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ORIGINAL ARTICLE

Novel self-fixation chest drain device tested in a swine model of pneumo-hemothorax

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ABSTRACT

Introduction: Thoracic injuries account for 20–25% of trauma-related deaths. In cases of pneumothorax the insertion of a chest tube is mandatory but associated with high complication rates particularly when inserted under difficult conditions. The C-Lant is a novel chest-tube insertion device that provides integrated double fixation capabilities and can be used by responders with minimal experience. The aim of the study was to test the device in a large animal model.

Material and methods: Pneumothorax, tension pneumothorax, and hemothorax were induced in four white domestic female pigs. The C-Lant device (Vigor Medical Technologies, Haifa, Israel) was inserted as any chest-drain to decompress the thorax. Pull test was applied to test the strength of device fixation.

Results: The insertion of the device was simple and effective without detectable negative physiological effects. Reliable fixation was achieved without difficulty. Air and liquid were promptly drained from the chest cavity. Minimal tissue laceration occurred when applying the device in a scenario of erroneous pneumothorax diagnosis with fully expanded lungs. Interconnection with other surgical accessories was smooth.

Conclusion: The C-Lant is a novel device that facilitates easy insertion and fixation of chest-tubes by minimally experienced medical providers and reduces the likelihood of unwanted expulsion. Clinical studies are planned.

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Pneumothorax; chest trauma; thoracic injury; chest drain; pre-hospital care

Introduction

Thoracic injuries account for 20–25% of trauma-related deaths in the US [1] and UK [2]. These include blunt force mechanisms, such as motor vehicle collisions, or penetrating mechanisms including stab or gunshot wounds. Air (pneumothorax) or blood (hemothorax) in the pleural cavity may result in respiratory failure and/or cardiovascular dysfunction requiring urgent intervention [2,3]. In the military setting, 20% of thoracic injuries are reportedly associated with a traumatic hemo-pneumothorax [4] with the latter considered the third leading cause of death [5].

Treatment modalities include combinations of chest seals, needle thoracentesis, and chest tubes [3,5]. Treatment selection depends on factors including the indication, medical personnel experience, field conditions, distance to definitive care facility, expected evacuation time, and local treatment guidelines [6]. The chest tube (chest drain or tube thoracostomy) is considered the gold standard and often represents definite treatment [7]. The flexible tube is usually inserted in an area described as the "safe zone" accessed through the fifth intercostal space anterior to the mid-axillary line. This permits draining of air/fluid while reducing the danger of injuring internal organs. The tube is then sutured to the skin for fixation [8]. This lifesaving procedure requires quick and effective performance. As such, it is particularly stressful for non-experienced providers and especially so under hostile conditions. The most frequent complication, particularly under difficult field conditions, is unwanted dislodgement and expulsion. [9]. According to a recent systematic review,

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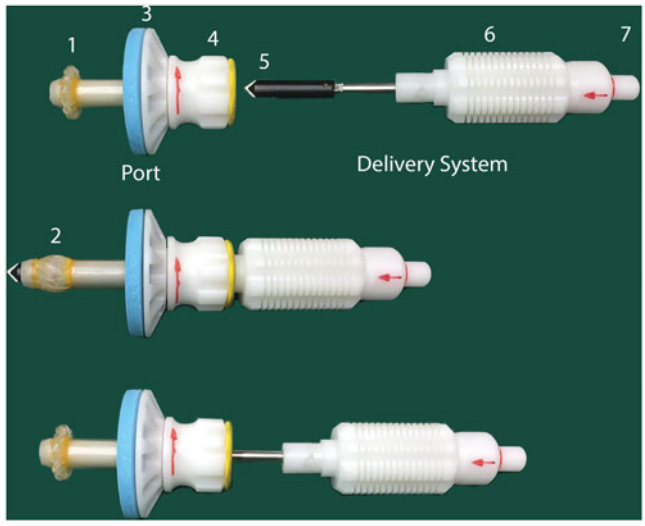

