Use of an impedance threshold device in spontaneously breathing patients with hypotension secondary to trauma: An observational cohort feasibility study

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BACKGROUND: An impedance threshold device (ITD) intended for use in the spontaneously breathing patient has been shown to raise blood pressure in hypotensive patients. This device has not been evaluated in patients with hypotension secondary to trauma. This study focused on changes in key vital signs when the ITD was added to the paramedic treatment protocol for hypotensive patients with prehospital traumatic injury.

METHODS: A 6-month prospective nonrandomized observational cohort study was conducted of 200 spontaneously breathing symptomatic adult patients with prehospital hypotension due to multiple causes; the patients of primary interest experienced a traumatic injury. Upon determination of hypotension (systolic blood pressure of approximately ≤90 mm Hg), standard therapy was initiated by application of the mask-style ITD. Vital signs were documented every 2 minutes to 5 minutes after intervention. A change in mean arterial pressure (MAP) with ITD use was the primary study endpoint.

RESULTS: Of the 200 hypotensive subjects treated, 29 (3 were excluded because of incomplete data sets and 3 patients treated with the ITD were excluded because their blood pressure did not meet inclusion criterion) were hypotensive secondary to trauma. Their MAP increased from 60 mm Hg (SD, 11 mm Hg; 95% confidence interval [CI], 8.17–15.432) to 78 mm Hg (16 mm Hg; 95% CI, 12.43–23.46) (p = 0.001), without significant change in mean heart rate. Approximately 75% of the patients reported moderate to easy tolerance. Similar increases in MAP were observed in the nontraumatic patients, from 60 mm Hg (10 mm Hg; 95% CI, 9.4–11.5) to 70 (15; 95% CI, 13.4–16.7) (p = 0.0001).

CONCLUSION: In this observational cohort study of patients with hypotension secondary to trauma, the ITD was well tolerated, and MAP as well as systolic and diastolic blood pressure were improved. The patients were not overresuscitated with this intervention. On the basis of these findings, additional studies in patients with hypotension secondary to traumatic injury should be performed to better define the need and benefit of additional fluid resuscitation when the ITD is used. (*J Trauma Acute Care Surg*. 2014;77: S140–S145. Copyright © 2014 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Therapeutic study, level IV.

KEY WORDS: Permissive hypotension; impedance threshold device; prehospital; noninvasive therapy.

In the trauma patient, shock resulting from hemorrhage often portends poor outcomes. Fluid administration has traditionally been the therapy of choice for the hypotensive patient. Crystalloid infusion is not necessarily benign.[1,2] Difficult vascular access, hemodilution, acidosis, decreased oxygen delivery, and loss of clotting factors continue to be problematic in the poorly perfused patient.[3] Optimizing cardiac output and tissue perfusion in this patient population is a core therapeutic goal during transport to definitive care.

Submitted: January 9, 2014, Revised: March 3, 2014, Accepted: April 1, 2014.

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DOI: 10.1097/TA.0000000000000368

In spontaneously breathing patients, use of an impedance threshold device (ITD-7) generates a small degree of inspiratory resistance (−7 cm H_2O at a flow rate of 20 L/min) that further reduces intrathoracic pressure during inspiration. ITD use enhances blood return from the peripheral vascular system into the heart each time the patient takes a breath.[4] Clinical and experimental evidence supports the application of the ITD to modulate intrathoracic pressures, with the intent to (1) ameliorate hypotension secondary to severe blood loss, hemorrhagic shock, and hypovolemia; (2) relieve the adverse clinical effects of orthostatic hypotension and hypotension secondary to vasovagal syncope, dehydration, and renal dialysis; (3) provide a treatment of right-sided heart failure after myocardial infarction; and (4) reduce intracranial pressure for the treatment of secondary brain damage after head trauma.[5–7] In each of these medical emergencies, rapid restoration of perfusion is essential to maintain vital organ function. In cases of severe blood loss, the ITD is able to help rapidly restore central blood volume by transforming the thorax into a more active vacuum, drawing venous extrathoracic blood to central circulation. Use of the ITD may reduce the need for immediate fluid resuscitation[5,8] and, unlike fluid resuscitation and vasopressor therapy, can be rapidly removed upon reaching the

