

Effectiveness of Sternal Intraosseous Device in Patients Presenting with Circulatory Shock

A Retrospective Observational Study

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ABSTRACT

Background: Hemorrhagic shock requires timely administration of blood products and resuscitative adjuncts through multiple access sites. Intraosseous (IO) devices offer an alternative to intravenous (IV) access as recommended by the massive hemorrhage, A-airway, R-respiratory, C-circulation, and H-hypothermia (MARCH) algorithm of Tactical Combat Casualty Care (TCCC). However, venous injuries proximal to the site of IO access may complicate resuscitative attempts. Sternal IO access represents an alternative pioneered by military personnel. However, its effectiveness in patients with shock is supported by limited evidence. We conducted a pilot study of two sternal-IO devices to investigate the efficacy of sternal-IO access in civilian trauma care. **Methods:** A retrospective review (October 2020 to June 2021) involving injured patients receiving either a TALON™ or a FAST1™ sternal-IO device was performed at a large urban quaternary academic medical center. Baseline demographics, injury characteristics, vascular access sites, blood products and medications administered, and outcomes were analyzed. The primary outcome was a successful sternal-IO attempt. **Results:** Nine males with gunshot wounds transported to the hospital by police were included in this study. Eight patients were pulseless on arrival, and one became pulseless shortly thereafter. Seven (78%) sternal-IO placements were successful, including six TALON devices and one of the three FAST1 devices, as FAST1 placement required attention to Operator positioning following resuscitative thoracotomy. Three patients achieved return of spontaneous circulation, two proceeded to the operating room, but none survived to discharge. **Conclusions:** Sternal-IO access was successful in nearly 80% of attempts. The indications for sternal-IO placement among civilians require further evaluation compared with IV and extremity IO access.

KEYWORDS: *intraosseous; resuscitation; sternum; sternal intraosseous; sternal vascular access; vascular access*

Introduction

Rapid intravenous (IV) access represents a crucial step in the initial resuscitation of a trauma patient in extremis. Tactical Combat Casualty Care (TCCC) emphasizes the need for vascular access in patients with evidence of hemorrhagic shock during the circulatory phase of the MARCH (M-massive hemorrhage, A-airway, R-respiratory, C-circulation, and H-hypothermia) algorithm.¹ However, obtaining IV access can be arduous in patients with circulatory shock and venous shutdown, delaying such resuscitation.² Intraosseous (IO) device placement to bypass peripheral circulation has been recognized as an alternative strategy for immediate access and initial resuscitation of the injured patient.³⁻⁷ However, in patients with multiple orthopedic and/or vascular injuries, IO infusions may extravasate into the soft tissues of extremities or into a central body cavity before reaching the heart. Dismounted complex blast injury represents one such injury pattern.⁸ The recent Afghanistan and Iraq conflicts demonstrated a preponderance of such blast injuries from improvised explosive devices. Similar to prior combat settings, more than 50% of casualties involved injuries to extremities, including amputations.⁹

To circumvent extravasation into soft tissues or central cavity, an alternative approach using a sternal-IO device has been identified to facilitate rapid and reliable initial resuscitation.⁴ In World War II, combat personnel had access to these devices in their medical kits.¹⁰ The advent of the polyvinyl chloride intravenous catheter led to the discontinuation of the IO until its resurgence in the 1970s.¹¹ However, limited evidence supports the efficacy of the sternal-IO device in combat settings based on an autopsy review and findings involving healthy uninjured military personnel.^{4,5}

By contrast, patients with high-energy blunt trauma or multiple gunshot wounds may have limited sites for effective extremity IV or IO access. Therefore, we sought to analyze the success

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rate of the sternal-IO access in patients at risk for circulatory collapse, as prior work has focused on a more stable patient population. Further, we conducted a pilot clinical study to test our hypothesis that placement of a sternal-IO device represents a viable option for early vascular access and resuscitation of critically injured civilian trauma patients.