Figure 1. C-Lant device description. The C-Lant is a disposable, self-fixating chest drain device. It includes a port (1–4) and a delivery system (5–7) (A). The port is composed of an internal fixation component connected to the device shaft that can change from an expanded, protruding flower-like configuration (1) to a collapsed tube-like configuration (2). An external fixation disk made of foam adjacent to a plastic disc is in contact with the external surface of the chest wall (3), and a rotatable sealing system (4) provides for fixation of the inserted tube. The delivery system is composed of a handle (6) that has a blade (5) on one end and a button that controls the blade (7) on the other end. The delivery system is inserted into the port (middle picture). By pushing the button, the blade springs out and the internal fixation disk transforms to collapsed form. In order to insert the port into the chest wall, the blade is used to create an entry by applying force on the external skin between the ribs. When the blade passes through the chest wall, and pressure is decreased, the blade automatically retracts thereby preventing unintentional damage to surrounding and internal tissue (e.g., lung, heart). Removal of the central delivery system (lower picture) results in a configurational change of the internal fixation disk from the collapsed to the expanded flower-like configuration. In this configuration, the device is fixed to the internal surface of the thoracic wall. The external fixation disc limits the depth of insertion, while the foam part enables adjustment to the individual thoracic wall. At this stage, a chest tube, or any available catheter/tube, can be inserted, instead of the delivery system, at any required depth through the shaft of the port body into the pleural cavity, draining air and liquid. Once inside, the sealing system is rotated clockwise around the accessory tube to achieve hermetic seal and fixation. Removal of the device is accomplished by counterclockwise rotation of the sealing system, removing the drainage tube and re-inserting the delivery system that results in a configurational change of the internal fixation disk back to the collapsed form. The device is then pulled out of the thoracic cavity.

positional complications related to chest tubes occur in more than 50% of cases. Other complications related to insertion, removal, and infections occur in approximately 15% of the cases each [10]. The C-Lant, tested in the current study (Figure 1), is a relatively simple, disposable, self-fixating port that allows for rapid insertion, fixation and replacement of any standard chest tube while dramatically reducing the likelihood of the most common complication of test tube insertion – dislodgement and untoward expulsion. The objective of the current study was to test the feasibility and safety of this novel device in a pig model of hemo-pneumothorax including the ease-of-application and interface with other standard accessories.

Material and methods

This study was approved by the Institutional Animal Care and Use Committee (IACUC) of The Hebrew University of Jerusalem (MD-13–13751-3) and conformed to the *Guide for the Care and Use of Laboratory Animals*, (National Academy Press, Washington, D.C. 1996). Animals were cared for in the institutional animal facility accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Study overview

Following general anesthesia, female pigs were positioned in the right lateral decubitus position, and a 10 mm trocar and thoracoscope were inserted under vision into the left thoracic cavity. Pneumothorax was created by insufflation of CO_2 gas using the trocar port. Hemothorax was simulated by injection of 2 L of methylene blue colored water into the thoracic cavity. Following a skin incision, the C-Lant device was inserted into the thoracic cavity and its performance was tested for ease of draining air/liquid, adequacy of sealing, and strength of fixation to the chest wall. Hemodynamic and respiratory parameters were

monitored and documented every five minutes throughout the study. Thoracoscopy was used to monitor any sign of tissue damage. At the end of the experimental procedures, the animals were euthanized, and the thoracic cavity was examined. This model is frequently used in large animal chest trauma studies [11].

Animals

Four white domestic female pigs (Laboratory Animals Farm, Lahav, Israel), age four months (41–50 kg), were acclimated in the facility for at least seven days before intervention. Water and appropriate normal diet were available ad libitum. On the night before the procedure, food was withdrawn, but the animals had unlimited access to water.

C-Lant device and accessories

The C-Lant device (Vigor Medical Technologies LTD., Haifa, Israel) is a disposable, self-fixating port, intended to allow insertion, fixation and replacement of any standard tube for effective chest drainage. See Figure 1 for a detailed description of the device and application protocol. The device consists of a port and a delivery system (Figure 1).

Since porcine skin is thicker than human skin, the device was inserted through a pre-made cut through the outer layers. The device blade was then used to cut through the intercostal muscles and fascia. The intended use in humans does not include performing a skin cut before using the device.