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
09 SEP 2014	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Use of an impedance threshold device in spontaneously breathing patients with hypotension secondary to trauma: An observational cohort feasibility study	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
Wampler D., Convertino V. A., Weeks S., Hernandez M., Larrumbide J., Manifold C.,	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
US Army Institute of Surgical Research, JBSA Fort Sam Houston, TX	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**UU**	**6**	

target blood pressure without known long-term untoward effects. On the basis of collaborative research with the National Aeronautics and Space Administration and the US Army Institute for Surgical Research, the ITD has been used for treatment of hypotension due to multiple causes in spontaneously breathing patients.[6,9] The US Army is specifically interested in ITD technology for use on the battlefield as circulatory adjunct for the wounded warrior.

This study was primarily focused on spontaneously breathing patients who developed hypotension after traumatic injury. It was designed as a prospective cohort observational study wherein ITD-7 use was integrated into the basic life support (BLS) and advanced life support (ALS) protocols for the treatment of prehospital hypotension. We encouraged ITD use in all prehospital hypotension patients in whom it was indicated to enhance circulation. We were particularly interested in hemodynamic improvements in patients with traumatic injuries in this environment. As such, the objective of this study was to test the hypothesis that application of an ITD would result in a moderate elevation of mean arterial blood pressure in hypotensive patients with a traumatic injury in the prehospital setting without adverse effects.

PATIENTS AND METHODS

Study Design

This observational cohort study was approved by the University of Texas Health Science Center at San Antonio Institutional Review Board as a minimal-risk nonrandomized observational cohort study as a component of a comprehensive Quality Assurance/Quality Improvement (QA/QI) program conducted by the Office of the Medical Director for the San Antonio Fire Department (SAFD). It was designed to assess the postmarket field use of a Food and Drug Administration–cleared ITD device specifically in a large urban emergency medical service (EMS) system. The ResQGARD is an ITD-7 that was developed by Advanced Circulatory (Roseville, MN).

Setting

San Antonio, Texas, is the seventh largest city in the United States with approximately 1.4 million residents. The SAFD is the exclusive provider of 911 EMS for the City of San Antonio. The SAFD responds with a Mobile Intensive Care Unit ambulance with a minimum of two paramedics, typically supported by fire division first responders, and responds to approximately 125,000 medical calls per year. SAFD medical oversight and QA/QI are provided by the University of Texas Health Science Center at San Antonio, Department of Emergency Health Sciences, Office of the Medical Director, by written medical protocol and direct online medical consultation. Data collection was performed by abstraction from the electronic medical record.

Selection of Participants

The study inclusion criteria were symptomatic adult hypotensive patients with a systolic blood pressure (SBP) of approximately 90 mm Hg or lower. The primary intent was to discern if the ITD would be of clinical benefit to patients with traumatic injuries. However, the potential value of the ITD for the treatment of patients with symptomatic hypotension from all causes was also of interest. Data were collected for all patients from the perspective of device safety, effectiveness, and tolerance. The trauma subsets were considered inclusive of the total patient population and a specific subgroup. As such, EMS personnel treated all 911 patients with hypotension. This cohort was inclusive of suspected dehydration, sepsis, hypovolemia, or orthostatic intolerance. The exclusion criteria were as follows: the patient met the definition of a special population (e.g., children, pregnant women, or prisoners), the patient was unable to maintain his or her own airway, the patient had clinical pulmonary edema, the patient was complaining of feeling "air starved," and the patient was unable to or will not tolerate the device. Any patient meeting at least one exclusion criterion was not included in the study.