Methods

This study was approved by the University of Pennsylvania Institutional Review Board and informed consent was waived. The investigators adhered to policies regarding the protection of human subjects as prescribed by the Code of Federal Regulations Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).^{12,13}

Patients and Data Collection

We conducted a retrospective observational study of patients presenting to our large, urban, academic, civilian medical center from 1 October 2020 to 30 June 2021. Data were curated from our institutional trauma registry and electronic medical records (EMR). As the sternal-IO device was novel to our division, clinicians understood that the insertion attempts would be scrutinized during the performance improvement process, which would later supplement the retrospective EMR review. We included all patients who received a sternal-IO device in our trauma resuscitation bay. Patients were excluded from the analysis if they were pregnant, incarcerated, or younger than 18 years of age.

Exposures

In this pilot study, we evaluated two different sternal-IO devices: TALON™ (Tactically Advanced Lifesaving IO Needle, Teleflex, <https://myteleflex.com>) and FAST1™ (First Access for Shock and Trauma, Teleflex, <https://www.teleflex.com>). The TALON IO device was deployed over a 3-month period from Fall 2020 to the beginning of 2021, until our institution used the supplied devices. The TALON IO utilizes a baseplate with anchoring needles that inserts into the manubrium, which allows safe placement of the 15-gauge infusion needle with manual pressure (Figure 1). The FAST1 IO device utilizes a ring of stabilization needles (which are removed during the insertion) around a central infusion needle (Figure 1). A spring-loaded deployment mechanism is activated when adequate downward axial pressure is applied to the FAST1 handle. The device was on backorder and therefore deployed in late Spring 2021 over a 1-week timeframe.

As a pilot study, our institution allowed limited access to the device. Accordingly, our division limited the deployment of the sternal-IO device at the user's discretion to a cohort of patients not expected to survive. This allowed for extensive review of the device in our performance improvement program before it was considered for patients who were more likely to survive. Additionally, the treating physician had the final authority to decide whether or not to deploy the device.

Outcomes

The primary outcome was the ability to successfully implant a sternal-IO device. A successfully implanted sternal-IO device was judged by its ability to facilitate infusion of blood products or medications. Additionally, visualization of malposition, including visualization during an emergency department

FIGURE 1 Images of TALON IO and FAST1 IO devices.



thoracotomy (EDT) or autopsy, was considered as failure. Considering that our institution was trialing a limited number of devices, this outcome was immediately discussed with the faculty member for performance improvement. Prior to using these devices, physicians attended a virtual training session organized by the vendor and/or a personal in-service demonstration by the trauma program manager.

Secondary outcomes included the type and location of vascular access in relation to the patient's underlying injury mechanism (potentially impeded IO placement), return of spontaneous circulation (ROSC), operating room interventions, 6-hour survival, and discharge survival. As these devices were being deployed during periods of shock, such that, the clinician would not know if a true underline injury existed, potentially impeded IOs were defined as IOs placed with a possible injury, including potential fractures, proximal to the IO placement. For example, if a patient had a right tibial-IO placement and an abdominal gunshot wound, this was classified as a potentially impeded IO placement. Patients were classified as dead on arrival if no signs of life were detected on presentation to the trauma bay. Finally, the patient demographics, injury mechanism, and details of resuscitation, including the infused blood products and medications, were analyzed.

Statistical Analysis

Medians and interquartile ranges (IQR) were determined. The analysis was performed using STATA version 16.0 (StataCorp, <https://www.stata.com/>). The manuscript was prepared in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (Supplemental Digital Content).¹⁴

Results

The analysis included nine patients who received the sternal-IO device in the pilot study. All patients were male with a median age of 26 years (IQR 24–31 y) (Table 1). In addition, all nine were victims of gunshot wounds and brought to our trauma bay by police transport as part of a Philadelphia Police Department initiative that allows police officers to transport trauma victims directly from the scene of injury (Table 1). Eight patients arrived after short transport times with no signs of life, and the ninth patient presented in extremis with a witnessed arrest shortly thereafter. All nine underwent EDT, including six clamshell thoracotomies. In addition, all patients required ED intubation and vigilant monitoring of resuscitation with adjunctive medications and procedures, such as arterial lines, venous access other than sternal IO, thoracostomy tubes, and tourniquets.

