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Original Article

Use of the iTClamp versus standard suturing techniques for securing chest tubes: A randomized controlled cadaver study

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ABSTRACT

Objectives: Tube thoracostomy (TT) is a common yet potentially life-saving trauma procedure. After successful placement however, securing a TT through suturing is a skillset that requires practice, risking that the TT may become dislodged during prehospital transport. The purpose of this study was to examine if the iTClamp was a simpler technique with equivalent effectiveness for securing TTs.

Materials and methods: In a cadaver model, a 1.5 inch incision was utilized along the upper border of the rib below the 5th intercostal space at the anterior axillary line. TTs (sizes 28Fr, 32Fr, 36Fr and 40Fr) were inserted and secured with both suturing and iTClamp techniques according to the preset randomization. TT were then functionally tested for positive and negative pressure as well as the force required to remove the TT (pull test-up to 5 lbs). Time to secure the TT was also recorded.

Results: When sutured is placed by a trained surgeon, the sutures and iTClamp were functionally equivalent for holding a positive and negative pressure. Mean pull force for both sutures and iTClamp exceeded the 5 lb threshold; there was no significant difference between the groups. Securing the TT with the iTClamp was significantly faster ($p < 0.0001$) with the iTClamp having a mean application time of 37.0 ± 22.8 s and using a suture had a man application time of 96.3 ± 29.0 s.

Conclusion: The iTClamp was effective in securing TTs. The main benefit to the iTClamp is that minimal skill is required to adequately secure a TT to ensure that it does not become dislodged during transport to a trauma center.

1. Introduction

Tube thoracostomy (TT) is the insertion of a thoracic catheter (TC) into the pleural cavity to facilitate drainage of air and fluid and is used as either a diagnostic or therapeutic intervention. Proper technique for the placement of a TC stresses insertion in Bulau's or Monaldi's[1] position within the "triangle of safety," without "directed" placement.[2] "In thoracic trauma, when an intervention is required TT is the most common intervention and of the thoracic trauma that require an intervention 85% of these cases only require a TT".[3] Consequently, it is an expectation that any care provider dealing with trauma have a firm understanding and skill set for performing and thereafter securing TTs.[4]

However, despite this expectation of baseline competency the complication rate in TT is alarmingly high (5%–38%).[1,4–11] These

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complications have been linked to lack of surgical training[11–13] and placement outside of a trauma bay.[11] One frequent complication identified is in securing the TC itself. This has led to several methods for securing TC being suggested in the literature.[13–18] The majority of these securing methods require the ability to not only suture, but suture proficiency. However, if one of the issues with TT complications is lack of surgical training, where proficiency in suturing is not assured, then perhaps other methods for securing TT should be examined, especially in the austere environment, rural hospital setting or prehospital setting.

A new technique to potentially secure TTs may be the iTClamp. This is a light-weight hemostatic clamp that was described by Barnung[18] for securing TT in the pre-hospital setting. Barnung[18] describes an “effortless” procedure resulting in TT with an airtight seal. Therefore, while TT securement constitutes an off-label use for the iTClamp, the authors set out to determine if the iTClamp was a viable option to secure TT.

2. Materials and methods

2.1. Objective

The objective of this study was to evaluate the effectiveness of the iTClamp to secure TT (Straight Argyle PVC Thoracic Catheters by Covidien Corp, Minneapolis, MN) compared to a standard suturing technique. Effectiveness was evaluated using a pull test and occlusion tests with both fluid and air after the TT was secured. A comparison of the time required to apply the iTClamp and time to suture was also evaluated. The same surgeon performed all the interventions. This study was ethically reviewed and approved by and conducted at the Medical Education and Research Institute (MERI) in Memphis, TN, USA.

2.2. Cadaver model

A human cadaver model was utilized to compare the anchoring of a TT using the iTClamp versus anchoring with sutures. Each cadaver is thawed for 72 h prior to the initiation of any study procedure. A total of three cadavers were supplied by the Medical Education Research Institute (Memphis, TN) (Cadaver A: male, 78 years old, 181 lbs. Cadaver B: female, 92 years old, 113 lbs. Cadaver C: female, 78 years old, 151 lbs).