Anesthesia and vital sign monitoring

Animals were sedated with Xylazine (1 mg/Kg, IM, Eurovet Animal Health B.V., Bladel, Netherlands) followed by induction with Ketamine (10 mg/Kg, IM, Vétoquinol S A, Lure, France). The ear vein was then cannulated for intravenous administration of a mixture of Diazepam (2 mg, IV, TEVA Pharmaceutical Industries Ltd., Jerusalem, Israel), Ketamine (400 mg, IV), Propofol (1-4 mg/Kg, IV, Fresenius Kabi Austria Gmbh, Linz, Austria), and Tramadol (5 mg/Kg, IM, Rafa Laboratories Ltd. Israel) for analgesia. Cefazolin (1 g, IV, Panpharma S.A., Luitré, France) was administered for prophylaxis. The pigs were then intubated with a cuffed silastic endotracheal tube (7.0-mm, Portex Tracheal Tube, Kent, UK). Anesthesia was maintained with 2% isoflurane (Piramal Critical Care Inc., Bethlehem, PA, USA) in 100% oxygen. Animals were mechanically ventilated (Excel 210-SE anesthesia machine m-Datex-Ohmeda Inc, Madison, WI, USA or Narkomed-2B Anesthesia Machine – North American Drager, Houston, TX, USA) with tidal volumes of 10 ml/kg and a respiratory rate of 13–15 breaths per minute adjusted to an end-tidal CO_2 ($EtCO_2$) of 35 mmHg at baseline. The pigs were placed on a warming blanket set at 39 °C to maintain body temperature that was monitored rectally.

Hemodynamic and respiratory parameters were monitored as follows: The left common carotid artery was cannulated using an over-the-wire (Seldinger) technique with an introducer (Cordis, Fremont, CA, USA) for invasive blood pressure monitoring and heart rate. Systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, heart rate, arterial oxygen saturation, and $ETCO_2$ were monitored continuously using a Datex-Ohmeda Cardiocap 5 (Datex-Ohmeda Inc., Madison, WI, USA). Peak pressure and tidal volume were monitored by the Excel 210 SE Anesthesia Machine (Datex-Ohmeda Inc, Madison, WI, USA). All parameters were documented every five minutes to allow proper stabilization of the animals. Continuous three-lead ECG monitoring (Datex-Ohmeda Inc., Madison, WI, USA) was obtained throughout the study.

Observing the thoracic space

A thoracoscope (STORZ 264305 20 Endoscope SCB Electronic Endoflator; STORZ Aida Control 200961 20; STORZ xenon nova 300 201340 20; STORZ tricam SL II; KARL STORZ Industrial-America, Inc. Segundo, CA, USA) was inserted into the thoracic space through a skin incision for observation of the thoracic cavity and position of the heart and lungs.

Induction of pneumothorax and hemothorax

Pneumothorax was induced by insufflation of CO_2 gas through the trocar port. The extent of pneumothorax was controlled by visual inspection of the collapsed lung and monitoring the amount of CO_2 gas insuflated into the thoracic cavity. A separate standard chest tube (Argyle, Sherwood medical, Tullamore, Ireland) was inserted to relieve the pneumothorax when needed, but during the experimental phases it was occluded to enable valid simulation. Hemothorax was simulated by introducing 2 L of methylene blue-colored water into the thoracic cavity using a funnel through drainage tube (not through the port). This enabled easy monitoring of fluid flow and drainage.