TABLE 1 Baseline Demographics Including Injuries and Survival Outcomes

	Entire Cohort, no. (%)*; n=9
Baseline Demographics	
Age, y, median (IQR)	26 (24–31)
Male	9 (100)
Penetrating-gunshot wound	9 (100)
Glasgow Coma Scale, median (IQR)	3 (3–3)
Injury Severity Scale, median (IQR)	26 (17–75)
Patients with a head/neck injury	3 (33)
Patients with a thoracoabdominal injury	8 (89)
Patients presenting with a potential extremity injury†	8 (89)
Patients presenting with 1 potential extremity injured	4
Patients with 2 potential extremities injured	2
Patients with 3 potential extremities injured	1
Patients with 4 potential extremities injured	1
Outcomes	
Return of spontaneous circulation	3 (33)
Operating room intervention	2 (22)
6-hour survival	1 (11)
Discharge survival	0 (0)

*Unless otherwise specified.

†As patients died before the diagnosis of injured extremities was established, the potential injuries are listed.

Patients' presenting characteristics, gunshot wound locations, and wound characteristics based on physical examination are listed in Table 2. Six patients (67%) received a TALON IO device while three (33%) received a FAST1 IO. Seven (78%) sternal-IO devices were successfully inserted (Table 1). All six (100%) TALON IO devices were successfully inserted, while one (33%) of the FAST1 IOs was successfully deployed, as the unsuccessful ones were visually malpositioned.

Seven sternal-IO devices were deployed by the trauma faculty. Additionally, the trauma patients were managed by three different personnel. Our trauma leader, who has military training, inserted five sternal-IO devices, four of which were successful. The other two personnel had no prior military training. One of the Operators placed a sternal-IO device successfully. The other Operator supervised two successful attempts and attempted a third unsuccessfully. Two of the devices were successfully deployed by emergency department faculty.

A list of comprehensive modes of intravascular access is presented in Table 3, including the total amount of fluids and medications infused through all sites of access. Notably, seven (78%) patients had at least one tibial-IO device placed during their resuscitation. Six (67%) patients had tibial-IO access that was potentially impeded by either a potential proximal venous injury or a potential underlying fracture. A total of 10 tibial-IO devices, three humeral-IO devices, two femoral central line catheters, and four peripheral IVs were potentially impeded. However, two tibial-IO devices, one humeral-IO device, none of the central lines, and three peripheral IVs were unimpeded (Table 4).

Three (33%) of the patients achieved ROSC while in the trauma bay, although one had a non-survivable traumatic brain injury (multi-compartmental intracerebral hemorrhage).

TABLE 2 Patient Presentation and Injury Details*

1	PDO, uncertain time of injury; DOA; GSW: chest × 2, back × 1, groin × 7, thigh × 4. Injuries: right ventricle laceration extends to spine and right ventricle outflow tract, posterior mediastinal structures with palpable bone fragments in the base of the wound from the spinal canal.
2	PDO, uncertain time of injury; DOA; GSW: left chest, right chest × 2, left shoulder, back × 3; Injuries: bilateral pulmonary hilar injury, left AV junction.
3	PDO, uncertain time of injury; DOA; GSW: left hip and right hip/thigh, left maxilla, left lateral posterior neck; Injuries: transection of right iliac artery and several enterotomies.
4	PDO, lost pulses in trauma bay; GSW: left lateral neck with bullet fragment involving right mandible; Injuries: left vertebral artery and fractured spinous process.
5	PDO, uncertain time of injury; DOA; GSW: right shoulder, right hip, multiple right thigh, left thigh and peripheral GSWs; Injuries: right upper lobe, right axillary or subclavian vessel, with unidentified mediastinal and abdominal injuries.
6	PDO, uncertain time of injury; DOA; GSW: left clavicle, left thigh, left knee, multiple peripheral; Injuries: left subclavian artery and vein, penetrating.
7	PDO, uncertain time of injury; DOA; GSW: left chest × 2, right posterior shoulder, left posterior shoulder, left temple, several bilateral groin, thigh, several peripheral. Injuries: multicompartment intracerebral hemorrhage with intraventricular hemorrhage, left lung and left thoracic inlet.
8	PDO, uncertain time of injury; DOA; GSW: left hip, right gluteal, left flank × 2, left thigh × 3; Injuries: right ventricle, right lung, right diaphragm, right liver.
9	PDO, uncertain time of injury; DOA; GSW: back × 5, right axilla; Injuries: right lung, diaphragm, and abdominal injuries.