Training of Paramedic Staff

All paramedics underwent 30 minutes to 45 minutes of training regarding patient inclusion and exclusion criteria, use of the device, and human subject protection. This training was reinforced by a web-based training video (http://www.youtube.com/watch?v=kg2e_agYyBo) along with an 8.5-in × 11-in laminated visual reminder posted inside the ambulance. In addition, the Office of the Medical Director staff would periodically reinforce the training through online medical control communication.

Interventions

The ITD was supplied to all BLS and ALS EMS field personnel in a kit containing the ITD, facemask, oxygen tubing, and head strap. Upon determination of hypotension (SBP < 90 mm Hg) and absence of exclusion criteria, all vital signs were documented as standard practice and the ITD was applied to the patient in accordance with the manufacturer's recommendations. The subject was coached to control breathing, using deep and slow breaths, and supplemental oxygen was used if the paramedics deemed it necessary. Continuous reassessment and documentation of vital signs every 2 minutes to 5 minutes were performed. The EMS personnel also assessed patient tolerance, as observed by the patient's reaction to the device, and the patient's comfort, reported on a scale of 1 to 5, with 1 being not tolerated and 5 being easily tolerated. The BLS and ALS personnel were instructed to apply the ITD and to use other therapeutic interventions as clinically indicated according to their hypotension treatment algorithms, including intravenous (IV) fluid, vasopressors, and changes in body position (e.g., Trendelenburg).

Measurements

SBP, diastolic blood pressure, heart rate (HR), respiratory rate, and arterial oxygen saturation (SpO_2) were recorded immediately before application of the ITD. This set of vital signs was defined as before ITD. The device was then secured to the patient's face with a mask, and the next set of vital signs was recorded 2 minutes to 4 minutes later. This set of vital signs was defined as after ITD therapy. If any data elements were missing, the vital sign set with the closest proximity (while still meeting the definition of before or after application of the device) would be substituted for the protocol set of vital signs. In an effort to minimize missing data elements, the electronic medical record used a "closed call rule" that required the paramedic to address ITD use data elements if an adult was documented with an SBP between 80 mm Hg and 100 mm Hg. The treating paramedic

could not close the electronic medical record until satisfying all data collection requirements.

Outcomes

The primary study endpoint was the difference in the calculated mean arterial pressure (MAP), from before to after ITD use, in patients with hypotension secondary to traumatic injury. Secondary outcomes included changes in vital signs for all treated subjects, patient tolerance, and patient comfort.

Analysis

A sample size of 200 patients was determined a priori for this feasibility study to accumulate enough data to estimate a potential effect size and the relative safety of the ITD in the subgroup of patients with hypotension secondary to trauma. Mean (SD) and 95% confidence intervals (CIs) were calculated for the key hemodynamic variables, and p values were determined using paired Student's t test.

RESULTS

The mean (SD) patient age was 57 years (18 years), and 54% were male. The primary indications for ITD use, as determined by the treating paramedic at the scene, are summarized in Table 1. Trauma accounted for 29 (14.5%) of 200 of the overall patient population, although 3 were excluded because of incomplete documentation of vital signs. All patients treated with the ITD were alive at the time they arrived to the hospital, and their care was transferred to emergency department personnel. Further follow-up outcome data were not available, as this study was performed as part of our EMS QA/QI program and consent for participation in subject follow-up was not intended or obtained.

Using standard electronic medical record abstraction processes, we captured 200 complete patient records with documented cases of hypotension. Complete before and after vital sign data were available on 174 patients of the 200 patients enrolled in this study, regardless of the cause of hypotension

TABLE 1. Primary Impressions of the Patients Who Were Treated With the ITD

	All Patients (n = 200)	
Primary Impression	**n**	**%**
Altered mental status	13	7
Chest/abdominal complications (nontraumatic)	22	11
Diabetic complications	4	2
Dizziness	20	10
Generalized weakness	34	17
Primary dehydration	4	2
Sepsis	6	3
Syncopal episode	18	9
Toxic ingestion/stings	6	3
Blunt and penetrating trauma	29	15
Undifferentiated hypotension	24	12
Other	20	10

Of the 29 subjects with trauma, 3 were treated although their SBP was higher than 95 mm Hg, and there were 3 subjects who had incomplete data in this subgroup.

