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Original Contributions

A RANDOMIZED CONTROLLED TRIAL USING ITCLAMP, DIRECT PRESSURE, AND BALLOON CATHETER TAMPONADE TO CONTROL NECK HEMORRHAGE IN A PERFUSED HUMAN CADAVER MODEL

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☐ **Abstract—Background: Penetrating neck wounds are common in the civilian and military realms. Whether high or low velocity, they carry a substantial morbidity and mortality rate. Objectives: We endeavored to ascertain whether the iTClamp is equivalent to direct manual pressure (DMP) and Foley catheter balloon tamponade (BCT). Methods: Using a perfused cadaver, a 4.5-cm wound was made in Zone 2 of the neck with a 1-cm carotid arteriotomy. Each of the hemorrhage control modalities was randomized and then applied to the wound separately. Time to apply the device and fluid loss with and without neck motion was recorded. Results: There was no significant difference between the fluid loss/no movement ($p > 0.450$) and fluid loss/movement ($p > 0.215$) between BCT and iTClamp. There was significantly more fluid lost with DMP than iTClamp with no movement ($p > 0.000$) and movement ($p > 0.000$). The iTClamp was also significantly faster to apply than the Foley ($p > 0.000$). Conclusions: The iTClamp and BCT were associated with significantly less fluid loss than DMP in a perfused cadaver model. The iTClamp required significantly less time to apply than the BCT. Both the iTClamp and the BCT were more effective than simple DMP. The iTClamp offers an additional option for managing hard-to-control bleeding in the neck. © 2018 Elsevier Inc. All rights reserved.**

☐ **Keywords—hemorrhage; neck hemorrhage; hemorrhage control; penetrating neck injury**

INTRODUCTION

First described 5000 years ago in the Edwin Smith Surgical Papyrus, penetrating neck trauma is a longstanding and particularly challenging wound that occurs in both the military and civilian settings (1). Recently, with the reduction in deaths from torso injuries and the increased use and improvements in the technology of body armor, the relative burden of severe head and neck injuries in survivors has greatly increased in the ongoing U.S. military

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operations in Iraq and Afghanistan. From historical rates of 16% to 21% of battle injuries, craniomaxillofacial (CMF) battle injuries to the head and neck were found to have increased to 42.2% of patients evacuated out of theater in a recent report by Chan et al. (2,3). Wade and colleagues also reported during the study period, more than 50% of all battle injury patients in the Navy-Marine Corps Combat Trauma Registry incurred one or more injuries to the head, face, or neck, the majority of which were caused by improvised explosive devices (4).

There are six important systems in the neck with an overabundance of vital structures. Given the teleological need for mobility, the skeletal system does not have the same protective capacity for these vital structures in the neck as it does in other areas of the body (5). Leaving critical systems such as the aerodigestive tract and major arterial vessels in an unprotected location results in a high mortality and complication rate when injury occurs (6,7). The mechanism of injury is important to understand in penetrating neck trauma as the mortality ranges from 10% to 50%, depending on mechanism, with major vascular injury and exsanguination being the most common cause of death (6,8,9).

As hemorrhage accounts for 50% of mortality in penetrating neck injury, ensuring that on-scene providers, both military and civilian, are properly equipped to immediately manage exsanguination, is paramount (9). Current recommendations from the Western Trauma Association Critical Decisions in Trauma dictate that direct manual pressure (DMP) should be used in the initial management of exsanguinating hemorrhage from penetrating neck injury followed by Foley balloon catheter tamponade (BCT) (10). However, both these methods require at least one member of the medical team to be solely devoted to cervical hemorrhage control, and frequently, these providers may have modest to minimal technical training and be operating in extreme environments with minimal logistical support (11). This is especially problematic when the patient has other life-threatening injuries; or in an operational situation requiring the medical personnel to defend themselves and the patient. These situations include tactical scenarios where the casualty is involved in a care-under-fire situation, the caregivers are focused by necessity on maintaining effective counter fire, or where the casualty may have to self-administer care as no responder can safely provide care (12).

The iTClamp is a simple physical tissue compression device applied for hemorrhage control that has demonstrated efficacy in exsanguinating hemorrhage (13–17). Given the need to expedite and simplify prehospital hemorrhage control for exsanguinating penetrating cervical hemorrhage, we conducted a prospectively randomized controlled trial of Western Trauma Association-recommended hemorrhage control strategies (DMP and BCT), as well as assessing the iTClamp using a perfused human cadaver model. The primary objective of this study was to ascertain if the iTClamp was noninferior to the current standards of DMP and BCT for controlling exsanguinating cervical hemorrhage with and without movement of the neck. A secondary objective was to compare the time to hemorrhage control between groups.

