leaks after pulmonary surgery, a clogged tube can lead to pneumothorax (lung collapse), which can be another life threatening condition if left untreated.[1] Several reports have been recently published on the effectiveness of implementing protocols for chest tube clearance to avoid complications related to chest tube clogging. [22, 23]

In this study, cardiac and/or thoracic surgeons (n = 108) and cardiothoracic nurses (n = 108) responded to our survey. A total of 772 surgeon surveys were sent out by electronic mail. A total of 150 nurses surveys were distributed in the cardiac surgery intensive care unit setting. Surveys were completed by 108 of 772 (14%) surgeons and 108 of 150 (72%) nurses. The survey was constructed in two variant forms, one to surgeons (20 questions; Table 1) and another to nurses (10 questions; Table 2). The majority of participating nurses worked in an intensive care unit for postoperative heart surgery patients and had experience in managing patients with chest tubes.

The survey focused on the impact of particular factors (bleeding, clogging and patient discomfort) on surgeon's choice of chest tube and on the effectiveness of currently employed clearance methods, including milking, tapping, squeezing, folding and stripping of the chest tube, applied by nurses to minimize the potential of chest tube-related complications. Additionally, the surgeon's survey assessed the doctors' experience with alternative methods of chest drainage, including heparin-coated tubes and Blake drains. Finally, some questions were specifically focused on the impact of chest-tube size and methods of management on patient pain and discomfort.

Most questions were answered with one of four percentage ranges (from 0-24%, 25-49%, 50-74%, and 75-99%) and finally 100%. For some questions, the answers were divided into any of four answers for ease of selection: completely negative, partially negative, totally positive, and partially positive. Some questions needed simply a "yes" or "no" answer. The survey questionnaires were prepared by a group of surgeons and nurses with extensive experience related to all aspects of chest tube-related care.

Table 1 shows response of the surgeons. All the 106 surgeons responding had seen chest-tube clogging and nearly all reported adverse patient outcomes from clogging. Nurses caring for patients with chest tubes reported a similar experience. For the surgeon, the potential for clogging is a major consideration. In this survey, adverse patient outcome related to clogging was experienced by 93/106 (87.7%) surgeons and 87/107 (81.3%) nurses. This experience influenced the surgeon's choice of chest-tube size. Ninety-two of 106 (86.8%) surgeons reported that concern for the potential clogging within a chest tube affects their choice of chest-tube diameter (e.g., 36 F vs. 20 F).

Concern about postoperative bleeding had an important impact on the decision of most appropriate chest tube size. In particular, 47/106 responding surgeons (44.3%) reported that they are more likely to insert a larger diameter tube in the setting of anticipated bleeding. In contrast, 22/106 surgeons (20.8%) would not let bleeding influence their choice of the size of chest tube selected. In addition, 71/106 surgeons (67%) routinely placed more than one large chest tube when clogging was anticipated in more than 50% of times.

Regarding chest tube related pain and discomfort, surgeons and nurses reported the potential for chest tubes to cause pain. Eighty-five of 102 responding surgeons (83%) considered the pain resulting from a chest tube to be significant after a cardiothoracic procedure. In addition, 76/102 surgeons (74%) reported that the level of patient discomfort is related to the diameter of the chest tube. Ninety-seven of 106 responding nurses (91%) reported that pain is moderate to severe in patients with chest tubes. Further, considering chest-tube management, sixty-five of 106 responding surgeons (61.3%) reported that they have standard protocols to manage chest tube clogging. These protocols include milking, tapping, squeezing, folding and

stripping the chest tube. Regarding stripping of the chest tube, this procedure is allowed by 78/106 surgeons (73.6%), discouraged by 24/106 (22.6%) and forbidden by 4/106 (3.8%) of the surgeons. In contrast, 76/106 responding nurses (71.7%) asserted that stripping the chest tube was not allowed as a means to manage the clogged chest tube at their institution. Over half of all surgeons responding were unsatisfied with available techniques to clear a clogged or clogging chest tube. 52/106 (49.1%) usually unsatisfied; 2/106 (1.8 %) completely unsatisfied; none was completely satisfied. Correspondingly, only 3/105 responding nurses (2.9%) considered the currently available techniques including tapping, milking, squeezing, or bending the tube to be completely satisfactory. Furthermore, the majority of nurses, 80/107 (74.8%), stated that management of clogged chest tubes is a time-consuming procedure that takes them away from other important care-related tasks.

