

The PleuraFlow Active Chest Tube Clearance System

Initial Clinical Experience in Adult Cardiac Surgery

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Objective: To address the clinical consequences related to chest tube clogging, a novel chest drainage apparatus, the PleuraFlow Active Tube Clearance System (Clear Catheter Systems, Bend, OR), was developed. The aim of this world's first clinical experience study was to follow clinicians using the PleuraFlow system to assess usability issues and potential areas of improvement in the heart surgery setting.

Methods: A user preference study was conducted to assess how specified users (surgeons, nurses, and intensive care physicians) used the PleuraFlow system to achieve specified goals in an efficient manner. Data were collected from patient charts and by a questionnaire that they had filled.

Results: All the surgeons (n = 7) noted that the device was not any more difficult to insert than a conventional chest tube and was easy to assemble and use. There were no reports of malfunction or complications related to the installation or use of the system. A majority, 77% (24/31), of nurses felt that the device was more time efficient than stripping, milking, or tapping the chest tubes to keep them open. A majority (16/19, 84%) of the PleuraFlow chest tubes and guide tubes were removed together in one piece within 1 day of surgery (on postoperative day 1).

Conclusions: Overall, the physicians and nurses rated the PleuraFlow system positively for its ability to be incorporated into the postoperative workflow of managing the drainage of patients after heart surgery. This device may be useful to allow caregivers to be certain that chest tubes are functioning in the early hours after surgery, when active bleeding is resolving and when complications from undrained blood can ensue.

Key Words: Cardiac surgery, Hemorrhage, Complications, Clogging, Blood, Chest tubes.

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Chest tubes are routinely used to evacuate air and drain blood and other fluids from around the heart and lungs in the postoperative period after heart surgery. When blood encounters the surfaces of chest tubes, there is initiation of the coagulation cascade that can lead to partial or complete chest tube clogging. Chest tube clogging with blood and other fibrinous material in the setting of continued postoperative fluid or clot accumulation can contribute to retained hemothorax, pleural effusion, and hemodynamic compromise by cardiac tamponade, which cause poor patient outcomes and even death.¹ To allay potential complications from tube clogging and obstruction, clinicians often use a dual strategy of using large-diameter tubes and redundant tube placement with the goal of maintaining patency and drainage; however, multiple tubes and large-diameter tubes are associated with increased pain, and even they may become clogged.² In an effort to address pain issues, smaller drains have been used, but not surprisingly, they have a greater propensity to clog, which limits their usefulness.^{2,3}

To address the unmet clinical needs related to chest tube clogging, a novel chest drainage apparatus, the PleuraFlow Active Tube Clearance System (Clear Catheter Systems, Bend, OR USA), was developed that incorporates an integrated internal tube clearance apparatus designed to maintain the patency of the chest tube.⁴ The aim of this study was to document the observations of clinicians using the product to discover usability issues and potential areas of improvement. This report constitutes the world's first human clinical experience with this novel system.

METHODS

The research protocol for this study was approved by the local institutional review board and ethics committee. Written informed consent was obtained from all patients enrolled in this study.

Patients

Eligible patients were between 18 and 90 years old, undergoing nonemergent cardiac surgery using cardiopulmonary bypass at a single institution. Patients undergoing emergent surgery were excluded.

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Disclosures: Edward M. Boyle, MD, is an inventor of the PleuraFlow® Active Tube Clearance System and owns stock in the company. Louis P. Perrault, MD, PhD, Michel Pellerin, MD, Michel Carrier, MD, Raymond Cartier, MD, Denis Bouchard, MD, and Philippe Demers, MD, declare no conflict of interest.

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Study Design

A user preference study was conducted to assess how different users (surgeons, nurses, and intensive care physicians) perceived the PleuraFlow system to achieve its specified goals in an effective and efficient manner and evaluate user satisfaction. Data were collected from patient charts and through follow-up interviews and surveys conducted with the implanting surgeons, intensive care unit (ICU) nurses, and intensive care physicians caring for the patients in the postoperative period. A study questionnaire was completed by the surgeon placing the chest tube, ICU nurses taking care of the patient before removal of the chest tube, and by the physician assistant or resident removing the chest tube. The questionnaires given to the subjects were developed to rate various attributes of the device. In some cases, the questions were not answered (>5%), which is reflected by a lower denominator to calculate the reply percentages.

The PleuraFlow Active Tube Clearance System

The PleuraFlow System (Clear Catheter Systems) is a chest tube clearance apparatus that uses an integrated internal tube clearance apparatus to keep the inner diameter of a tube clear of clogging material such as blood clot or fibrinous debris.⁴ The device consists of two parts: a chest tube (32 F or 20 F) and a guide tube (Fig. 1). The chest tube is placed in the usual fashion and the guide tube is inserted between the chest tube and the extension tubing that connects to the tubing to the drainage canister. When trimming the catheter after insertion, the proximal end is cut precisely where indicated to ensure proper length.⁴ This prevents the clearance member from extending beyond the end of the tube. The PleuraFlow device has an internal guide wire with a small loop at its end, which is contained within the PleuraFlow guide tube (Fig. 1).