3. Procedures

3.1. Tube thoracostomy

TCs were placed in the 4/5th intercostal space at the anterior axillary line. A 1.5 inch incision was made along the upper border of the rib below the intercostal space to be used. The drain track was directed over the top surface of the rib to avoid the intercostal vessels lying below each rib. The incision could easily accommodate the operator's finger. Using a curved clamp the track was developed by blunt dissection only. The clamp was inserted into muscle tissue and spread to split the fibers. The track was then further developed with the operator's finger. Once the track came onto the rib, the clamp was angled just over the rib and dissection continued until the pleural space was entered. A finger was inserted into the pleural cavity and the area explored for pleural adhesions. A TC was mounted on the clamp and passed along the track into the pleural cavity, with confirmation of placement performed digitally after insertion of the TC.

Fig. 1. Using the iTClamp to secure a Thoracic Catheter in a Tube Thoracostomy. The iTClamp was placed in-line with the TC and squeezed closed ensuring the TC and cadaver skin were in-between the needles of the iTClamp, as illustrated on an artificial skin.

3.2. Securing the tube thoracostomy

TT's were thereafter secured with either an iTClamp or 0 silk sutures with a large cutting needle. **iTClamp:** When using the iTClamp to secure the TT the iTClamp was partially closed prior to securing the TT. The iTClamp was placed in-line with the TC and squeezed closed ensuring the TC and cadaver skin were between the needles of the iTClamp (Fig. 1). When placing the iTClamp one needle from the iTClamp is inserted into the chest tube but does not penetrate to the inner lumen. **Suturing:** A 0 silk suture is placed across the incision to partially close it. The suture was then wrapped around the TC twice and a knot was tied to secure it. This was done two times on either side of the incision. Random number generation was used to allocate which device (iTClamp or Suture) was used first to secure the TC, for each TT performed.

3.3. Occlusion test

Once the TC was placed and secured a 60 cc syringe (containing 30 cc of saline) was inserted into the exposed end of the TC and saline was pushed through. If all the saline did not go into the chest cavity then only the amount infused was recorded. Using the same syringe we drew back on the plunger to 30 cc creating negative pressure for the air and fluid to return. Once the negative pressure seal was obtained it was held for 30 s. If the negative pressure seal released before 30 s or if the retracted plunger did not achieve 30 cc then the retracted amount was recorded, as was the time the seal failed.

3.4. Pull test

To evaluate the amount of force required to dislodge the TC (to a maximum of 5 lbs) a force gauge was attached to the exposed end of the TC by placing the hook on the force gauge though the drainage holes at the end of the TC. The force gauge was pulled steadily (not yanked) until failure or a maximum force of 5lbs was reached. The force reached was recorded. The TC was deemed dislodged when it started to slide out of the cadaver when under tension.

3.5. Randomization

Randomization was completed using https://www.random.org/lists/. A "1" was entered for suture and a "2" was entered for iTClamp. Random.org would generate a list of whether it was iTClamp or suture that was to be used first for each chest tube insertion. After the randomized method was used the other method would be performed. A new randomization was used for each chest tube insertion.

3.6. Study procedure

The TT wound track was created by a trained surgeon on the right side of the cadaver as per the TT placement instructions. First the 28Fr TC was inserted and secured by the randomized device. Once the TT was secured, the occlusion test was performed followed by the pull test. The securing method was removed and the other method applied to the same TC according to the randomization and the study procedure repeated. The TC was removed and the next size TC was inserted until all four sizes were evaluated using both the sutures and iTClamp, on each wound. The identical protocol was used successively for the 32Fr, 36Fr and 40 Fr TCs. The sequence of TC insertion from smallest to largest was chosen as the larger TCs would stretch the wound track for the smaller TCs. Once the testing on the right side was complete the left side was used. Each device was tested a total of 6 times on each TC size for a total of 24 tests per device.