When a surgeon selects a chest tube, the main question to address is the tube's internal diameter. This survey revealed that the choice of tube size nearly always involves the surgeon's perception of the risk of clogging. It is generally thought that the higher the perceived risk, the bigger the diameter of the tube chosen. If a surgeon is simply draining a small amount of air or fluid, a small-diameter tube is often chosen (20 F). Ongoing production of more viscous fluids such as blood or pus, particularly if being generated rapidly, requires a larger bore tube (32 F or 36 F) to try to limit the potential for clogging. Even these tubes, however, frequently become occluded with clotted blood, fibrinous debris, or in the case of an empyema, pus.[13] Nearly all surgeons responding reported that the potential for a patient to experience clogging within the chest tube influences the size (internal diameter) of the drainage tube selected. Furthermore,

nearly two thirds of the time, the surgeon will place more than one tube when there is concern that the clinical scenario suggests increased potential for clogging.

When clinicians caring for patients in the perioperative period following chest trauma and surgery notice that clots are forming in the visible portion of the tube external to the patient, they often undertake measures to try to remove the clot. There are several commonly used techniques for nurses to manage chest-tube drainage when bleeding and clogging occur, including milking, stripping, tapping and, in some circumstances, open suction.[17] Protocols exist in many institutions to direct how nurses manage clogging of a chest tube. However, none of these methods is considered totally reliable, and none of them is without risk of further complications. In addition, these manipulations can be painful for the patient.

One of the most controversial methods of clearing a chest tube is stripping. Stripping the connecting tubing between the chest tube and the collection canister was once one of the most commonly used techniques for trying to maintain chest tube patency. The "stripping" technique generates short bursts of extremely negative pressure at the ends of the tube. The safety of this method has been questioned, as pressures exceeding -400 cm of water can be generated adjacent to suture lines, leading some to think that this technique actually makes bleeding worse.[17] Nevertheless, because there are currently limited options to try to maintain tube patency, most surgeons allow chest tube stripping. In contrast to the surgeon's willingness to allow chest tube stripping, most nurses are under the impression that they are not allowed to strip a chest tube to keep it clear of clogging and clot.

Surgeons responding to the survey were split on their perception of current methods available to clear a clogging tube. Half felt the current methods are usually or completely

unsatisfactory, and none of the surgeons surveyed felt they are completely satisfactory. Likewise, nurses were split on the effectiveness of current techniques to clear chest tubes once they become occluded or clogged, with over half stating that the current techniques are usually or completely unsatisfactory. Furthermore, 75% of nurses felt that managing chest tube clogging takes them away from other important tasks.

Attempts at technological improvement have failed to solve the clinical problem of maintaining drain patency. Heparin-coated chest tubes were introduced with the thought that the treatment would retard clot formation. This approach seemed promising theoretically, but has not proven useful, as clot and thick material formation still occur, debris still accumulates, and the clinical benefit is generally marginal. To date, specialty coating of the tubes has done little to ameliorate the clogging issue, likely because when blood encounters the foreign surfaces of any tube, it coagulates. The surgeons who responded to our survey clearly do not believe that tube coating is the answer.

Table 1. Cardiothoracic Surgeon Chest Tube Survey

	Question	Response (%)	Response (n)
1.	**Primary specialty?**		
	Cardiac Surgery only	33.3%	36
	Cardiac and Thoracic Surgery	38.9%	42
	Thoracic Surgery only	20.4%	22
	Pediatric Heart Surgery only	2.8%	3
	Adult and Pediatric Heart Surgery and Thoracic Surgery	2.8%	3
	Other	1.9%	2
	Answered Question		**108**
	Skipped question		**0**
2.	**Region of your practice?**		
	North America	98.1%	106
	South America	0.9%	1
	Asia	0.9%	1
	Answered question		**108**
	Skipped question		**0**
3.	**Do you insert chest tubes and/or manage patients with chest tubes in your practice?**		
	Yes	100.0%	108
	No	0.0%	0
	Answered question		**108**
	Skipped question		**0**
4.	**Does the concern for the potential for clogging within a chest tube impact your choice of chest tube diameter size to be inserted into a patient (e.g. 36F vs. 20F)?**		
	Yes	86.8%	92
	No	13.2%	14
	Answered question		**106**
	Skipped question		**2**