TABLE 2. Mechanism of Injury for Trauma Patients Treated With the ITD

	Trauma Subgroup (n = 23)	
Primary Impression	**n**	**%**
Motor vehicle collision	6	26
Fall	10	43
Shooting/stabbing	5	22
Laceration	2	9

(Table 2). In the overall patient cohort, 67% of all patients demonstrated an increase in MAP. The mean (SD) MAP before application of the device was 60 (10) mm Hg and increased to 70 (15) mm Hg after ITD therapy (Table 3). The HR decreased by a modest two beats per minute ($p = 0.007$). The respiratory rate was constant: 19 (7) breaths before to 18 (4) breaths ($p = 0.31$) per minute after ITD use. Oxygen saturation remained unchanged and within normal clinical values with ITD use. of the 200 patients, 54 (27%) received no intravascular fluids before ITD application. In this "no fluid group," MAP increased from 60 (9) to 74 (16) ($p \leq 0.0001$). There was no statistical difference in the MAP after ITD use between the "no fluid group" and the overall cohort after ITD (Table 3).

In patients with trauma, there was an increase in MAP in 19 (82%) of 23 trauma patients treated with the ITD. The data from this patient subgroup are shown in Table 2. MAP in the hypotensive trauma patients increased from 60 mm Hg (11 mm Hg; 95% CI, 8.1–15.4) to 78 mm Hg (16 mm Hg; 95% CI, 12.43–23.46). There was no change in the HR or other vital signs. There was a consistent increase ($p = <0.0001$) in both mean SBP (from 79 [14] to 103 [22]) and diastolic blood pressure (from 54 [14] to 71 [19]) in patients with hypotension secondary to trauma.

The trauma subgroup was further divided into three subgroups: (1) those patients treated with IV fluids before ITD application (fluids first; n = 6); (2) those patients treated with IV fluids concomitant with ITD treatment (fluids during; n = 9); or (3) ITD application before or without IV fluid therapy (ITD first; n = 7). Although not statistically distinguishable ($p = 0.26$), the fluids first group tended to have a lower mean (SD) initial MAP of 46 (25) mm Hg than the patients in the fluids during group (MAP, 58 [11] mm Hg, n = 9) and the ITD first group (64 [9] mm Hg). The mean (SD) elevation in MAP for the fluids first group increased from 46 (25) mm Hg to 53 (28) mm Hg ($p = 0.66$) after initiation of the ITD therapy. MAP increased from 58 (11) mm Hg to 80 (20) mm Hg ($p = 0.006$) in the fluids during group and from 64 (9) mm Hg to 86 (9) mm Hg ($p = 0.002$) in the ITD first group. Other vital sign Δ values for these subgroups are shown in Table 4.

Device tolerance and comfort of the overall patient population were similar to that of the trauma patient subgroup. A total of 155 patients (78%) self-reported easy to moderate comfort, whereas 26 patients (13%) reported difficulty in tolerating the device. Fifteen (65%) of the 23 trauma patients were able to use the ITD without difficulty, with 2 (9%) additional patients reporting only moderate difficulty. Patient tolerance, as reported by paramedics, was similar. The change in MAP was slightly reduced in the subjects who did not tolerate the ITD; their mean δ MAP before to after ITD was 10 mm Hg in the

