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Improved drainage with active chest tube clearance *,**

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Abstract

This study was performed to evaluate the efficacy of a novel chest drainage system. This system employs guide wire-based active chest tube clearance to improve drainage and maintain patency. A 32 Fr chest tube was inserted into pleural cavities of five pigs. 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 $(670 \pm 105 \text{ ml})$ was significantly (P=0.01) higher than that with the standard tube $(239 \pm 131 \text{ ml})$. The amount of retained pleural blood and clots with this system $(150 \pm 107 \text{ ml})$ was significantly (P=0.04) lower than that with the standard tube $(571 \pm 248 \text{ ml})$. In conclusion, a novel chest drainage system with active tube clearance significantly improved drainage without tube manipulations.

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1. Introduction

Chest tubes are routinely used to drain blood and other matter from the chest cavity after heart and lung surgery, following surgery for acute hemothorax, and in cases of chest trauma [1]. Clogging of the chest tube with blood and other fibrinous material in the setting of continued postoperative drainage can contribute to retained hemothorax, pleural effusion, empyema, pneumothorax, and subcutaneous emphysema, all of which can result in poor patient outcomes and even death [2]. To allay complications from tube clogging and obstruction, clinicians often employ large-diameter tubes, however, such large-diameter tubes are associated with increased pain. In an effort to address the issue of pain, smaller drains have been developed, but they have a propensity to clog, which limits their usefulness [3]. Furthermore, none of these methods have ever been

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proven to increase chest tube function once clogging occurs [4].

To address these clinical issues, we developed and tested a novel chest drainage system that incorporates an integrated internal active tube clearance system to keep the tube from clogging [5]. The purposes of this study were to evaluate the efficacy of this newly designed system and to test the hypothesis that active is superior to passive chest tube clearance in a swine model of acute hemothorax.

2. Materials and methods

2.1. Device design

The newly developed PleuraFlow[™] active tube clearance system (Clear Catheter Systems, Bend, OR) is a clearance apparatus that employs a guide wire-based tube clearance device to keep the inner diameter of a tube clear of clogging material, such as blood clots or fibrinous debris. This system is easily inserted between the standard chest tube and the extension tubing that leads to the collection canister (Fig. 1). The active tube clearance system consists of three parts: a 0.035 mm internal guide wire, a guide tube, and an outer polycarbonate housing. The internal guide wire has a small loop at its distal end and a magnet at the proximal end. The guide wire distal loop sits at the distal end of the standard chest tube (default position) (Fig. 2a). When the shuttle guide housing on the guide tube is manually moved along the length of the shuttle

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¹Disclosure: Dr. Boyle is the inventor on patents related to this device, owns stock in Clear Catheter Systems, and holds a paid executive position with the company. Dr. Gillinov is an inventor on patents related to this device, is a consultant to the company, and holds stock and stock options in the company. The Cleveland Clinic has an ownership position on patents licensed to the company, and holds stock in the company.

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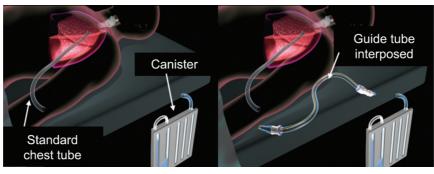


Fig. 1. Active tube clearance system connected to the standard chest tube.

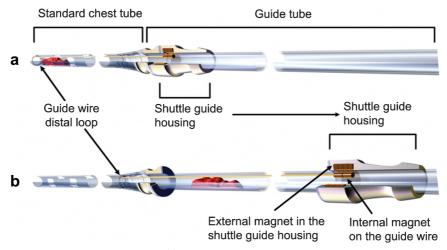


Fig. 2. Clearance action with the active tube clearance system. (a) The guide wire's loop sits at the distal end of the standard chest tube (default position). (b) When the shuttle guide housing on the guide tube is manually moved along the length of the shuttle tube toward the canister (rightwards in this figure), the guide wire also moves toward the canister due to magnetic coupling between the external magnet in the shuttle guide housing and the internal magnet on the guide wire (clearance position).

tube toward the canister, the guide wire also moves toward the canister due to magnetic coupling between the external magnet in the shuttle guide housing and the internal magnet on the guide wire (clearance position) (Fig. 2b). Therefore, when moved along the guide tube, the guide wire distal loop morcellates any clots from inside the chest tube and moves them towards the collection canister. This tube clearance action is performed in a closed environment, maintaining sterility.

2.2. Acute hemothorax model and device insertion

Five healthy pigs (Yorkshire mix, 57.2 ± 3.8 kg; Fanning Farms, Howe, IN, USA) were used to evaluate the performance of the active tube clearance system. The study was approved by the Cleveland Clinic's Institutional Animal Care and Use Committee, and all animals received humane care in compliance with the 'Guide for the Care and Use of Laboratory Animals' prepared by the Institute of Laboratory Animal Resources, National Research Council. The animals were guarantined for at least three days before use.