Table 1. Continued

	Question	Response (%)	Response (n)
5.	**If you have a case in which you expect bleeding, are you more likely to insert large diameter chest tube (e.g. 36F vs. 20F)?**		
	0 to 24% of time	20.8%	22
	25% and 49% of time	3.7%	4
	50% and 74% of time	12.3%	13
	75% and 99% of time	18.8%	20
	100% of time	44.3%	47
	Answered question		**106**
	Skipped question		**2**
6.	**Does your concern for the potential for clogging in a particular case impact your choice of the number of chest tubes to be inserted?**		
	0 to 24% of time	24.5%	26
	25% to 49% of time	8.4%	9
	50% to 74% of time	18.8%	20
	75% to 99% of time	17.9%	19
	100% of time	30.2%	32
	Answered question		**106**
	Skipped question		**2**
7.	**Have you ever observed an adverse patient outcome related to chest tube clogging?**		
	Yes	87.7%	93
	No	12.3%	13
	Answered question		**106**
	Skipped question		**2**

Table 1. Continued

Question	Response (%)	Response (n)
8. Have you ever observed a blood clot or other debris clogging a chest tube (e.g. when the tube is removed or when you take a patient back to the operating room)?		
Yes	100.0%	106
No	0.0%	0
Answered question		**106**
Skipped question		**2**
9. Do you have a standard protocol(s) for nurses managing tube blood clots or debris (assume you have decided that the patient does not need to go back to the operating room)?		
Yes	61.3%	65
No	38.7%	41
Answered question		**106**
Skipped question		**2**
10. Which statement best suits your attitude towards chest tube "Stripping"?		
I allow it	73.6%	78
I discourage it	22.6%	24
I absolutely forbid it	3.8%	4
Answered question		**106**
Skipped question		**2**
11. Do you believe that the currently available techniques for nurses to deal with active chest tube clogging (for example tapping, folding, squeezing and milking the tube) in the setting of bleeding are:		
Completely unsatisfactory	1.8%	2
Usually unsatisfactory	49.1%	52
Usually satisfactory	49.1%	52
Completely satisfactory	0.0%	0
Answered question		**106**
Skipped question		**2**

Table 1. Continued

Question	Response (%)	Response (n)
12. Do you ever temporarily insert a suction catheter into a chest tube while you are closing the wound at the end of a case in the operating room?		
0 to 24% of time	36.8%	39
25% to 49% of time	10.4%	11
50% to 74% of time	11.3%	12
75% to 99% of time	17.0%	18
100% of time	24.5%	26
Answered question		**106**
Skipped question		**2**
13. In your opinion does heparin coating a chest tube significantly prevent clogging or clotting		
Yes	21.2%	22
No	78.8%	82
Answered question		**104**
Skipped question		**4**
14. Which of the following best characterizes your use pattern for small diameter (e.g. 20F) Blake drains in cardiothoracic cases?		
I have never put one in	12.6%	13
I tried them, but no longer use them	20.4%	21
I tried them, but rarely use them	34.0%	35
I routinely use them	33.0%	34
Answered question		**103**
Skipped question		**5**

Table 1. Continued

Question	Response (%)	Response (n)
15. Would you insert a small diameter Blake drain in a case where you expect significant bleeding or clogging?		
0 to 24% of time	69.6%	71
25% to 49% of time	8.8%	9
50% to 74% of time	7.8%	8
75% to 99% of time	3.9%	4
100% of time	9.8%	10
Answered question		**102**
Skipped question		**6**
16. What is the perceived advantage of using a Blake drain rather than a standard chest tube in a cardiothoracic case?		
It causes less pain	76.7%	79
Design of the drain tip	20.4%	21
Flexibility of catheter	50.5%	52
Resistance to clogging	18.4%	19
Other	9.7%	10
Answered question		**103**
Skipped question		**5**
17. What is the perceived disadvantage of using a Blake drain rather than a standard chest tube in a cardiothoracic case?		
Potential for clogging	54.4%	56
Potential for kinking	17.5%	18
Inability to clear needed volume of fluid due to tube diameter	47.6%	49
Inability to reliably clear air in setting of an air leak	35.9%	37
Other	9.7%	10
Answered question		**103**
Skipped question		**5**