*No extremity injuries are repeated with their respective reported injuries. AV = atrioventricular; DOA = dead on arrival; GSW = gunshot wound; PDO = police drop off.

Consequently, goals of care were changed. Two of the patients who obtained ROSC went to the operating theater. The two patients (patients 3 and 4) were transfused with more than 60 units of blood products (Table 3). One of these patients survived for at least six hours; however, this patient died of coagulopathy. The other patient succumbed to possible refractory vasoplegic and neurogenic shock.

Discussion

Despite a rich historical military experience during World War II of routine placement of IO catheters, including sternal-IO placement, and an increasing number of studies documenting the use of sternal-IO devices in both the modern military sector and research/cadaver laboratories, limited data support their effectiveness in patients with hemorrhagic shock.^{6,7} In this pilot study, we investigated a novel application of military resuscitation in a civilian population at risk for potentially preventable death from trauma.¹⁵ We sought to determine whether the sternal-IO device was a plausible mode of resuscitation in patients with multiple gunshot wounds who are at high risk for difficult and obstructed extremity IV access. In this study, sternal-IO placement was successful in nearly 80% of cases, indicating a potential role in mitigating hemorrhagic shock in the civilian sector.

An 80% success rate is consistent with the prior two decades of preexisting literature, consisting of a compilation of cadaver, military, and prehospital studies.^{4,5,16–17,18–22} However, these sternal-IO devices have never been studied in patients with severe traumatic injury in extremis. Cadavers encompassed

TABLE 3 Access Obtained, Fluids and Medications Infused

Patient #	Access Obtained	Fluid and Medications Infused
1	Sternal (TALON), right humeral, right tibial	1u PRBC, 1u Plasma, 2 amps epi
2	Sternal (TALON), right femoral, right tibial, left tibial	1u PRBC, 1u plasma, 3 amps epi, 1-amp CaCl, 1 amp NaHCO ₃
3	Sternal (TALON), right femoral, right tibial, left tibial, right humeral, peripheral IV	MTP (In total 19 PRBC, 13 FFP, 3 platelets, cell saver, TXA, several amps of Ca and NaHCO ₃ , vasoactive medications in OR, Unasyn
4	Sternal (TALON), right tibial, left tibial, peripheral IV x 2	MTP (2u WB, 14u PRBC, 10u FFP, 2u platelets and cell saver), 7 amps epi, 5 amps CaCl, 3 amps NaHCO ₃ , vasoactive medications in OR
5	Sternal (TALON), left humeral	2u PRBC, 2u FFP, 6 amps epi, 1 amps CaCl, 2 amps NaHCO ₃
6	Sternal (TALON), left tibial, right humeral, peripheral IV	2u PRBC, 2u FFP, 9 amps epi, 2 amps Ca, 4 amps NaHCO ₃
7	1 unsuccessful sternal (FAST1), 2 peripheral IVs	2u PRBC, 2u FFP, HTS, TXA, ancef, 2 amps epi, 1 amp, CaCl, 2 amps NaHCO ₃
8	1 unsuccessful sternal (FAST1), left tibial, right tibial	1 amp epi
9	Sternal (FAST1), left tibial, right tibial, peripheral IV	3 amps epi

Ca = calcium; CaCl = calcium chloride; epi = epinephrine; FFP = fresh frozen plasma; HTS = hypertonic saline; IV = intravenous; MTP = massive transfusion protocol; NaHCO₃ = sodium bicarbonate; OR = operating room; PRBC = packed red blood cells; TXA = tranexamic acid; U = unit; WB = whole blood.