MATERIALS AND METHODS

Perfused Cadaver Model

We used a perfused human cadaver hemorrhage control model to compare the iTClamp with DMP with standard gauze and a BCT's effectiveness in controlling fluid loss from a neck wound. Each cadaver was thawed for 72 h prior to the initiation of any study procedure. Any cadaver with a history of peripheral vascular disease or late-stage diabetes was excluded from the study. The morning of the experiment, the femoral artery was dissected and cannulated by laboratory staff. Thereafter, an embalming machine with 475 mL of anticoagulant mixed with 60 L of water was used to flush the cadaver through the femoral artery, removing any residual clots. The Medical Education Research Institute (Memphis, TN) supplied a total of three cadavers for this study (Cadaver A: male, 78 years old, 181 lbs, died of cardiac arrest. Cadaver B: female, 92 years old, 113 lbs, died of heart failure. Cadaver C: female, 78 years old, 151 lbs, died from Parkinson's disease). All three cadavers had good vasculature that supported sterile water being pumped through the arteries with a pulsatile peristaltic pump (Sarns Delphin Cardiac Centrifugal Pump, Terumo Cardiovascular Group, Ann Arbor, MI) to simulate blood flow. To create flow in the carotid artery, a balloon catheter was inflated in the descending thoracic aorta using the left common femoral artery as the access site. Inflow and outflow lines were placed in the brachial arteries so perfusion occurred in close proximity of the neck. Sterile water was pumped at a rate of 700–1000 RPM (200–500 mL/min) and was turned off between active hemorrhage control interventions to allow the saline to move through the system and prevent too much saline extravasation through the vasculature into the soft tissues.

Wound Creation

The left side of the neck was standardized as the testing site for the exsanguinating wound. A 4.5-cm incision was made over the anterior border of the sternocleidomastoid muscle. The carotid artery was dissected out and isolated. A 1-cm arteriotomy was created on the anterior surface of the common carotid artery. For Cadaver C,

the same procedure was followed, except adequate flow could not be achieved through the left carotid artery wound because the brachial arteries were small. Therefore, the inflow of the perfusion was moved from the right brachial artery to the right common carotid artery (necessitating an open cut down on the right side of the neck).

Hemorrhage Control Device Application

Three hemorrhage control devices/strategies were used to address the exsanguinating fluid loss model: DMP, BCT, and application of the iTClamp. For all interventions there was a 30-s period of uncontrolled free bleeding from the wound prior to any attempts at hemorrhage control to assess the baseline equivalence of the model. After this free bleeding period, the randomized hemorrhage control strategy was applied.

Direct manual pressure. With a gloved hand, a first responder with 19 years of field experience applied gauze and direct pressure to the exterior of the wound in an attempt to stop fluid loss. Timing began when the study participant was handed the gauze pads and was stopped once hemorrhage control was gained, to the stated satisfaction of the responder (Figure 1).

Balloon catheter tamponade. With a gloved hand, an 18Fr 30-mL Medline Foley Catheter (100% Silicone, Serial Number 1401021743; Medline, Mundelein, IL) was used to tamponade neck bleeding following the technique outlined by Gilroy et al. (18). A trauma surgeon with over a decade of critical care medicine experience performed the examination and catheterizations of the wounds. The amount of saline used to fill the balloon was recorded. Timing began when the study participant was handed the catheter (Foley catheter was already prepared with the inflation syringe attached) and was stopped once hemorrhage control was gained (Figure 2).

iTClamp. With a gloved hand, the same first responder who applied direct pressure opened a sealed iTClamp and applied it to the neck wound in an attempt to stop fluid loss. The iTClamp is a temporary wound closure device consisting of a self-locking hemostatic clamp with four pairs of opposing needles reinforced by U-shaped pressure bars. The needles penetrate the skin and the action of the pressure bars is to evert the wound edges and create a fluid tight seal. The needles anchor the device in the skin to reduce movement and leakage. Once the mechanical re-approximation of the wound edges creates a temporary, closed cavity, pressure develops to create tamponade against the damaged vessel. The combination of blood stasis and hydrostatic pressure develops a hematoma and clot formation. The contained hematoma remains in place until the device is removed. A new device was used for each application. Timing began when the study participant started to open the iTClamp packaging and was stopped once hemorrhage control was gained. The time to apply the device was recorded; this time included any reapplications of the device (Figures 3 and 4).