3.7. Statistical analysis

Descriptive statistics were used to describe the results. Time (seconds) and pull force (lbs) are reported as mean ± standard deviation (SD). The following comparisons were made between the two groups: pull force and application time required for suture vs iTClamp for each gauge of TC (28, 32, 36 and 40 Fr). The Mann-Whitney *U* Test was used to determine statistical significance for the pull test because of the non-parametric distribution of data. Independent sample *t*-test was used to compare time to secure chest tubes. An alpha value of 0.05 was accepted as nominal level of significance.

4. Results

Each device was tested a total of 24 times, six times for each chest tube size (26Fr, 32Fr, 36Fr, 40Fr). Overall, using the iTClamp (37.0 ± 22.8 s; 95% CI [27.4, 46.6]) to secure the chest tube was significantly faster than using a suture (96.3 ± 29.0 s; 95% CI [84.1, 108.6]) technique ($p < 0.001$). When examining the time to secure each size of TC the iTClamp was faster for 28Fr ($p = 0.009$), 32Fr ($p < 0.001$), 36Fr ($p = 0.001$) and 40Fr ($p = 0.010$) (Table 1). When examining pull force between the two groups there was no difference ($p = 0.292$) for overall pull force and no difference seen with each of the TC sizes (Table 1). Seven iTClamps needed to be re-applied for a total of 15 applications. The re-applications were done to ensure proper seal with the iTClamp. This is part of the standard training for the product. If the care provider feels a better seal would be advantageous they are instructed to re-apply the iTClamp. None of the functional testing was performed prior to re-application. Three iTClamps and one sutured TC did not meet the 5 lb pull threshold, none of the TC were occluded and all TT held negative pressure regardless of device used to secure them.

5. Discussion

In critically ill patients with undifferentiated shock or whom are in extremis, rapid bilateral TT drainage is a useful procedure for guiding diagnostic evaluation.[19,20] Other indications for TT may include: pneumothorax,[8,21] hemothorax,[8] hemopneumothorax[5] and pleural effusion.[22] Complications from TT are associated with lack of surgical training and insertion outside of a trauma bay.[11] TCs becoming dislodged is a problem especially when they are placed by an inexperienced care provider, in an austere environment where the patient has to be transported, or when time is an issue.[13,17,18] Suturing ability, such as those required to secure a chest tube, is a skill that takes time both to master and to maintain. Single instructional sessions, such as those taught in ATLS, may not be enough to maintain suture proficiency,[23] especially when securing a TT. These are not esoteric concerns, but are instead extremely relevant in contemporary trauma management.

Tension pneumothoraces continue to inflict a severe burden of potentially preventable post-traumatic mortality on injured personnel. It has been reported that pneumothoraces are found in one in five victims of major trauma found alive in civilian settings,[24,25] and that up to 33% of all preventable deaths on the battlefield result from tension pneumothoraces.[26,27] This has resulted in new emphasis on decompressing pneumothoraces in tactical prehospital settings, with subsequent TT if there is no improvement and/or a long transport time is anticipated.[27] Remarkable technical advances are now being made in enabling relatively untrained care providers to obtain pre-hospital ultrasound diagnoses of pneumothoraces and other innovative technologies might allow automatic diagnoses of pneumothoraces.[28,29] Further, non-invasive tele-mentored interventions are currently

Table 1
Pull force (lbs) and application time (seconds) for iTClamp and suture.

Chest Tube Size (Fr)	Device Used	Median Pull Force (lbs) (IQR)	Full Force (lbs) p value[a]	Mean Application time in seconds ± SD, [95% CI]	Time (s) p value[b]
28					
	Suture	5.0 (0.0)	p = 1.000	100.0 ± 20.7, 95% CI [78.2, 121.8]	p = 0.009
	iTClamp	5.0 (0.0)		42.5 ± 38.3, 95% CI [2.3, 82.7]	
32					
	Suture	5.0 (0.0)	p = 0.394	97.7 ± 15.1, 95% CI [75.9, 107.5]	p < 0.001
	iTClamp	5.0 (1.8)		33.0 ± 13.3, 95% CI [19.1, 46.9]	
36					
	Suture	5.0 (0.0)	p = 1.000	88.7 ± 17.9, 95% CI [69.9, 107.5]	p = 0.001
	iTClamp	5.0 (0.0)		39.0 ± 16.5, 95% CI [21.6, 56.4]	
40					
	Suture	5.0 (0.2)	p = 1.000	105.0 ± 51.8, 95% CI [50.7, 159.3]	p = 0.001
	iTClamp	5.0 (0.1)		33.5 ± 20.1, 95% CI [12.4, 54.6]	

[a] Mann-Whitney *U* test.
[b] Independent sample *t*-test.

being examined,[30] which are planned to address prehospital TT in the future. In such settings, if TT placement was successful, actually securing the TT might become the most challenging concern, for which the iTClamp may have practical utility.

