Use of pelvic hemostasis belt to control lethal pelvic arterial hemorrhage in a swine model

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BACKGROUND: Hemorrhage is the leading cause of death for both civilian and battlefield injuries. Hemorrhage from pelvic vascular wounds is of concern since it is difficult to control before surgical intervention. This has resulted in renewed interest in developing presurgical endovascular approaches to hemorrhage control. However, it is likely that other short-term techniques may be needed as a bridge to such approaches. We tested a prototype device called the pelvic hemostasis belt (PHB) for its ability to reduce or halt blood flow in a lethal model of pelvic arterial injury.

METHODS: Seventeen male swine, 42 (5.2)kg were anesthetized, instrumented, and then randomized into three groups (control, military antishock trousers [MAST], and PHB). Animals underwent laparotomy with placement of a 4-0 stainless steel monofilament suture through the right iliac artery. The laparotomy was closed, and the iliac suture was exteriorized. Hemorrhage was produced by pulling the suture through the iliac artery. In both PHB and MAST groups, the devices were applied over the pelvis and lower abdomen for 60 minutes, followed by release and monitoring for 30 minutes or until the animal expired. Hetastarch (500 mL) was infused immediately after commencement of hemorrhage.

RESULTS: All PHB group animals and only two from the MAST group survived for 60 minutes. Mean (SD) survival time for the control group was 13 (12.3) minutes. Log-rank (Mantel-Cox) survival analysis demonstrated a significant difference in survival time when comparing all groups ($p < 0.0001$) as well as when comparing PHB and MAST groups ($p = 0.018$). Significant differences were noted between groups in mean arterial pressure, lactate, and central venous hemoglobin oxygen saturation levels.

CONCLUSION: The PHB was successful in improving survival for 60 minutes after a lethal vascular injury. Such a device may be helpful to bridge endovascular methods of hemorrhage control. (*J Trauma Acute Care Surg*. 2015;78: 524–529. Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.)

KEY WORDS: Trauma; hemorrhagic shock; pelvic injury; hemostasis; swine.

Hemorrhage continues to be the leading cause of potentially preventable death in both civilian and military trauma.[1–3] Injuries to vascular structures within the pelvis are challenging to treat rapidly, including those at the pelvic-femoral vascular juncture where the use of tourniquets and/or the ability to apply direct pressure are difficult, if not impossible to perform.[4,5] Such injuries have led to the resurgence of the use of endovascular balloon occlusion of the aorta proximal to these injuries as a bridge to definitive surgical or interventional angiographic repair.[6–14] The latest of these endovascular techniques has been termed *Resuscitative Endovascular Balloon Occlusion of the Aorta* (REBOA). While REBOA is a very promising approach to these extremely lethal injuries, its application requires time and skill and may be difficult to implement outside the civilian trauma center or the first surgical level of combat casualty care. The development of additional countermeasures as an initial bridge to REBOA and definitive repair is needed.

Attempts at external tamponade of these complex injuries as a bridge to definitive surgical care of such injuries are not new. Numerous reports exist in which the military antishock trousers (MAST), in particular, its pelvic/abdominal compartment, have been used in attempts to control such hemorrhage with variable results.[15–21] While newer pelvic devices are now available to stabilize pelvic fractures and to reduce pelvic bleeding by reducing the pelvic space, they are not designed to apply direct pressure to the deep pelvic cavity.[22–24]

The aims of this study were to pilot a prototype device designed to apply and direct pressure to the pelvic cavity for temporary control of lethal arterial pelvic hemorrhage and to compare this device with both MAST and no treatment.

MATERIALS AND METHODS

The University of Michigan Committee on Use and Care of Animals approved this study, which adhered to the *Guide for the Care and Use of Laboratory Animals* (National Research Council, revised 2011).

Male swine were used in the study. Animals were fasted overnight with free access to water. Animals were sedated before anesthesia with intramuscular mixture of ketamine (20 mg/kg) and xylazine (2 mg/kg). Anesthesia was induced with intravenous bolus of propofol (2–4 mg/kg) and maintained with inhalant isoflurane (1–2%). Animals were intubated and provided mechanical ventilation (Fabius GS, Draeger Medical Inc., Telford, PA) at an FIO_2 of 0.3. Minute ventilation was adjusted to maintain an end-tidal CO_2 level between 38 mmHg and 44 mmHg. Core body temperature of 38°C to 38.5°C was maintained through feedback via a rectal temperature probe and heating blanket (Blanketrol II, Cincinnati Sub-Zero Products, Cincinnati, OH).