Device training. Although neither the first responder nor the surgeon has field experience with the iTClamp or BCT, respectively, they were both given training for their respective devices. The first responder was trained by Innovative Trauma Care on the iTClamp, which included an oral presentation, hands-on training, and a test to ensure understanding and compliance. The same first responder did not receive any addition training for DMP. As a first responder he was already sufficiently trained in DMP, however, his skill set was tested on the perfused cadaver prior to starting the training. The surgeon was also previously training on using a tamponade modality to stop bleeding, although he had not deployed this technique in the field. The surgeon was also given the opportunity to utilize the perfused cadaver prior to the start of the study to ensure model compliance and authenticity.

Randomization. Each cadaver was block randomized to ensure there were five BCT applications, five DMP applications, and five iTClamp applications on each cadaver. The order of application was based on random number generation. Each device completed the 150-s data collection as described above.

Procedure

The pulsatile pump was turned on and once the saline began to overflow the wound, the timer was started. The saline was allowed to flow from the wound for 30 s (0–30 s). The leaking fluid from the wound was collected with preweighed gauze. After 30 s, the randomly allocated hemorrhage control device was applied. The skin proximal to the wound was quickly dried and the gauze used to collect the free-flow fluid was removed and replaced. This was used to calculate the flow rate. A flow rate of 200–500 mL/min was used to simulate normal blood pressure. Fluid leaking from the wound once the hemorrhage control device was in place was collected with preweighed gauze for 1 min (30–90 s). This was used to calculate external fluid loss. Thereafter, the head/neck was then rotated 10 times and fluid collection continued for another 60 s (90–150 s) using the same measurement methods, only with fresh gauze. This was used to calculate external fluid loss with movement. At 150 s post device application, the pump was turned off.

Figure 1. This image depicts the use of direct pressure with gauze to stop bleeding from a simulated neck wound. This image is simulated skin not the perfused cadaver model.

Figure 2. This image depicts the use of a Foley Catheter Balloon to stop bleeding from a simulated neck wound. This image is simulated skin not the perfused cadaver model.

Statistical Analysis

Descriptive statistics were reported using median and interquartile range. Flow rate, fluid loss with no movement, and fluid loss with movement were compared across each of the groups. Application time could only be compared between BCT and iTClamp, as time for DMP could not be recorded appropriately. The Mann-Whitney *U* Test was used to determine statistical significance. This test was chosen due to the nonparametric distribution of data.

RESULTS

Each of the allocated interventions, DMP, BCT, and iTClamp were randomly applied a total of 15 times each on three perfused cadavers. Table 1 displays the descriptive statistics for each of the groups. There was no significant difference in baseline flow rates prior to hemorrhage-control device allocation seen when comparing iTClamp preallocation to DMP (p = 1.000), iTClamp to BCT preallocation (p = 1.000) or DMP preallocation to BCT (p = 0.0806). After allocation to specific hemorrhage control strategies, there was, overall, a statistically greater fluid loss with DMP, compared with either iTClamp or BCT for both the nonmovement (p = 0.000 for both) and movement (p = 0.000 and p = 0.006, respectively) phases of assessment. There was no statistical difference between fluid loss during application of the BCT and fluid loss during application of the iTClamp for no movement (p = 0.450) or during movement (p = 0.215).

Figure 3. This image depicts the use of an iTClamp to stop bleeding from a simulated neck wound. This image is simulated skin not the perfused cadaver model.