TABLE 3. Vital Signs for All Patients

	Systolic, mm Hg	Diastolic, mm Hg	MAP, mm Hg	Pulse (per minute)	Respirations (per Minute)	SaO_2, %
Before ITD Use						
Mean	78	51	60	87	19	97
SD	13	13	10	25	7	3
Median (Q1–Q3)	80 (71–86)	52 (45–59)	62 (62–67)	86 (68–101)	18 (16–20)	98 (96–100)
After ITD Use						
Mean	97	63	70	85	18	99
SD	19	15	15	22	4	2
Median (Q1–Q2)	93 (84–107)	60 (53–70)	68 (63–81)	84 (69–99)	18 (16–20)	100 (98–100)
p	<0.001	<0.001	<0.001	0.07	0.31	0.28

SaO_2, arterial oxygen saturation.

nontolerant group versus 17 mm Hg in the ITD-tolerant group (Fig. 1, Table 5).

DISCUSSION

This study demonstrated that the ITD could be integrated into the treatment algorithm for spontaneously breathing patients with hypotension secondary to trauma by prehospital EMS care providers. The device was well tolerated and increased MAP in most of the patients receiving the intervention. Importantly, the ITD reduced the hypotension secondary to trauma but MAPs were not restored to "normal." These observations are consistent with prior preclinical studies with the ITD in pigs in which ITD use without concurrent fluid administration raised MAPs to "permissive hypotension" levels without exceeding pressures typically associated with popping the clot. By contrast, in the animal studies, fluid boluses caused a marked spike in SBP.[6]

During the past two decades, there have been multiple preclinical and clinical studies that have called into question the wisdom of using isotonic crystalloids to treat hypovolemic shock. In the current study, there was no appreciable benefit of IV fluid administration on MAP in hypotensive patients treated with the ITD. These observations suggest that, at a minimum, the ITD by itself may be a reasonable first step for spontaneously breathing patients with hypotension secondary to trauma. Undoubtedly, some patients will also benefit and/or need additional fluid resuscitation or vasopressors resuscitation between the time EMS personnel begin treatment and when more definitive treatment can be provided. Given the often austere environment where patients, including wounded warriors, often present with hypotension secondary to trauma, ITD use is a new and noninvasive way to help restore central blood volume. This increased preload serves to increase cerebral and peripheral tissue perfusion in the absence of, or delayed, definitive surgical repair, whole blood, plasma, or large quantities of crystalloids. Importantly, improved feeling of well-being is consistent with mechanisms by which the ITD has been shown to enhance cerebral perfusion.[7,10]

Hypotensive resuscitation has become a clinical practice guideline in an attempt to minimize the possibility of dislodging clot formation.[11] The results from the present study indicate that use of the ITD allows for the successful elevation in perfusion (arterial) pressure while maintaining a permissive hypotension consistent with this guidance. The current findings are also consistent with data obtained from a recently reported clinical study in patients treated by EMS personnel, and controlled laboratory experiments conducted on healthy humans showing use of the device in individuals with low blood pressure resulted in a consistent but moderate increase in blood pressure.[6] Taken together, these findings provide evidence that the device could be safely and effectively used in patients with low blood pressure secondary to trauma, with minimal concern for exacerbating hemorrhage.

The current data presented, in combination with the Toledo study,[6] have implications for military casualties. The ITD technology could be a significant clinical improvement in battlefield prehospital treatment, particularly in cases in which the casualty has noncompressible hemorrhage. In the current and prior

TABLE 4. Vital Signs for Trauma Patients

	Systolic, mm Hg	Diastolic, mm Hg	Pulse (per minute)	Respirations (per Minute)	SaO_2, %
Before ITD Use					
Mean	79	54	90	18	97
SD	14	13	29	4	3
Median (Q1–Q3)	78 (69–88)	55 (46–62)	84 (71–102)	18 (14–20)	98 (96–99)
After ITD Use					
Mean	101	70	83	18	99
SD	23	19	20	4	2
Median (Q1–Q2)	100 (89–108)	66 (59–76)	83 (69–98)	18 (16–22)	99 (98–100)
p	<0.001	<0.001	0.26	0.18	0.01

SaO_2, arterial oxygen saturation.