The internal wire with a loop is advanced into the chest tube for clearance via magnetic coupling between the outer shuttle and an internal magnet on the guide wire. As the outer

shuttle is slid along the guide tube, the inner wire is moved in and out of the chest tube, allowing the distal loop to mechanically break up any clot, which is then pulled out by the suction in the drainage canister (Fig. 2). This tube clearance action is performed in a closed environment, maintaining sterility within the chest drainage system.

Surgical Procedure

Patients undergoing cardiac surgery through a median sternotomy had two chest tubes placed in the midline. One was a 32-F conventional chest tube (Teleflex, Research Triangle, NC USA). The second was a PleuraFlow Active Tube Clearance System (Clear Catheter Systems), sized 32 or 20 F. These were placed 3 cm apart, and both were positioned anterior to the heart. The surgeons were permitted to place additional pleural tube(s) at their discretion.

Instructions for the ICU Nurses

The admitting nurse in the ICU was shown how to use the PleuraFlow Active Tube Clearance System and was instructed to use the device every 15 minutes during the first 8 hours after placement, when bleeding is typically more common, then every 30 minutes for the next 16 hours, then every hour thereafter.

RESULTS

Patient Characteristics

A total of 20 patients were enrolled in the study, and 19 PleuraFlow systems were implanted in 19 different patients. One patient was enrolled, but the system was not placed in the operating room (OR), so this patient was excluded from the analysis. Ten patients had a 20-F PleuraFlow inserted and 9 patients had a 32-F PleuraFlow inserted. The age range was 51 to 83 years old, with an average of 65.3 years. Seventy-four percent were men and 26% were women. Nine patients had an isolated coronary artery bypass grafting surgery; three patients,

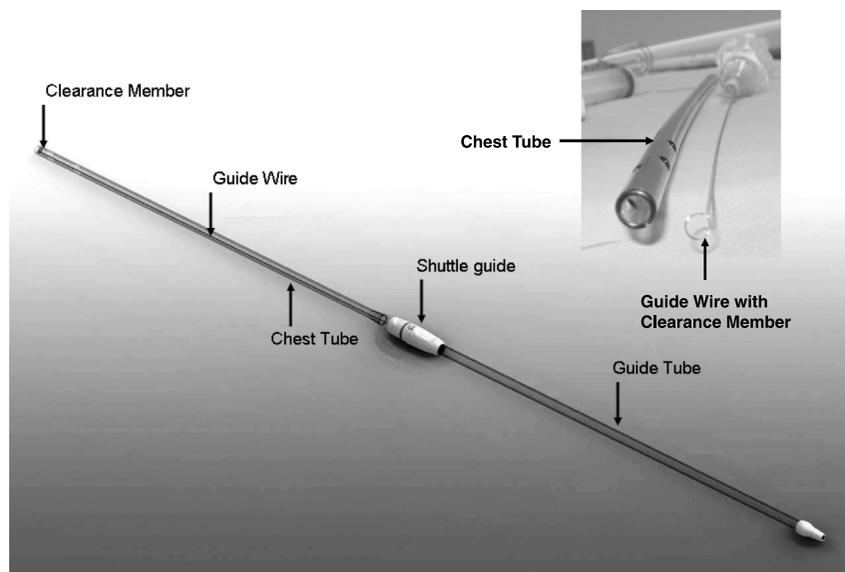


FIGURE 1. The PleuraFlow active chest tube clearance system components. Reprinted with permission from Shalli et al.⁴