Table 1. Continued

18.	**In your opinion, to what degree does chest tube pain impact a patient's overall comfort after a cardiothoracic procedure?**		
	Significant	83.3%	85
	Insignificant	16.7%	17
	Answered question		**102**
	Skipped question		**6**
19.	**Is this discomfort impacted by the diameter size of the chest tube (e.g. 36F vs. 20F)?**		
	Yes	74.5%	76
	No	25.5%	26
	Answered question		**102**
	Skipped question		**6**
20.	**Do you find that your patients with chest tubes complain of pain related to the chest tube?**		
	0 to 24% of the time	15.7%	16
	25% and 49% of the time	15.7%	16
	50% and 74% of the time	34.3%	35
	75% and 99% of the time	26.5%	27
	100% of the time	7.8%	8
	Answered question		**102**
	Skipped question		**6**

In recent years, there has been increasing interest in minimally invasive surgery and the use of smaller diameter chest tubes to limit incision size and pain after cardiothoracic interventions. Chest tubes, however, are generally considered painful to the patient by surgeons and nurses. More than 80% of surgeons responding felt that the chest tube contributed significantly to patient pain in the postoperative period (Table 1). Similarly, a high percentage of nurses caring for patients with chest tubes reported that chest tubes are associated with significant pain. Table 2 shows response of the nurses to the survey.

It has been suggested that chest-tube-related pain increases the demand for postoperative analgesia [24] and also negatively affects respiratory mechanism, consequently increasing the risk of postoperative respiratory complications. [25] In addition, pain from chest tubes could impair patients' early ambulation after surgery, increasing the risk for a thromboembolic event. [26] In this survey, the large majority of surgeons and nurses stated that the diameter size of the chest tube contributed to the degree of pain experienced by the patient. Thus the concern for clogging competes with the concern for pain for the patient when choosing a chest-tube diameter, suggesting that the surgeons are more likely to choose a larger diameter tube even though it will result in more pain for the patient.

Table 2. Nurses Chest Tube Survey

Question	Response (%)	Response (n)
1. Do you manage patients with chest tubes?		
Yes	100.0%	108
No	0.0%	0
Answered question		**108**
Skipped question		**0**
2. In what location(s) do you care for patients with chest tubes?		
In the intensive care unit	88.6%	93
On the wards	11.4%	12
In the emergency room	1.0%	1
In the operating room	2.9%	3
Other	8.6%	9
Answered question		**105**
Skipped question		**3**
3. What is the primary reason the patients for whom you provide care have chest tubes?		
After heart surgery	91.7%	99
After thoracic surgery	7.4%	8
After trauma	0.9%	1
Medical intensive care unit	0.0%	0
Other	0.0%	0
Answered question		**108**
Skipped question		**0**

Table 2. Continued

4. Do you find that your patients with chest tubes complain of pain related to the chest tube?		
0 to 24% of the time	3.7%	4
25% and 49% of the time	13.1%	14
50% and 74% of the time	30.8%	33
75% and 99% of the time	37.4%	40
100% of the time	15.0%	16
Answered question		**107**
Skipped question		**1**
5. To what degree would you say chest tube pain impacts a patient's comfort?		
None	0.0%	0
Minimal	8.5%	9
Moderate	67.0%	71
Severe	24.5%	26
Answered question		**106**
Skipped question		**2**
6. Have you ever noted a chest tube to be clogged or to contain material in the tube that impairs outflow?		
Yes	94.2%	98
No	5.8%	6
Answered question		**104**
Skipped question		**4**