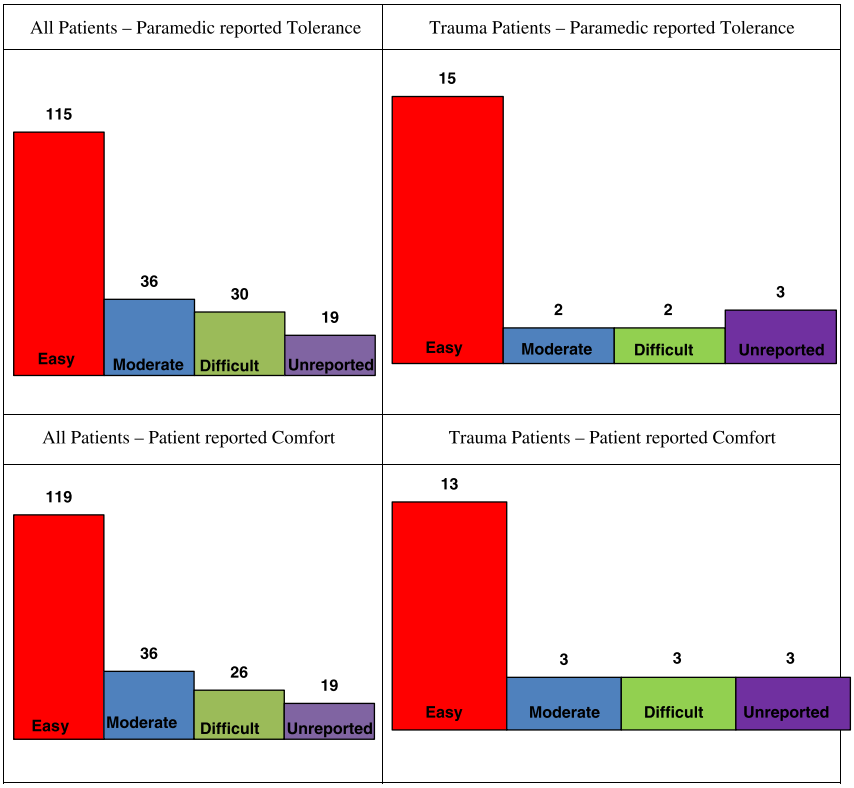

Figure 1. Tolerance and comfort of the ITD in the total population and the trauma subset.

studies, the ITD was well tolerated, easy to use, and effective in increasing blood pressure in patients with severe hypotension in the prehospital environment. What makes the ITD attractive is that it is small, it can be self-administered, it is much lighter weight than IV fluids, it will not result in hemodilution, and there is no evidence of overresuscitation. In addition, the ITD can be self-administered or provided by combat medics and more easily applied in the short-term as compared with vascular access. A question that remains for the EMS community is at what level this intervention should be considered, ALS, BLS, or both? As this device is noninvasive and easily applied, it seems to be applicable to both levels provided that there is adequate training.

There are several potential limitations of this study. By design, each patient served as his or her own control. As such, there was no group of patients who intentionally did not receive IV fluids for comparison. Although this approach presents a potential selection bias issue, we chose this approach because it allowed us to easily, rapidly, safely, and ethically execute the deployment of the ITD as an adjunct to the hypotension bundle of care without withholding any therapies that may otherwise be considered the standard of care. Second, the number of patients treated who had hypotension secondary to trauma was relatively low. However, the current investigation adds to a growing number of studies showing the benefits of noninvasive circulatory enhancement achieved through resistance breathing in patients with hypotension from multiple different causes, including trauma.[6] Third, we did not follow patients long-term, although all of the subjects treated in this observational cohort survived at least for the duration of the EMS prehospital encounter to the time of clinical transfer to emergency department personnel. Fourth, further studies are needed to determine if IV fluids will provide additional clinical benefit when the ITD is used. We suspect that the answer to this question will depend upon clinical circumstances including the severity and cause of the hypotension.