The animal was placed on the surgical table in a supine position under general anesthesia with isoflurane (0.5-2.5%). An arterial line was placed into both carotid arteries to draw blood for subsequent blood infusions in the chest cavities. Bilateral mini-thoracotomies were performed

through the 6th intercostal space. A 32 Fr polyvinyl chloride chest tube (COVIDIEN, Mansfield, MA, USA) and a 32 Fr silicone chest tube for the active tube clearance system were inserted into the right and left chest cavities, respectively, through the right and left 7th intercostal space. These were directed manually behind the lungs (17 cm of tubing was inserted on each side). The chest tube of the active clearance system was connected to its clearance device, located between the chest tube and the tubing to the drainage canister (Fig. 1). The extension tube was adjusted so that it was equidistant from the blood chamber and the skin, then the blood chamber (-20 cm H_20) was connected to each chest tube. Acute bleeding was mimicked by the periodic infusion of blood into the pleural cavities as described in detail below [6]. A soft catheter, 10 cm in length, was inserted through the thoracotomy incision into the pleural cavity on each side to allow blood injection into the pleural space. A 0-Prolene suture was placed on each lung about 2 cm from the lung edge to enable the investigators to induce distal lung injury and hemorrhage later in the procedure by pulling both ends of the placed suture and tearing the lung tissue to activate the coagulation system. The thoracotomies were closed. Once the sutures were pulled to induce lung injury at the beginning of the procedure, blood (120 ml) was injected

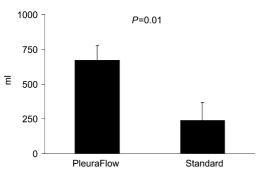


Fig. 3. Total amount of drainage with active tube clearance system vs. the standard tube.

into the pleural space through the catheters. The chest tube clamps were released to allow drainage just after blood infusion. Intravenous fluid resuscitation was employed to keep the mean arterial pressure above 60 mmHg. Every 15 min, another 120 ml of blood was withdrawn from the arterial line and infused into each pleural cavity (a total of seven times) until a total of 840 ml of blood had been introduced into each pleural cavity in the same manner. The amount of blood drained from each thoracic cavity was recorded every 15 min for 2 h. The active tube clearance system incorporated active drainage by an internal clearance by the guide wire every 15 min (a 5-s process); neither chest tube was milked, tapped, or stripped.

2.3. Autopsy evaluation

At the end of 2 h, the animals were sacrificed by intravenous administration of potassium chloride (120 mEq) under deep anesthesia with 5% isoflurane, and a median sternotomy was performed. Both chest tubes were evaluated to confirm correct placement inside the chest cavities away from the injection catheters. Lung injury was assessed on both sides. All residual blood and clots in each pleural space were removed and weighed. After removal, the inside of each tube was inspected macroscopically for thrombus formation.

2.4. Statistical analysis

All data are expressed as mean \pm standard deviation (S.D.). A paired Student's *t*-test was performed to analyze data about the amounts of drainage and residual blood and clots. In all analyses, a value of *P*<0.05 was considered statistically significant.

3. Results

Drainage with the new active tube clearance system $(670 \pm 105 \text{ ml})$ was significantly higher than that with the standard chest tube $(239 \pm 131 \text{ ml}, P=0.01)$ (Fig. 3). The volume of clot and blood remaining in the chest with the new system $(150 \pm 107 \text{ ml})$ was significantly lower than the volume remaining with the standard chest tube $(571 \pm 248 \text{ ml}, P=0.04)$. It was confirmed that both tubes were correctly placed inside the chest cavities. Both lungs were successfully torn by pulling the sutures placed on the

lungs, still showing bleeding and air leakage at the end of the procedures. Many clots were found inside all standard tubes, almost totally occluding the lumen, however, there was minimal clot formation with no significant obstruction of the inner diameter in any of the active clearance system's tubes.

4. Discussion

This is the first study to demonstrate that an active chest tube clearance system significantly improved drainage compared to a standard chest tube of the same size. The operation of the clearance apparatus was judged by the operators as simple, and at autopsy, it was noted that this method kept the actively managed chest tubes from clogging within the internal diameter of the tube. In addition to keeping the chest tubes clear of clots, the use of this new system translated into significantly improved drainage vs. the standard chest tube, without chest tube manipulation. This study suggests that this clearance system may provide clinicians with a better way to safely manage the growing number of patients with a tendency to bleed when on powerful antiplatelet agents and who need to maintain patent chest tubes while their platelets are replaced in the early postoperative period [7]. In some cases with this system, some blood and clot remained in the pleural cavity and may have been due to the supine position of the animals. However, such retained blood was substantially less than the amount observed with standard drainage tubes. This result is consistent with the clinical impressions of many surgeons and nurses who routinely manipulate chest tubes; they assert that something active should always be done to the tube to address clogging whenever it is suspected [8].

This new system appears to offer an excellent alternative to time-consuming and sometimes ineffective methods of milking and stripping chest tubes. Given the demonstrated ease of use, this device may serve to free healthcare providers to carry on with other activities in the postoperative management of the patient, while allowing them to periodically actuate the device to ensure that the tube is free of any internal clogging and thus is draining adequately. One important design advantage of this system is that the internal diameter of the chest tube, including the proximal portion that is inside the patient, can be cleared as needed without breaking the sterile seal.

A subsequent hypothesis that will be tested with the active tube clearance system is that an active clearance mechanism allows a small-diameter chest tube to drain better than a large-diameter chest tube managed passively.

There is one consideration in the chest tube material evaluated in this study. We used silicone for PleuraFlow because this material is considered more flexible and less painful to patients [8]. However, we used polyvinyl chloride for the standard chest tubes in this study because a majority of chest tubes in contemporary practice are polyvinyl chloride tubes.

In conclusion, active chest tube clearance with an easyto-use, internally contained tube clearance apparatus significantly improved drainage and reduced the degree of retained hemothorax compared to a standard chest tube.

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