The iTClamp is predominately used to control hemorrhage from open wounds within compressible zones by creating a fluid tight seal at the wound edges. It has been shown to be effective in controlling complex vascular groin injury,[31,32] as well as, bleeding from the scalp, neck, and extremities.[33] No issues have been found on histological examination of the skin and the iTClamp was effective when applied over military clothing and denim.[34] The iTClamp has also been shown to be easy to use, even without surgical training or experience. Physicians, paramedics, police officers and military medics have all used the iTClamp safely and effectively.[34–36] While an off-label use for the product in the USA (it is not off-label in Canada or Europe), the use of the iTClamp to secure a TT pre-hospital, arose out of necessity in austere environments. The patient was agitated, covered in blood, adhesive securing methods were ineffective and time was critical.[18] The iTClamp may thus offer a feasible option to securing TT particularly in those environments where the care provider is inexperienced, does not have surgical training, the environment is less than ideal and only until the patient reaches a trauma centre and can receive definitive care and fixation.

5.1. Limitations

This study demonstrated the feasibility of using the iTClamp as an alternative for securing chest tubes. Despite this, there are several limitations for this study. First, the chest tubes were only monitored for a one-two minute interval that may not accurately represent practical conditions with patient movement and the chest tube connected to a drainage system. Secondly, the tissue behavior of the cadaver may not represent the true mechanical behavior of living tissue, thus altering the results of the tensile load test. Finally, the cadaver skin was not infiltrated with anesthetic, as is common practice in a real world setting. Although the researchers did not feel this would have an impact on the outcomes.

6. Conclusion

This cadaver model was practical for comparing the iTClamp to suturing for securing chest tubes. Even though the iTClamp required several re-applications it was still significantly faster and as effective in securing the chest tubes. Both groups were able to sustain positive and negative pressure as well as with stand 5 lbs of pull force.

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Conflict of Interest Statement

Conflict of Interest: Jessica Mckee is a contractor for Innovative Trauma Care, the company that funded this study and manufactures and distributes the iTClamp, one of the devices tested in this study. Jessica Mckee has had her travel covered by Innovative Trauma Care as part of her contract with the company. Dennis Filips is the Chief Medical Officer of Innovative Trauma Care, the company that funded this study and manufactures and distributes the iTClamp, one of the devices tested in this study. Dennis Filips sits on the Board for Innovative Trauma Care, has stock in the company and has his name on several patents with Innovative Trauma Care. Dennis Filips has received a honorarium to speak for the University Of Calgary Department Of Surgery and his travel is covered by Innovative Trauma Care as part of his position with the company. Ian Atkinson is the Chief Technical Officer of Innovative Trauma Care, the company that funded this study and manufactures and distributes the iTClamp, one of the devices tested in this study. Ian Atkinson also sits on the board for Innovative Trauma Care, is entitled to stock options and is on several patents with the company. Innovative Trauma Care has also covered Ian Atkinsons travel when it is related to his employment with the company. Ian Mckee is the husband of Jessica Mckee contractor for Innovative Trauma Care. Ian is also a contract educator for Innovative Trauma Care and the company has paid for his travel when it is a result of his position with the company. Major Andrew W. Kirkpatrick has been paid a consulting fee and travel compensation from Innovative Trauma Care. Andrew Kirkpatrick has also consulted for Acelity and Cook Medical, Cook Medical has also paid for his travel on other projects. Melanie Bouclin declares that she has no conflict of interest. Chad Ball declares that he has no conflict of interest. Paul McBeth declares that he has no conflict of interest.

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