Finally of the 200 patients enrolled under the institutional review board–approved protocol, only 176 patients had complete sets of vital signs before and after application of the ITD. Missing data resulted in part because of the limited number of personnel treating this sick patient population. However, given the positive results, the sample size proved adequate to reflect the consistent clinical effects of increasing MAP and patient well-being by optimizing the respiratory pump with the ITD technology.

In summary, the ITD was readily assimilated into the standard bundle of care for the treatment of hypotensive trauma patients. We observed a consistent and significant increase in MAP with the ITD in this patient cohort without any untoward effects. These clinical findings, together with the observation that the ITD provided permissive hypotension without overresuscitation in patients with trauma, add to the growing support for use of the ITD as part of the first-line noninvasive therapy for hypotension in this patient population.

AUTHORSHIP

D.W. was the principal investigator and responsible for all aspects of the research project. V.C. and C.M. were coinvestigators and were involved in study design and data interpretation. S.W., M.H., and J.L. were study staff involved in study of medic deployment to the field, data collection processes, and manuscript development.

TABLE 5. Vital Sign Parameters for Trauma Patients With IV Fluid Therapy Before ITD Therapy, IV Therapy and ITD Therapy Initiated at the Same Time, and ITD Therapy Initiated Either Before or Instead of IV Therapy

	Systolic, mm Hg	Diastolic, mm Hg	MAP, mm Hg	Pulse (per Minute)	Respirations (per Minute)	SaO_2, %
ITD application after IV fluid therapy (n = 6) (ΔMAP p = 0.66)						
Vital signs before ITD application						
Mean	70	49	46	126	20	98
SD	12	12	25	37	7	2
Median (Q1–Q3)	65 (61–83)	43 (39–62)	48 (34–67)	122 (99–157)	18 (15–26)	98 (97–100)
Vital signs after ITD application						
Mean	78	57	53	96	17	99
SD	14	10	28	29	2	1
Median (Q1–Q3)	74 (66–92)	62 (46–65)	61 (39–72)	109 (66–121)	16 (15–19)	99 (98–100)
ITD application concomitant with IV fluid therapy (n = 9) (ΔMAP p = 0.010)						
Vital signs before ITD application						
Mean	75	50	58	83	19	97
SD	14	11	11	18	3	3
Median (Q1–Q2)	80 (66–85)	53 (46–57)	62 (53–66)	86 (64–96)	18 (16–21)	98 (93–98)
Vital signs after ITD application						
Mean	101	69	80	85	18	98
SD	21	19	20	19	4	2
Median (Q1–Q2)	101 (87–107)	63 (57–76)	75 (66–86)	89 (67–96)	18 (14–22)	98 (96–100)
ITD application before or without IV fluid therapy (n = 7) (ΔMAP p = 0.0006)						
Vital signs before ITD application						
Mean	80	56	64	81	18	96
SD	8	10	9	14	4	4
Median (Q1–Q2)	82 (72–88)	61 (46–65)	68 (55–74)	80 (68–98)	17 (14–20)	97 (95–98)
Vital signs after ITD application						
Mean	108	75	86	77	19	98
SD	18	7	9	11	3	2
Median (Q1–Q2)	105 (93–123)	76 (68–77)	83 (81–89)	78 (67–86)	19 (18–22)	98 (96–100)

SaO_2, arterial oxygen saturation.

ACKNOWLEDGMENT

We thank the men and women of the San Antonio Fire Department for their participation in this study; Advanced Circulatory Systems, the manufacturer of the ITD, for initial training of the paramedics on the use of the device; and Dr. Keith Lurie for comments on this manuscript and help in securing Department of Defense funding.

DISCLOSURE

This project was supported by the Combat Casualty Care Research Program, United States Department of Defense, United States Army Medical Research and Material Command (W81XWH-12-2-0027).

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