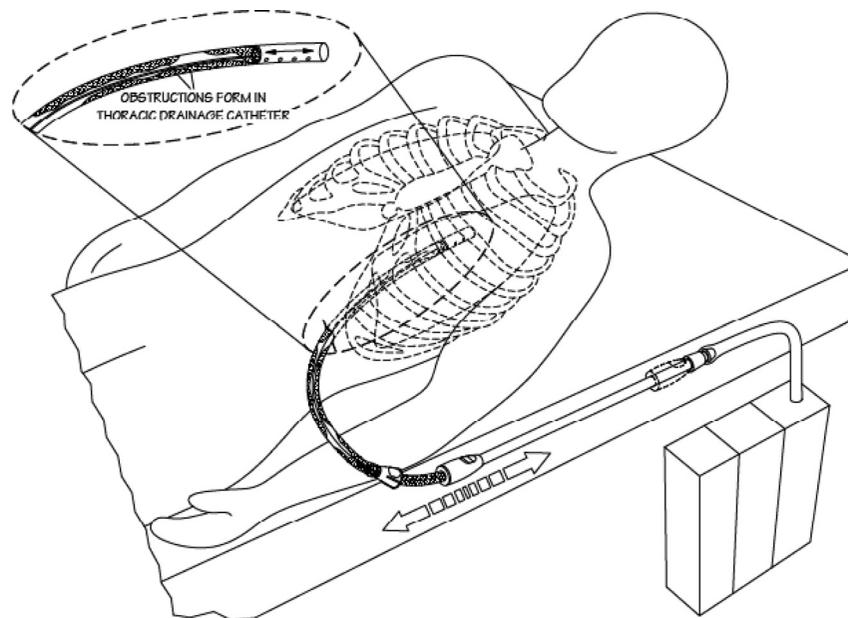


FIGURE 2. Chest tube clearance mechanism. Reprinted with permission from Shalli et al.⁴

aortic valve replacement; two patients, mitral valve repair with Maze procedure; two patients, ascending aortic replacement procedures; one patient, mitral valve replacement; one patient, reoperative mitral valve replacement; and one patient, aortic valve replacement with coronary artery bypass. The median number of hours in the ICU was 64 hours, with a range of 17 to 189 hours. The average hospital stay was 6 days, with a range of 3 to 12 days. There were no device-related complications.

Subjective Surgeon Findings

Seven different surgeons implanted the PleuraFlow Active Tube Clearance System in 19 patients in this study. None of the surgeons identified usability concerns that impacted their implantation and setup of the device. All surgeons noted that the device was not any more difficult to insert than a conventional chest tube. Furthermore, all surgeons noted that the device was easy to assemble and use and did not require a change in their routine of chest tube placement or increased time to insert and assemble the system in the OR. There were no reports of malfunction or complications related to the PleuraFlow Active Tube Clearance System before the transfer of the patient from the OR to the ICU. In one instance, the suture used to secure the tube was tight enough to cause an indentation in the tube at the skin level, which obstructed the tube from advancing past this point. It was immediately recognized and remedied before transferring the patient from the OR to the ICU. No other user issues related to the implanting surgeon were observed.

Subjective Intensive Care Nurse Findings

There were 42 intensive care nurses who responded to the surveys regarding the usability issues of the PleuraFlow Active Tube Clearance System. Ninety-eight percent (41/42) responded that the system was easy to use. All nurses responded that the product was easy to understand (41/41).

Thirty-five percent (15/39) of the nurses reported that they had to strip or milk the conventional chest tubes when they noted clot forming in them. A majority, 77% (24/31), of nurses felt that the device was more time efficient for them than stripping, milking, or tapping the chest tubes to keep them open. In addition, a majority, 86% (24/28), felt that the active tube clearance system was more effective in clearing chest tubes than stripping, milking, and tapping the tubes.

Intensive Care Physician Findings

The decision to remove the chest tube was made by the surgeon caring for the patient in the postoperative period. A majority (16/19, 84%) of the PleuraFlow chest tubes and guide tubes were removed together in one piece within 1 day of surgery (on postoperative day 1). In 1 of 19 patients, the PleuraFlow chest tube and guide tube system were left in for 2 days. In 2 of 19 patients, the guide tube was removed on day 1 and the chest tube left in for 5 and 7 days, respectively.

The ICU specialist was asked to inspect the tubes upon removal. These observations were available in 15 patients. The standard chest tubes were visually noted to be obstructed upon removal 33% (5/15) of the time. This correlated with a lack of respiratory variation in the tube just before removal. The intensivist noted some nonobstructive clot on the guide wire in the PleuraFlow chest tubes in only 13% (2/15). Respiratory variation, however, was intact in all the PleuraFlow systems, suggesting that the tubes were open and functional. Upon removal, all the PleuraFlow tubes were found to be functional.

DISCUSSION

Maintenance of chest tube patency is critical in the optimal postoperative management of the cardiac surgery patient for both monitoring of the hemostasis of the surgical field and optimization of the hemodynamic status. This is of paramount importance during the early hours after surgery, when

life-threatening complications such as cardiac tamponade may ensue if there is inadequate drainage. Bleeding diathesis in surgical patients occurs more frequently in the current era, where patients are referred for surgery having received powerful antiplatelet agents such as clopidogrel (Plavix), which is known to significantly increase postoperative bleeding and the complications from bleeding.⁵ When bleeding is noted and clotting is seen through the visible portion of the tube exiting the skin, nurses have traditionally relied on makeshift bedside maneuvers to keep chest tubes patent, such as stripping, milking, and tapping the tubes.^{1,6,7} Alternatively, caregivers sometimes rely on open chest tube suction to clear chest tubes.⁸ These methods are controversial and, at best, unproven because they have not been shown to reliably increase drainage, and the potential for complications have been cited as a concern, especially with chest tube stripping or open suctioning of the tubes. To date, no reliable method to monitor and ensure chest tube patency has been available to aid in the early postoperative management of heart surgery patients.