Electrocardiogram was monitored continuously using a standard 3-lead configuration (Biopac Systems Inc., Goleta, CA). The carotid artery was cannulated for continuous arterial pressure monitoring (MAP) and arterial blood sampling. A pulmonary artery catheter (Swan-Ganz Catheter, 746 F8, Edwards Lifesciences, Irvine, CA) was inserted into the pulmonary artery via the right external jugular vein for sampling of central venous hemoglobin oxygen saturation ($ScvO_2$). The left external jugular vein was cannulated for fluid administration. The left femoral artery was cannulated for continuous monitoring of femoral artery pressure. A laparotomy was performed, the bladder was drained, and the right iliac artery was dissected and exposed. A 4-0 stainless steel monofilament suture (ETHICON Surgical Steel Suture, Johnson and Johnson, San Lorenzo, Puerto Rico) was inserted through a 1.5 to 2 mm length of the iliac artery's wall less than 1 cm from its bifurcation from the aorta. The ends of the suture were exteriorized and held together using forceps outside the abdomen. The abdominal wall was closed using 2-0 silk sutures (ETHICON PERMA-HAND SILK, Johnson & Johnson.)

Once instrumentation was completed, animals were monitored for a 20-minute baseline period. MAP, femoral arterial pressures, heart rate, and $PetCO_2$ were monitored and recorded. Baseline blood gas, hemoglobin, and lactate levels were obtained (ABL800, Radiometer America, Westlake, OH).

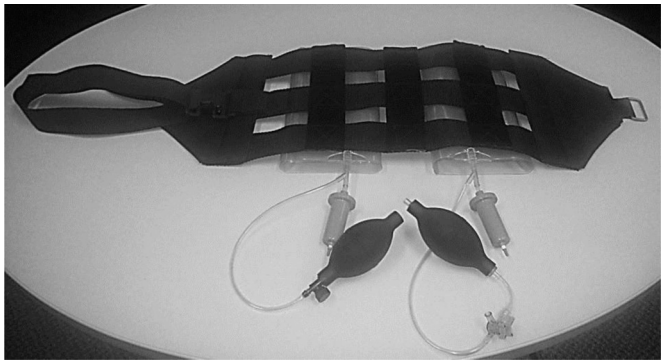

Figure 1. Pelvic hemostasis belt. See text for explanation.

At the end of baseline period, animals were randomized to one of three groups, namely, control, MAST, or PHB.

Hemorrhage and Resuscitation

Uncontrolled hemorrhage was achieved by pulling the stainless steel suture to tear the iliac artery to bleed freely. Hetastarch 500 mL (60 mL/min) (Hospira Inc., Lake Forest, IL) was infused concurrently with the iliac artery tear in all groups as a mean to produce additional hydrostatic stress. Control group animals were allowed to hemorrhage without any intervention other than the concurrent infusion of Hetastarch.

Hemorrhage in MAST group was treated by using pelvic compartment of a PEDI-MAST^{R} III-A (David Clark Company Inc., Worcester, MA), which is designed to produce pressure on the lower torso and legs. The leg compartments were not used. The upper portion of the garment contains one large air bladder that wraps around the abdomen/pelvis and is inflated by a manual pump as directed to 110 mmHg (at this pressure, crackling and popping of the Velcro straps begin).

Hemorrhage was treated in the PHB group, by applying a specialized garment over the pelvis and lower abdomen. The PHB (Fig. 1) consists of three lengths of 5cm wide nylon webbing (nondistendable) placed parallel with a 3cm space between them. The webbing is secured by three additional nylon straps placed at equidistant intervals along the length of the belt and attached with machine stitching at each junction. At each end of the belt, the three straps are connected with a reinforced piece of flat webbing that allows equal pressure to be applied to all three straps when the belt is tightened. A single adjustable 5cm wide strap is attached to one end of the belt and is placed around the back of the animal and attached to the other end of the belt with a plastic side release buckle. The belt is tightened by pulling the strap and securing it in a spring loaded clamp when desired pressure is met. Several flexible pouches are incorporated on the underside of the PHB, which allows placement and configuration of expandable members. In this case, we incorporated a pressure infuser cuff (Clear-Cuff, Smiths Medical ASD, Dublin, OH) into the pouch. This rugged pressure infuser is used to pressurize intravenous fluid bags and contains a calibrated pressure gauge, allowing for pressure in the bag to increase to up to 300 mmHg. Figure 2 demonstrates the PHB and MAST applied to separate animal subjects. Both the PHB and MAST were applied in their unactivated form before the beginning of hemorrhage.