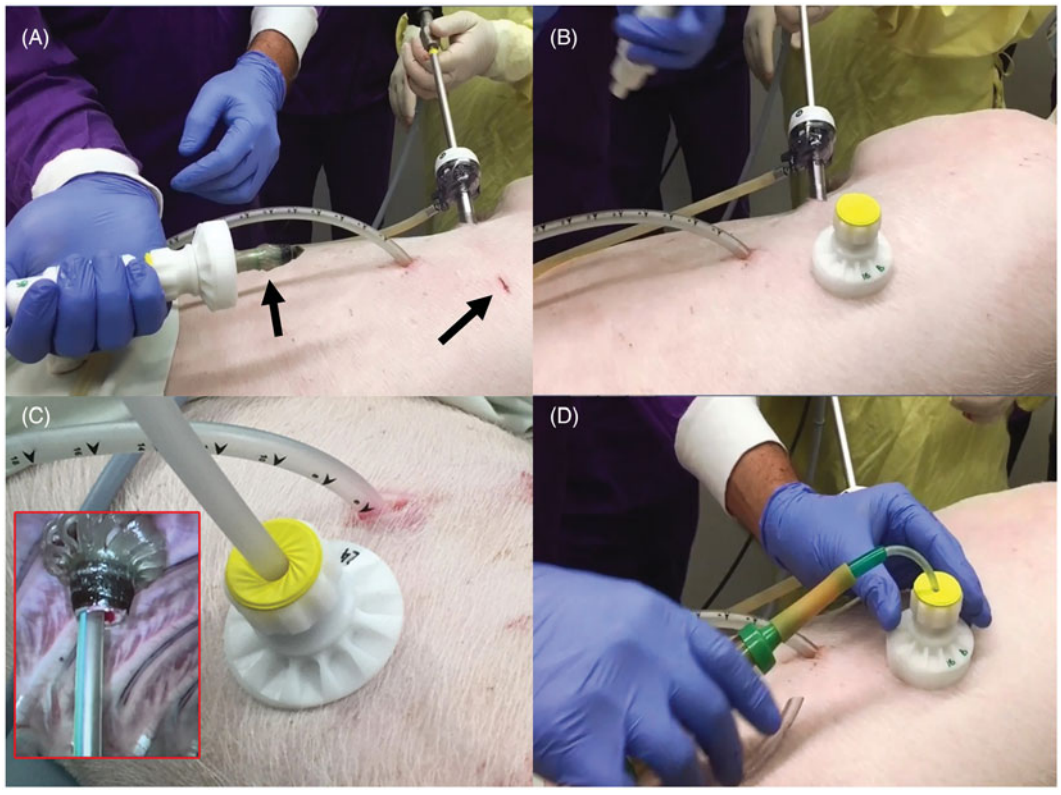

Figure 2. Experimental procedures. (A) The port was inserted through a pre-made cut (right black arrow) in the thoracic wall of an anesthetized pig. Note the blade is pointed to the direction of the cut and the internal fixation element is in its collapsed "tubelike" configuration (left black arrow). (B) The port after insertion with the sealing element closed. (C) A drainage tube was introduced through the port and fixed to it hermetically with the sealing element. The inset shows the port and the drainage tube from the thoracic cavity as viewed via the thoracoscope. Note the "flower-like" open configuration of the internal fixation component that fixes the port to the internal thoracic wall thereby preventing the port from exiting the thoracic wall. A second drainage tube is adjacent to the port and used to induce pneumothorax or hemothorax. (D) Other surgical accessories can be inserted into the port – in this example a suction tube is connected to the port.

Experimental procedures

After anesthesia was established, a skin incision was made to introduce the trocar and thoracoscope in order to achieve visualization of the thoracic cavity. Under direct view, a standard chest tube was inserted into the thoracic cavity for controlling the pneumothorax. A separate skin incision was made for the insertion of the C-Lant port (Figure 2(A)). The insertion was preceded by measurement of the thickness of the chest wall at the location of the incision using a Veress needle (120 mm Pneumoneedle, Ethicon endo-surgery, LLC 2007, Guaynabo, Puerto Rico, USA). Three experimental phases followed: In the first phase, after insertion of the C-Lant port (Figure 2(B)), a drainage tube was introduced and fixed hermetically with the device sealing system (Figure 2(C)). The pneumothorax was then drained by the tube through a one-directional, Heimlich valve (Bard-Parker, Becton Dickinson and Company, Franklin Lakes, NJ, USA) to a collection bag (Narang medical limited, New Delhi, India) which was then connected to a surgical suction system. The second phase was performed following evacuation of the pneumothorax and re-inflating the lungs to full capacity, and removal of the C-Lant. The C-Lant port was then re-introduced to test whether the blade injured the lung tissue. Damage was monitored using direct view of the thoracoscope and re-assessed during necropsy after euthanasia. In the third phase, "hemothorax" was induced and drained as described above. To test if the fixed port was hermetically sealed in cases of hemothorax (colored water was inside the thoracic cavity), the animals were turned from one side to the other, and the perimeter of the port was inspected for any leak of blue liquid.