58 FAST1 IO attempts overall, with a success rate of 94% in 31 attempts and 95% in 27 attempts.^{16,17} Bjerkvig et al. reported the use of sternal-IO devices by military personnel with a 91% (10/11) success rate with the FAST1 IO and a 71% (10/14) success rate with the TALON IO.⁵ Further, based on an autopsy review at Port Mortuary of Dover Air Force Base, Delaware, 80% (78/98) of sternal-IO devices were implanted successfully. The 20 cases of unsuccessful placement involved 17 placed outside of the periosteum and three in the periosteum other than the sternum.⁴ Prehospital data comprises the majority of the literature base. There were 199 attempts¹⁹⁻²² overall with a success rate of 90% (17/19)²⁰ FAST1 IOs placed by aeromedical nurses, 73% (30/41)²² FAST1 IOs placed by paramedics, 72% (64/89)¹⁹ FAST1 IOs placed by emergency medical technicians and registered nurses. In addition, Macnab et al. noted that the success rate depended on the clinician experience level.²¹ When physicians and paramedics deployed 50 FAST1 IO devices, the overall success rate was 84%.²¹ While all clinicians received training, those who had prior clinical experience in placing a sternal-IO device reported higher success rates (95%) than those who did not (74%).²¹

The angle of placement was thought to be a contributing factor in two unsuccessful attempts involving our FAST1 IO devices. During the first attempt, the thoracotomy was already performed, and the clinician inserting the IO had difficulty ensuring the correct 90° angle. Further, in the setting of a thoracotomy, the chest wall and sternum appeared to have insufficient structural support to allow the automated IO mechanism

TABLE 4 Potentially Impeded Devices

	Entire Cohort, % (n=9)
Humeral IO	
Unimpeded humeral IO	1
Impeded humeral IO	3
Injuries towards the chest resulting in potentially impeded IO	3
Tibial IO	
Unimpeded tibial IO	2
Impeded tibial IO	10
Injuries to the thigh resulting in potentially impeded IO	4
Injuries to the chest or abdomen/pelvis resulting in potentially impeded IO	6
Femoral Central Line	
Unimpeded femoral central line	0
Impeded femoral central line	2
Injuries to the thigh resulting in potentially impeded IO	1
Injuries to the chest or abdomen/pelvis resulting in potentially impeded IO	1
Peripheral IV Catheter	
Unimpeded peripheral IV catheter	3
Impeded peripheral IV catheter	4
Injuries to the chest resulting in potentially impeded peripheral IV	4
Sites Without Potential Impeding Injuries	
Humeral	
Sites with IO access	1
Sites without IO access	3
Tibia	
Sites with IO access	2
Sites without IO access	0

IO = intraosseous; IV = intravenous.

to deploy. During the second attempt, several procedures were performed simultaneously, which limited the clinician's ability to make a 90° attempt and apply continuous increasing pressure. The same surgeon who cared for the second FAST1 IO patient also managed the final FAST1 IO patient and made appropriate angle adjustments. Here, the surgeon found that it was easier to obtain an appropriate angle by standing at the head of the bed.

Notably, unlike the TALON IO, the FAST1 IO requires a considerable amount of force to insert the device into the sternum. EDT alters and ultimately limits the structural stability of the chest wall, thus making it difficult to generate enough force to activate the spring-loaded infusion needle. Accordingly, we discontinued further use of the FAST1 IO devices given the high number of EDT patients managed in our trauma bay. We believe that our success rate of the FAST1 IO cannot be extrapolated to patients who did not undergo an EDT because the FAST1 success rate may be considerably higher, as reported previously.^{5,16,17,19-22}

Additionally, we found that infusions through a manubrial IO can extravasate through an adjacent manubrial or perimanubrial ballistic injury site. However, the infusions did not extravasate through the cut edge of the sternum following a clamshell thoracotomy. One can surmise that the product

may extravasate from nearby vessels (e.g., the internal mammary vessels); however, this is not a known absolute contraindication. Further, our division did not observe any overt extravasation.