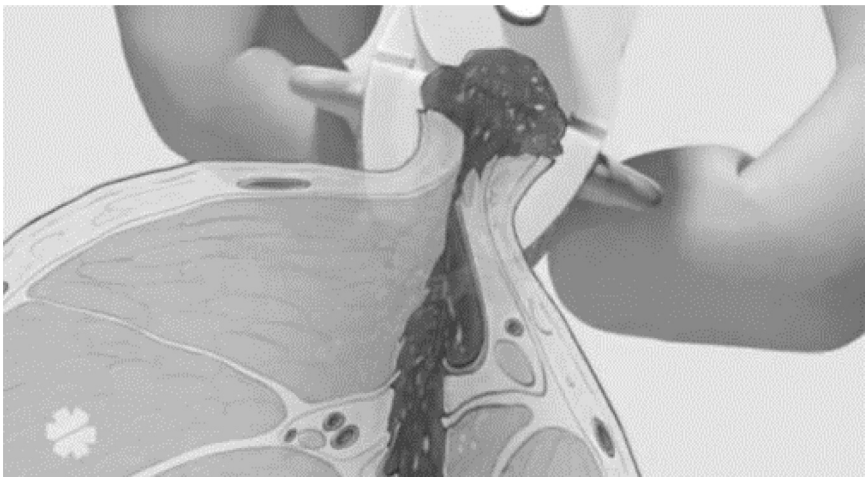

Figure 4. The iTClamp is a temporary wound closure device consisting of a self- locking hemostatic clamp with four pairs of opposing needles reinforced by U-shaped pressure bars. The needles penetrate the skin and the action of the pressure bars is to evert the wound edges and create a fluid tight seal.

There was, however, a statistical difference between application time of the BCT and application time of the iTClamp, with the iTClamp being faster to apply ($p < 0.000$).

DISCUSSION

The paradigm shift in the surgical management of penetrating neck injuries from observation to mandatory exploration with vascular repair back to selective nonoperative management has impacted the historic fluctuation of mortality rates seen in penetrating neck trauma (1,7). The pendulum swinging back to selective nonoperative management occurred as computed tomographic imaging allowed surgeons to better appreciate and select serious but occult injuries from those that could be safely observed. Another evolution in management, distilled from operational military experience, is the priority management of massive exsanguinating hemorrhage (19). Unfortunately, these are not rare injuries in practice. Improvements in tactical armor mean the head and neck encompass only 12% of the body surface area exposed during combat (4). However, injury rates to this area have increased from previous military endeavors to more than 50% of battle injury (4).

The manual application of packing and direct pressure to any resultant cavity or anatomic defect is the accepted default therapy for penetrating neck wounds. Another option is using BCT, which has been shown to be an effective strategy for emergency control of hemorrhage in both the civilian and military settings (4,11,20). There also may be merit to employing BCT rather than simply relying on DMP; Weppner demonstrated that DMP is less effective having a significantly higher mortality rate ($p < 0.05$) when compared with the BCT group, with and without delayed failure (11). DMP also has been shown to have a higher risk of re-bleeding and exsanguination prior to reaching definitive care (11). Given the low efficacy rate of DMP for treating penetrating neck trauma, the fact that these life-threatening injuries are treated at a forward aid station with limited interventions and surgical support or by minimally trained civilian first responders and the high mortality rate associated with CMF injuries, means finding a viable option other than DMP to stop CMF hemorrhage is exceedingly important (3,9,11,19). Such an option may be the iTClamp, a temporary wound closure device, which controls external hemorrhage from open wounds within compressible zones. A recent comparative animal laboratory study of a complex vascular groin injury revealed that all animals (100%) treated with the iTClamp lived through the end of the experiment, compared with 60% in standard gauze treated and 0% of untreated control animals (early and late iTClamp vs. control and standard gauze, Fisher's exact, $p = 0.003$) (13). In a lethal swine bleeding model (femoral artery injury), the iTClamp was 100% effective at controlling bleeding, packing + iTClamp reported a 100% survival rate, and the iTClamp improved survival and decreased hemorrhage in both packed and unpacked wounds (13,17). Another preclinical perfused cadaver study demonstrated that the iTClamp was effective at controlling blood loss from multiple compressible zones including the scalp, neck, groin, and extremities (14).

Unfortunately, the idea of treating a patient in a care-under-fire situation is not just a military scenario. In 2017, according to the Gun Violence Archive (https://www.gunviolencearchive.org/), there was almost one mass shooting a day in the United States (n = 342), which

Table 1. Median Flow Rate, Fluid Loss, and Application Time for DMP, Foley, and iTClamp

Device	Median Flow in mL/min (IQR)	Median No Movement Fluid Loss in mL/min (IQR)	Median with Movement Fluid Loss in mL/min (IQR)	Median Time to Application in Seconds (IQR)	Median Volume in Balloon in mL (IQR)
Foley	318.0 (216.0)	0.0 (2.0)	1.0 (3.0)	23.0 (8.0)	30.0 (20.0)
Gauze	318.0 (168.0)	7.0 (7.0)	6.0 (6.0)	n/a	n/a
iTClamp	318.0 (174.0)	0.0 (2.0)	0.0 (1.0)	11.0 (3.0)	n/a