Table 2. Continued

Question	Response (%)	Response (n)
7. Have you ever witnessed an adverse patient outcome from a clogged chest tube? (example includes pericardial tamponadeor progressive subcutaneous emphysema from an air leak)		
Yes	81.3%	87
No	18.7%	20
Answered question		**107**
Skipped question		**1**
8. Does your institution allow nurses to strip chest tubes and chest drainage tubing to remove clots?		
Yes	28.3%	30
No	71.7%	76
Answered question		**106**
Skipped question		**2**
9. Do you find the currently available techniques to manage chest tube clogging (i.e. tapping, milking, squeezing or bending the tube) in the setting of bleeding are:		
Completely unsatisfactory	1.9%	2
Usually unsatisfactory	48.6%	51
Usually satisfactory	46.7%	49
Completely satisfactory	2.9%	3
Answered question		**105**
Skipped question		**3**
10. Does managing chest tube clogging take you away from other important tasks?		
Yes	74.8%	80
No	25.2%	27
Answered question		**107**
Skipped question		**1**

Some surgeons have turned to the Blake-type fluted drain as a small-diameter alternative to the more commonly used polyvinyl chloride (PVC) chest drains. Only 33% of surgeons responding routinely use Blake-type fluted drains, while two thirds have tried them and rarely use them or have not tried them at all. Surgeons cited the small diameter and increased flexibility as having less potential for pain, as well as the increased flexibility of the drains as perceived advantages of the Blake drain. An overwhelming majority of surgeons responding would not use this type of drain when bleeding or thick secretions are expected, citing the potential for clogging and the inability to adequately drain a sufficient amount of air or blood as reasons to avoid these types of drains in this setting.

When chest tube clogging occurs in the setting of continued drainage requirements, this can impact recovery, leading to retained hemothorax, pleural effusion, empyema, pneumothorax, subcutaneous emphasema, and, more rarely, tension pneumothorax, pericardial tamponade, and even death. When clot is noticed forming in the tubes, efforts are undertaken to break up, strip out, or mechanically clear the clot by opening the chest tube and using a suction device to clear the internal diameter. Although these efforts are usually initiated when chest tube clot is noticed in the visible portion of the tube, chest tube occlusion from clot and other fibrinous material can occur in the proximal portion of the tube, that is, inside the patient, where it is not visible to those caring for the patient. When drainage ceases, it is usually assumed that there are no further drainage needs, and the tubes are removed, facilitating the patients continued postoperative recovery. Chest tubes, however, can become clogged while there is still fluid or air to be drained. Thus, the absence of drainage can in some cases be a false indication that adequate drainage has been achieved, especially when the chest tubes are occluded. Once the chest tubes are removed,

fluid retained in the chest is common after cardiothoracic surgery. In a study by Light et al,[27] the prevalence of pleural effusions in the patients undergoing cardiac surgery was 60%, and the prevalence of effusions occupying 25% of the hemithorax nearly 10%. In an era when maximizing optimal outcomes in the setting of more challenging cases is coupled with a clinical interest in minimizing the invasiveness of surgery, there is considerable room for improvement in the chest tubes that are commonly used in nearly all heart and lung surgery cases.

Therefore a novel active tube clearance system (Figure 1) was developed and tested.[19, 28] This novel system was developed to provide a simple mechanical mechanism to maintain patency of the chest tube without introducing harmful pressure changes in the system or compromising sterile conditions within the system. This system addresses the safety concerns that arise when chest tubes become clogged in the setting of bleeding or the production of other thick fibrous materials, for example, empyema. With this system, caregivers such as nurses can simply run the shuttle back on a periodic basis, for example, when they check and record chest tube output, and be assured that there is no clot obstructing the tube in the visible and nonvisible portion of the tube. When bleeding is noted to be brisk and thick clots are forming, the system can be used more frequently.

It is anticipated that another advantageous byproduct of this solution will be that fewer and perhaps smaller-diameter chest tubes can be placed via less invasive procedures, because a common reason cited to use larger and sometimes multiple tubes is to facilitate evacuation of blood and clots, which tend to more easily obstruct the smaller tubes. [19] In addition to facilitating the improved function of larger-sized chest tubes (such as 32 Fr), this system will facilitate drainage in smaller diameter tubes. In recent years, surgeons have sought small-diameter

alternatives to the standard chest tubes used after most heart and lung surgery procedures. The intent is that by using small diameter tubes, the patient's pain will be lessened and recovery hastened. Small-diameter tubes, however, are more likely to become clogged, which can result in a poor outcome.[21] Thus, there is an unmet clinical need to facilitate adequate drainage in smaller diameter tubes, so that they can more safely be used in cases where a minimally invasive diameter of tube (eg, 20 Fr or smaller) is used. Thus, it is anticipated that this approach ultimately will help to reduce pain and facilitate recovery by allowing the use of fewer, smaller-diameter chest tubes and by minimizing the complications, such as pneumothorax, pleural effusions, or tamponade, which can delay or compromise the course of recovery.