The strength of our study is that it combined details from our initial product trial and performance improvement review along with a structured manual chart review, to discuss the temporal events surrounding the placement of the sternal-IO device. Nonetheless, our analysis is not without inherent limitations. First, as a single-center pilot study, our analysis was limited to only nine patients. This limited our ability to detect any meaningful statistical significance. Second, our population was limited to patients in the arrest/peri-arrest period, yielding poor survival outcomes, as expected. Therefore, our findings cannot be extrapolated to patients outside of the arrest/peri-arrest period. Additionally, the success rate of the FAST1 IO would have likely been higher had the devices not been placed in patients undergoing an EDT. Lastly, as a retrospective review, data were collected for clinical reasons. Thus, we were unable to make any meaningful comparisons regarding the modes of intravascular access placement. For example, we could not delineate the flow rate of the sternal-IO device, the access site through which the products were infused, or the amount of time required to insert the device.

Our pilot study showed that sternal-IO devices were deployed successfully nearly 80% of the time. All sternal-IO devices were deployed by physicians; while this may limit generalizability, our success rates correlated with those of other practitioners.^{16,17,19,20,22} An alternative would be the other modes of intravascular access. Chreiman et al. compared IO access with central venous catheters and peripheral intravenous catheters.²³ Their findings indicated that IO access had a higher success rate than both the central venous catheters (46%) and peripheral intravenous catheters (42%).²³ Additionally, their findings noted that the IO placement was quicker than the placement of a central venous access catheter.

Other studies reported that the success rate of the sternal-IO device (71%–95%) was similar to those of both tibial-IO (91%–100%) and humeral-IO devices (77%–83%).^{4,5,16–20,22–24} However, when comparing the sternal-IO device with other modes of IO access, these studies fail to highlight cases where the venous injury may be interposed between the vascular access site and the heart. Although humeral-IO devices are in greater proximity to the heart than tibial-IO devices, the flow speed of humeral-IO devices often limits the speed of resuscitation. The sternal-IO device addressed this limitation with a faster documented flow rate than the humeral-IO device in two cadaver studies.^{17,25} Thus we sought to determine the plausibility of the sternal-IO device, when the patient had other possible sites of IO access. In addition, our pilot study used both a manual insertion device, TALON IO, and an impact-driven device, FAST1 IO. One may consider a handheld, battery-powered device, such as the Arrow EZ-IO (Teleflex, <https://myteleflex.com>); however, the evidence does not strongly support battery-powered sternal-IO devices over either of these devices, which would be a target for further investigation.²⁶

The sternal-IO device has the potential to benefit an exsanguinating casualty. With a nearly 80% successful placement rate, we believe future prospective trials should be performed to better capture its potential impact, including the time of

placement, infusion rates, and outcomes. These findings may then have civilian applications beyond the use of sternal-IO devices for impeded access, such as during a mass casualty incident. These findings could then have a profound impact on resuscitation during both in-hospital and prehospital trauma care and represent a potential mechanism to mitigate preventable death. This would reinforce military–civilian partnership in innovative trauma care.

Conclusion

In this single-center, retrospective observational pilot study involving an urban civilian academic trauma center, deploying the sternal-IO device in a mangled exsanguinating patient population was associated with a high success rate, which can be translated to combat casualty care. Furthermore, sternal-IO access facilitates the administration of products and adjunctive therapies into the central circulation while avoiding several potential impeded locations. Future studies are necessary to characterize the civilian trauma patient who would most benefit from this intervention and to determine performance parameters relative to other access strategies.

Author Contributions

AMH, KCC, NDM, and JWC designed the study. AMH, SM, ZQ, and JAY searched the literature. AMH collected the data. AMH analyzed the data. AMH, GAB, TK, NG, and JWC participated in data interpretation. AMH, SM, and JWC drafted the article. All authors critically revised and approved the manuscript.

Disclaimer

The views in this article are those of the authors and do not represent an endorsement by or the views of the United States Navy, the United States Air Force, the Department of Defense, or the United States Government.

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