DMP = direct manual pressure; IQR = interquartile range.

resulted in 437 people killed and 1803 injured. These civilian active shooter situations are treated similarly to military care-under-fire situations. First responders try to get to the injured parties as soon as possible, often risking their own lives. However, threat suppression remains a top priority. Therefore, if an injured party had the ability to apply a hemorrhage control modality to themselves, especially in a devastating area like the neck, more lives could be saved. The iTClamp could be self-applied to any area of the body, including the neck. As long as the victim could approximate the wound edges, they could apply the iTClamp to stop the bleeding. The pressure bars and needles on the iTClamp mean that the device will stay in place once applied. If the patient applied an iTClamp and bleeding persisted, they have the ability to reapply the device or apply a second one.

This cadaver model was useful in assessing the effectiveness of the iTClamp, BCT, and DMP to control fluid loss from neck wounds. The findings of this study suggest that the iTClamp may be considered and further examined as an alternative or adjunct to DMP and BCT for use in controlling exsanguination from CMF injuries in both the civilian and military settings. Ultimately, there was significantly less fluid loss using either the BCT or iTClamp compared with DMP. However, the iTClamp was much quicker to apply than the BCT, which has operational implications.

Limitations

This study is not without its limitations. The model was limited to a total observation period of 2 min with the devices applied. Extended periods of fluid through the cadaveric model was not possible due to fluid saturation causing swelling of the tissues. Fluid loss and accumulation within the tissues is a known limitation of even the best perfused cadaver models, and thus, stopping the fluid pumps during noncritical periods of any experiment is an accepted practice (21). Saline was used as the perfusate, which does not have any intrinsic blood-clotting capabilities, thus challenging any simulation of hemostasis. Despite these limitations, perfused cadaver models are being touted in recent literature as having the ability to "replicate human tissue handling, vascular anatomy and dissection … [and are] applicable to procedure-based specialties" (21). These models have been used for plastic surgery procedures, microvascular procedures, intraoperative aneurysmal rupture, central venous catheterization, and neuroendoscopic procedures, to evaluate the ability of both the Combat Ready Clamp and the iTClamp to control hemorrhage and are an accepted form of surgical training (14,21–27). A final limitation for the study is the fact that the participants could not be blinded to the study of the device. We had to ensure proper training and use of the cadaver. However, because we used two study candidates who are considered experts in the use of each device, coupled with the fact that we randomized the cadavers should help to alleviate any Hawthorn effect.

CONCLUSIONS

DMP and BCT are considered gold standard for controlling bleeding in the neck. The iTClamp was shown to outperform DMP and was equivalent to BCT for controlling fluid loss and as such, could be considered as a feasible alternative for controlling bleeding in the neck.

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ARTICLE SUMMARY

1. Why is this topic important?

Penetrating wounds to the neck are not uncommon in either the civilian or military realms. These injuries are difficult to treat given the anatomic structure of the neck. Whether high or low velocity they carry a substantial morbidity and mortality rate. As hemorrhage accounts for 50% of mortality in penetrating neck injury, ensuring on-scene providers, both military and civilian, are properly equipped to immediately manage exsanguination is paramount.

2. What does this study attempt to show?

With this study, we endeavored to ascertain whether the iTClamp is substantially equivalent to the current standards of treating penetrating neck trauma, namely direct pressure and Foley catheter balloon tamponade.

3. What are the key findings?

Both the Foley Balloon Catheter Tamponade and iTClamp application performed significantly better than Direct Manual Pressure for fluid loss with and without movement. The Foley Balloon Catheter and iTClamp were substantially equivalent for fluid loss however the iTClamp was significantly faster to apply.

4. How is patient care impacted?

As the iTClamp was substantially equivalent to Foley Balloon Catheter and outperformed Direct Manual Pressure it could be considered as an alternative to controlling hemorrhage in the neck. The patient benefit would be better and faster hemorrhage control in this lethal injury and care providers would no longer have to hold pressure with their hands, leaving them free to care for the patients' other needs. This could improve overall patient care and decrease mortality from penetrating neck injury in both civilian and military casualties.