As a measure of pelvic pressure dynamics, the pressure in the left femoral artery was continuously monitored as was central venous pressure and peak airway pressures. Arterial and mixed venous blood samples were obtained every 15 minutes. Animals were monitored for 60 minutes or until MAP dropped to less than 20 mmHg and $PetCO_2$ to less than 15 mmHg. At that time, animals were euthanized with intravenous potassium chloride (1–2 mEq/kg).

Animals surviving for 60 minutes had their garments (PHB or MAST) deflated, had Hetastarch infusion started to keep MAP greater than 65 mmHg, and were monitored for an additional 30 minutes or until death. Animals were euthanized as described earlier. At the time of death, the abdomen was opened, and blood was removed via suction into preweighed canisters and absorption with preweighed sponges for total blood loss determination. At this time, abdominal and pelvic organs were grossly examined for damage.

Data Analysis

Descriptive statistics are expressed as means and SDs. One-way analysis of variance was used to quantify differences between the groups at baseline. Tukey's correction for multiple comparisons was applied. An unpaired *t* test was used to quantify differences between baseline and end of hemorrhage period for some of the variables. Kaplan-Meier survival curve and log-rank (Mantel-Cox) test were used to compare groups' survival time. Data analysis was performed on GraphPad Prizm6 (GraphPad Software, Inc., La Jolla, CA).

RESULTS

Seventeen animals with a mean (SD) weight of 42 (5.2) kg were studied and divided into three groups as follows: control (5 animals), MAST (6 animals), and PHB (6 animals). Table 1

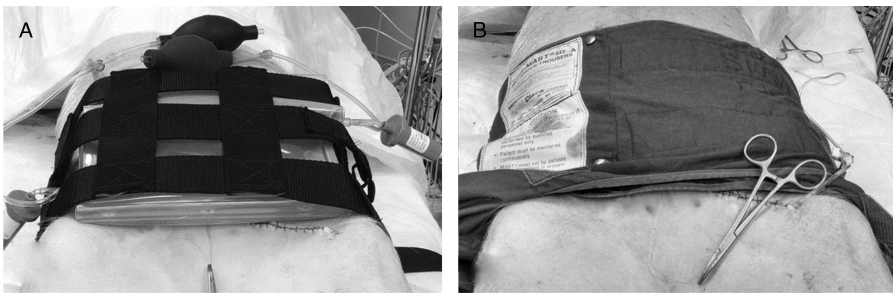

Figure 2. Pelvic hemostasis belt (*A*) and MAST (*B*) applied to separate animals.

TABLE 1. Baseline Parameters and Hemorrhage Total

		MAP, mmHg	Femoral Pressure, mmHg	Heart Rate, beats/min	$etCO_2$, mmHg	$ScvO_2$, %	Lactate, mEq/L	Hemoglobin, g/dL	Hemorrhage Total, mL
PHB	Mean	85	83	83	39	68	1.4	10	1,417
	SD	6	4.8	11.9	1.5	6.9	0.4	0.8	158.1
MAST	Mean	84	85	85	40	72	1.2	9.6	1,650
	SD	11.8	11.9	4.4	1.2	1.9	0.7	1.2	320.9
Control	Mean	88	88	87	39	71	1.2	10.2	1,420
	SD	16.1	17.3	14.4	0.5	6.4	0.3	0.6	152.5

lists the means and SDs for major hemodynamic variables at baseline and total blood loss for all groups. A one-way analysis of variance showed no differences for the baseline parameters between the groups ($p \geq 0.1$).