In an animal study, which was performed from our study group at the Cleveland Clinic, to prove the concept of this system, a 32 Fr chest tube was inserted into pleural cavities of five pigs.[28] On the left, a tube was connected to the chest canister, and on the right, the new system was inserted between the chest tube and chest canister. Acute bleeding was mimicked by periodic infusion of blood. The amount of blood drained from each chest cavity was recorded every 15 min for 2 h. After completion of the procedure, all residual blood and clots in each chest cavity were assessed. The new system remained widely patent, and the amount of drainage achieved with this system (670+/-105 ml) was significantly (P=0.01) higher than that with the standard tube (239+/-131 ml). The amount of retained pleural blood and clots with this system (150+/-107 ml) was significantly lower than that with the standard tube (571+/-248 ml) (P=0.04). Therefore, this novel chest drainage system with active tube clearance significantly improved drainage without tube manipulations.

In conclusion, our survey showed the issues associated with current post surgical chest drainage systems and necessitates innovative approaches to prevent or treat chest tube clogging when it occurs, as well as to miniaturize tube size to improve patient comfort. Innovation techniques may include adding suction systems or clearance apparatus to the chest tube that clears the tubes safely, effectively and reliably from clogging and may facilitate down sizing the currently available chest tube to minimize patient's pain and discomfort. Based on this survey, a novel chest tube system was developed and investigated in animal studies.[19, 28] The results of these animal studies were very encouraging and led to clinical application of the system with outstanding results. [29, 30]

6. REFERENCES

1. Jones PM, Hewer RD, Wolfenden HD and Thomas PS. Subcutaneous emphysema associated with chest tube drainage. *Respirology*. 2001;6:87-9.

2. Meyer DM, Jessen ME, Wait MA and Estrera AS. Early evacuation of traumatic retained hemothoraces using thoracoscopy: a prospective, randomized trial :. *Ann Thorac Surg*. 1997;64:1396-400; discussion 1400-1.

3. Watkins JA, Spain DA, Richardson JD and Polk HC, Jr. Empyema and restrictive pleural processes after blunt trauma: an under-recognized cause of respiratory failure. *The American surgeon*. 2000;66:210-4.

4. McGillicuddy D and Rosen P. Diagnostic dilemmas and current controversies in blunt chest trauma :. *Emerg Med Clin North Am*. 2007;25:695-711, viii-ix.

5. Velmahos GC, Demetriades D, Chan L, Tatevossian R, Cornwell EE, 3rd, Yassa N, Murray JA, Asensio JA and Berne TV. Predicting the need for thoracoscopic evacuation of residual traumatic hemothorax: chest radiograph is insufficient. *J Trauma*. 1999;46:65-70.

6. Baumann MH. What size chest tube? What drainage system is ideal? And other chest tube management questions :. *Curr Opin Pulm Med*. 2003;9:276-81.

7. Davies HE, Merchant S and McGown A. A study of the complications of small bore 'Seldinger' intercostal chest drains :. *Respirology*. 2008;13:603-7.

8. Horsley A, Jones L, White J and Henry M. Efficacy and complications of small-bore, wire-guided chest drains :. *Chest*. 2006;130:1857-63.

9. Duncan CR, Erickson RS and Weigel RM. Effect of chest tube management on drainage after cardiac surgery. *Heart & lung : the journal of critical care*. 1987;16:1-9.

10. Knauss PJ. Chest tube stripping: is it necessary? *Focus on critical care*. 1985;12:41-3.

11. Lim-Levy F, Babler SA, De Groot-Kosolcharoen J, Kosolcharoen P and Kroncke GM. Is milking and stripping chest tubes really necessary? *Ann Thorac Surg*. 1986;42:77-80.

12. Milas BL, Jobes DR and Gorman RC. Management of bleeding and coagulopathy after heart surgery. *Seminars in thoracic and cardiovascular surgery*. 2000;12:326-36.