We describe the first clinical use of a novel active chest tube clearance apparatus, the PleuraFlow Active Tube Clearance System. This device allows users to actively clear chest tubes of clot with an external-to-internal actuated guide wire-based clearance system. The device offers a mechanical internal mechanism to maintain patency in the early postoperative period, when clogging most often occurs. The aim of this study was to examine the ease of use the PleuraFlow device and to evaluate workflow efficiencies related to maintaining chest tube patency after heart surgery.

Several significant observations were noted in this study. One finding was that nurses frequently rely on visible evidence of clotting in the conventional chest tubes to initiate efforts to maintain patency. In this study, nurses stripped, milked, or tapped the conventional tubes 35% of the time when they noted clots in the visible portion of the conventional chest tube. Chest tube occlusion can occur in the proximal portion of the tube inside the patient; however, if it is not visible to those caring for the patient, it may go unnoticed by the care providers. Therefore, relying only on visible evidence of chest tube clogging in the section of the tube that exits the skin can lead to a false sense of security that nothing is occluding the tube where the lumen is not visible. In comparison, one advantage noted with the PleuraFlow Active Tube Clearance system was the ability to be certain that the tube is patent when the clearance wire can easily be advanced and retracted. The flexible guide wire with the clearance member runs the full length of the chest tube can be an assurance that the tube is patent. Thus, if the nurse runs the clearance guide wire back and forth, which takes only a few seconds, he/she can be assured the tube is open, in contrast to conventional tubes, in which there is no way to be sure of the endocavitary portion of the tube.

An additional finding was that decoupling, when it occurs, can be a signal that there is a clot forming in the tube and that maneuvers need to be undertaken to use the clearance mechanism to clear the tube. When this was encountered, the tubes could be reopened if the nurses worked the clearance member back and forth, breaking up clots into smaller pieces and restoring the suction from the canister to draw the clots out of the chest tube.

The comparative evaluation of conventional chest tube versus the PleuraFlow Active Tube Clearance System was not the purpose of the study. Preclinical studies comparing the PleuraFlow system directly with conventional chest tubes demonstrated that the PleuraFlow was more reliable in keeping chest tubes patent and that a patent tube resulted in superior drainage and less residual hemothorax.^{4,9} This suggests that if the tubes remain open and draining, there will be far less residual hemothorax. But if they become clogged or partially clogged, the suction from the drainage canister is not transmitted to the pleural or mediastinal space and fluid can build up inside the chest and subsequently clot outside the tubes. Thus, having a mechanism to know real-time that the tube is open, and if not, to actively work to keep it open is a clear advantage compared with the reliance on visible external evidence of clotting to initiate clearance efforts with conventional chest tubes. One of the weaknesses of this study was that it was not blinded, although a randomized, blinded superiority study is not likely needed. Although the PleuraFlow is a novel and promising tool for the postoperative care of patients recovering from cardiac surgery, the documentation of consistent patency and the overall performance of the device compared with conventional chest tubes may require further assessment in the clinical setting.

In conclusion, this is the first clinical study describing an investigation carried out to identify important usability features related to a novel chest tube clearance apparatus, the PleuraFlow Active Tube Clearance System, in the early postoperative management of heart surgery patients. This investigation found that the PleuraFlow could be easily and successfully integrated into the OR setting without changing the routine and was easily understood by the nurses in the ICU caring for patients in the early postoperative period after heart surgery and that the use of the device was obvious to learn, efficient, and effective. Overall, physicians and nurses rated the PleuraFlow positively for its integration into the postoperative workflow of managing the drainage of patients after heart surgery. This device may be useful to allow caregivers to be certain that chest tubes are functioning in the early hours after heart surgery, when active bleeding is resolving, and prevent occurrence of complications from undrained blood in the pericardium or chest cavities.

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CLINICAL PERSPECTIVE

In 2010, the description of a new chest tube clearance system was published in this journal, a combined effort of the Lerner Research Institute at the Cleveland Clinic, the St Charles Medical Center (Bend, OR USA), and the Texas Heart Institute (Shalli S, Boyle EM, Saeed D, et al. The active tube clearance system: a novel bedside chest-tube clearance device. *Innovations* 2010;5:42–47). At the time, it was concerning that there were no clinical data presented.

In this article, the authors present their initial clinical results from a single institution, the Montréal Heart Institute. They have performed a small phase II observational analysis in 20 patients, seven surgeons, and 42 nurses who were willing to fill out their questionnaires. This initial report provides some evidence that the chest tube clearing system for both the 20- and 32-F chest tubes is functional and effective. It appears that there is a “learning curve” in the use of this system, and we look forward to further clinical information and refinements.