The strength of the fixation of the port to the chest wall was determined by measuring the amount of force required to dislodge the C-Lant port using a dynamometer (Deluxe Electrical Corporation, Mumbai, India). The external part of the port was connected to the dynamometer using surgical sutures (ETHICON MERSILK Braided Silk Suture W225,

Livingston, Scotland). The dynamometer was then gradually pulled from the device in different directions (perpendicular, in parallel, and along the axis of the device fixation) until dislodgement, or until reaching a maximum force of 58.8 Newton (in this device, 1 Kg is ~10 Newton). The force reached was recorded. The fixation strength of the chest tube achieved by the device's rotating sealing element was tested similarly. At the conclusion of the tests, the C-Lant port was removed and the animals were euthanized by an intravenous injection of KCl solution (Fagron Group BV, Rotterdam, Netherlands). The skin of the animals in the area of C-Lant insertion was examined for any evidence of trauma. Researchers were asked about the ease of insertion, speed of fixation, and ease of port removal.

Results

The port was inserted with ease through a pre-cut incision in 29 separate repeats (seven or eight repeats in each of four animals) (Figure 2(A)). The blade of the device cut through the intercostal muscles without difficulty. Once the port was inserted and the delivery system removed (Figure 2(B)), the internal fixation component was deployed and fixation to the internal surface of the thoracic wall was achieved as viewed via the thoracoscope (Figure 2(C) inset). The fixation was reliably achieved in all 29 attempts. Sealing to the skin surface was achieved in all but one attempt (28 of 29) in which slight bleeding around the device was observed. No leaks were found through the external sealing element. The fixation strength of the device to the thoracic wall was measured in the perpendicular and parallel directions using a dynamometer. The port could not be pulled from the thoracic wall following a gradually applied pull force of up to the maximum force applied in both directions (58.8 Newton).

Pneumothorax was then induced four times in each animal and was accompanied by a significant decrease in oxygen saturation and blood pressure as expected. A drainage tube was inserted into the port (Figure 2(C)), and effective drainage of the pneumothorax was achieved by connecting the suction tube to the Heimlich chest drain valve in all four attempts. "Hemothorax," simulated as indicated in the Methods section was induced three times. Full resolution was achieved. When the animals were turned on their side, only minimal leakage was observed in one of the three animals around the edge of the fixed device. Thus, the interface between the port and the surface of the body was highly sealed. The strength of the fixation of the drainage tube to the device was measured by a dynamometer. Despite application of heavy force (58.8 Newton), the connection between the port and the tube was not compromised at any time.

A variety of surgical accessories were inserted into the port (see example in Figure 2(D)). These included chest tubes (28 Fr, 32 Fr, and 40 Fr), Foley urine catheters (12 Fr), and standard surgical suction tubes. In all cases, the insertions were simple and achieved within seconds, and were hermetic with no leaks throughout the study in all animals.

Regarding safety, when using the device in the presence of induced pneumothorax, no trauma to internal organs in the thoracic cavity (including the lungs, pericardium and heart) was observed. However, when inserting the device while the external surface of the lung was completely adjacent to the internal surface of the thoracic wall at inspiratory pause (i.e., simulating a scenario of erroneous pneumothorax diagnosis), two cases of superficial lung laceration (out of five attempts) were observed. None of the device-induced openings exceeded the shaft diameter of the device, and following its removal, the opening was >1 cm in diameter demonstrating that the insertion opening remains minimal. Since there was no space between the chest-wall perforation and the shaft of the device, hermetic fixation was achieved. Removal of the device was easily achieved in all 29 attempts. The time of port removal was five seconds or less in all cases.