13. Wallen M, Morrison A, Gillies D, O'Riordan E, Bridge C and Stoddart F. Mediastinal chest drain clearance for cardiac surgery. *The Cochrane database of systematic reviews*. 2004:CD003042.

14. Duncan C and Erickson R. Pressures associated with chest tube stripping. *Heart & lung : the journal of critical care*. 1982;11:166-71.

15. Pierce JD, Piazza D and Naftel DC. Effects of two chest tube clearance protocols on drainage in patients after myocardial revascularization surgery. *Heart & lung : the journal of critical care*. 1991;20:125-30.

16. Halejian BA, Badach MJ and Trilles F. Maintaining chest tube patency. *Surgery, gynecology & obstetrics*. 1988;167:521.

17. Day TG, Perring RR and Gofton K. Is manipulation of mediastinal chest drains useful or harmful after cardiac surgery? *Interactive cardiovascular and thoracic surgery*. 2008;7:888-90.

18. Halm MA. To strip or not to strip? Physiological effects of chest tube manipulation. *American journal of critical care : an official publication, American Association of Critical-Care Nurses*. 2007;16:609-12.

19. Shalli S, Saeed D, Fukamachi K, Gillinov AM, Cohn WE, Perrault LP and Boyle EM. Chest tube selection in cardiac and thoracic surgery: a survey of chest tube-related complications and their management. *Journal of cardiac surgery*. 2009;24:503-9.

20. Shalli S, Boyle EM, Saeed D, Fukamachi K, Cohn WE and Gillinov AM. The active tube clearance system: a novel bedside chest-tube clearance device. *Innovations*. 2010;5:42-7.

21. Clark G, Licker M, Bertin D and Spiliopoulos A. Small size new silastic drains: life-threatening hypovolemic shock after thoracic surgery associated with a non-functioning chest tube. *European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery*. 2007;31:566-8.

22. Maltais S, Davis ME, Haglund NA, Perrault L, Kushwaha SS, Stulak JM and Boyle EM. Active Clearance of Chest Tubes Reduces Re-Exploration for Bleeding After Ventricular Assist Device Implantation. *ASAIO journal*. 2016;62:704-709.

23. Sirch J, Ledwon M, Puski T, Boyle EM, Pfeiffer S and Fischlein T. Active clearance of chest drainage catheters reduces retained blood. *The Journal of thoracic and cardiovascular surgery*. 2016;151:832-838 e2.

24. Milgrom LB, Brooks JA, Qi R, Bunnell K, Wuestfeld S and Beckman D. Pain levels experienced with activities after cardiac surgery. *American journal of critical care : an official publication, American Association of Critical-Care Nurses*. 2004;13:116-25.

25. Craig DB. Postoperative recovery of pulmonary function. *Anesthesia and analgesia*. 1981;60:46-52.

26. Dean E and Ross J. Discordance between cardiopulmonary physiology and physical therapy. Toward a rational basis for practice. *Chest*. 1992;101:1694-8.

27. Light RW, Rogers JT, Moyers JP, Lee YC, Rodriguez RM, Alford WC, Jr., Ball SK, Burrus GR, Coltharp WH, Glassford DM, Jr., Hoff SJ, Lea JWt, Nesbitt JC, Petracek MR, Starkey TD, Stoney WS and Tedder M. Prevalence and clinical course of pleural effusions at 30 days after coronary artery and cardiac surgery. *American journal of respiratory and critical care medicine*. 2002;166:1567-71.

28. Shiose A, Takaseya T, Fumoto H, Arakawa Y, Horai T, Boyle EM, Gillinov AM and Fukamachi K. Improved drainage with active chest tube clearance. *Interactive cardiovascular and thoracic surgery*. 2010;10:685-8.

29. Perrault LP, Pellerin M, Carrier M, Cartier R, Bouchard D, Demers P and Boyle EM. The PleuraFlow Active Chest Tube Clearance System: initial clinical experience in adult cardiac surgery. *Innovations*. 2012;7:354-8.

30. Vistarini N, Gabrysz-Forget F, Beaulieu Y and Perrault LP. Tamponade Relief by Active Clearance of Chest Tubes. *Ann Thorac Surg*. 2016;101:1159-63.

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