Discussion

Traumatic pneumo-hemothorax is a life-threatening situation, and quick treatment is essential. Inexperience of first responders and shortcomings of conventional tools are partly responsible for high mortality rates in these situations. We tested a novel insertion device that can overcome some of the problems stemming from inexperience by providing a simple, quick and safe treatment protocol for these emergent circumstances. We tested the safety and feasibility of the novel C-Lant port in a large animal model under conditions of experimental pneumothorax and hemothorax as well as its interface with other standard accessories. The port was easily inserted, using the internal blade of the device that cut through the intercostal muscles and fascia, and drainage of air and liquid from the pleural cavity was achieved without difficulty. Standard accessories were easily inserted through the port into the pleural

cavity. Fixation of the port to the thoracic wall, and sealing and fixation of the chest tube to the port were achieved repeatedly with high reliability. Only minimal damage to subtending tissue was observed in one case that occurred upon insertion of the device into the pleural cavity of an animal in whom the diagnosis of pneumothorax was incorrect and the lungs were fully expanded.

Although there are many similarities between porcine skin and human skin, there are some differences [12]. Specifically, the mean elastic moduli (a quantity that measures the resistance to being deformed elastically when stress is applied) of pig skin is much larger than that of human skin, with the thick stratum corneum contributing largely to this additional stiffness and less penetrability of the pig skin [13]. This, therefore required a preliminary skin incision in this model to enable device insertion under tissue conditions that closely resemble passage of the device through human skin, muscle, and fascia.

We found that the novel port prevented unwanted dislodgment and expulsion of chest tubes even when a force of 6 Kg was applied. Securing a chest tube to prevent premature dislodgement is extremely important in the pre-hospital setting—particularly during evacuation and transport of the injured – be it by helicopter or by land and even more so through difficult terrain or other austere conditions [5]. In such scenarios, taping the tube to the chest wall is not enough, and suturing is necessary. Several methods of suturing were suggested [14–19], but all require time and appropriate experience, both of which are in short supply in emergency situations.

In a recent study, Barnung and Steinmetz suggested using an ITClamp for haemostatic control and fixation of chest tubes as a simpler technique with equivalent effectiveness for securing [20]. In a subsequent cadaver study, sutures and ITClamps were compared and found to be functionally equivalent in their ability to hold a thoracostomy tube using a maximum force of 2.3 Kg (5 lbs) [21]. In our study, we found that the C-Lant port secures the tube and prevents dislodgement when maximum pull force of even 6 Kg was applied in several directions. Thus, the current device not only provides for rapid accurate and effective insertion but also reliable prevention of unwanted dislodgement and expulsion under difficult field circumstances and unstable transport.

Additional complications of chest tube placement are accidental injury of internal organs [10]. In the present study, the novel port did not cause trauma to internal organs in the thoracic cavity when pneumothorax was present. However, superficial lung laceration was observed in one case where the diagnosis of pneumothorax was incorrect. This re-emphasizes the need for careful accurate diagnosis of pneumothorax prior to insertion of thoracostomy tubes of any kind.

Different sizes of drains and catheters passed through the device with ease and allowed complete drainage of both air and liquid, achieving the goals expected from tube thoracostomy. The time required for removal of the device was short, and the site of insertion was <1 cm in diameter facilitating easy closure for prevention of subsequent complications.

Limitations

The main limitation of this study was the inherent difference between pig skin and human skin. Nonetheless, prior incision to bypass the particularly tough stratum corneum permitted access to the intercostal muscles and fascia that closely resembles the anatomical consistency in humans. With appropriate ethics approval, this could be tested on fresh human cadaver models prior to fixation in advance of human clinical trials.

Conclusions

The C-Lant is a novel device for treatment of pneumo-hemo-thorax that facilitates easy insertion and secure fixation of chest tubes by minimally experienced responders and reduces the likelihood of unwanted dislodgement and expulsion. Clinical trials are planned following regulatory approval.

Declaration of interest

All authors report no conflicts of interest associated with this study.

Presentations

Data for this study was presented as a poster at the Military Health System Research Symposium (MHSRS), Kissimmee, FL, USA, August 2017.

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