All PHB animals survived for 60 minutes during the belt application. In all PHB animals, there was complete cessation of the left femoral artery pressure indicating what was likely to be complete tamponade of the injured right iliac artery. All animals assigned to the MAST group continued to have pulsatile arterial waveforms from the left femoral artery. In the PHB group, mean (SD) for MAP, lactate, and $ScvO_2$ were 81 (13.21) mmHg, 1.6 (0.5) mEq/L, and 67 (15.3)%, respectively, at the end of the application period. An unpaired *t* test showed no significant differences in these values from baseline ($p \geq 0.4$). Two animals of the MAST group survived to 60 minutes, with the other four surviving to a mean (SD) of 44 (17.9) minutes. Mean (SD) for MAP, lactate, and $ScvO_2$ for the MAST group at the end of hemorrhage period were 41 (22.1) mmHg, 5.6 (4.5) mEq/L, and 44.9 (34.9)% respectively. Both MAP and lactate levels at the end hemorrhage were significantly different from baseline ($p < 0.04$). The mean (SD) survival time for the control group following hemorrhage was 13 (12.3) minutes. Figure 3 shows survival curve for all groups.

Log-rank (Mantel-Cox) test revealed a significant difference in survival time for all three groups ($p < 0.0001$). In addition, Log-rank (Mantel-Cox) test showed a significant difference in survival between PHB to MAST groups ($p = 0.018$). Although two of the MAST animals survived to 60 minutes, the MAST failed to sustain MAP at greater than 50 mmHg and failed to stop flow in the femoral artery distal to the iliac tear. Figure 4*A to C* shows changes in MAP, lactate, and $ScvO_2$ over time for the PHB and MAST groups. Lack of enough survivors in the MAST and control groups prevented comparison of these variables across groups through the duration of the experiment.

Gross inspection of the liver, small and large intestines, spleen, and bladder was performed, demonstrating no obvious injuries in any of the groups. Although not shown, peak and mean airway pressures were not significantly increased in either the PHB or the MAST group compared with the baseline values.

DISCUSSION

This pilot study demonstrates the potential effectiveness of a new prototype device (PHB) capable of temporarily staunching lethal pelvic arterial hemorrhage. The PHB differs from the MAST device in an important design aspect, which is likely responsible for its ability to halt hemorrhage. Unlike the MAST, the PHB is designed to transmit pressure directly into the pelvic cavity. The nondistendable nylon webbing used forces the inflating pressure bags to be directed downward. The design of the MAST, however, results in a more circumferentially applied pressure, which was not capable of fully halting arterial bleeding as noted by continuous pulsatile pressure readings from the left femoral artery as well as the reduced survival metrics and oxygen transport variables. The inability of the MAST to faithfully transmit pressure has been noted in other studies as well.[15] Current pelvic binders designed for pelvic fracture stabilization, by their design, are also not capable of deep transmission of pressure into the pelvic cavity. We did note halting of femoral artery pressures during inflation of the PHB before reaching the bag limit of 300 mmHg. However, in this pilot study, we decided to control across the group by maximally inflating the device. This does not necessarily equate to the production of 300 mmHg of pressure in the pelvic cavity. Because we could not guarantee an air-tight abdominal closure and did not want to put a pressure transduction device on the iliac arteries themselves, we did not measure intrapelvic or topical iliac arterial pressure. Future studies will examine the distribution of pressure within the pelvic and abdominal cavities.

Morrison et al.[7] examined the use of REBOA and compared it with the use of Combat Gauze and manual pressure in an open model of external iliac artery injury, demonstrating that REBOA was as effective. The authors also performed the same in a model of dilutional coagulopathy and demonstrated that REBOA performed significantly better. In the models performed by Morrison et al., animals were allowed to bleed for 45 seconds before intervention. We chose to treat our animals immediately as a way to test the devices and approach at higher MAPs. In addition, we further stressed the

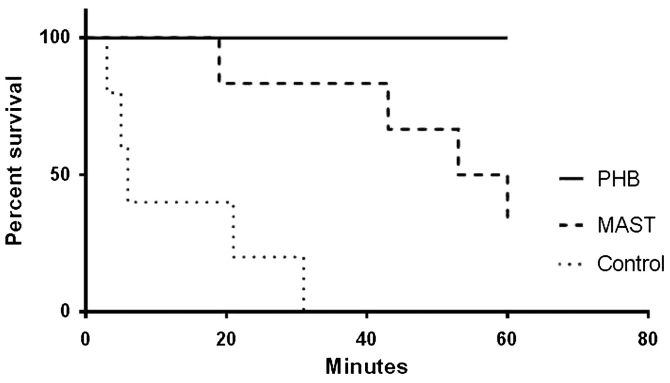

Figure 3. Survival time curve for all groups. See text for explanation.

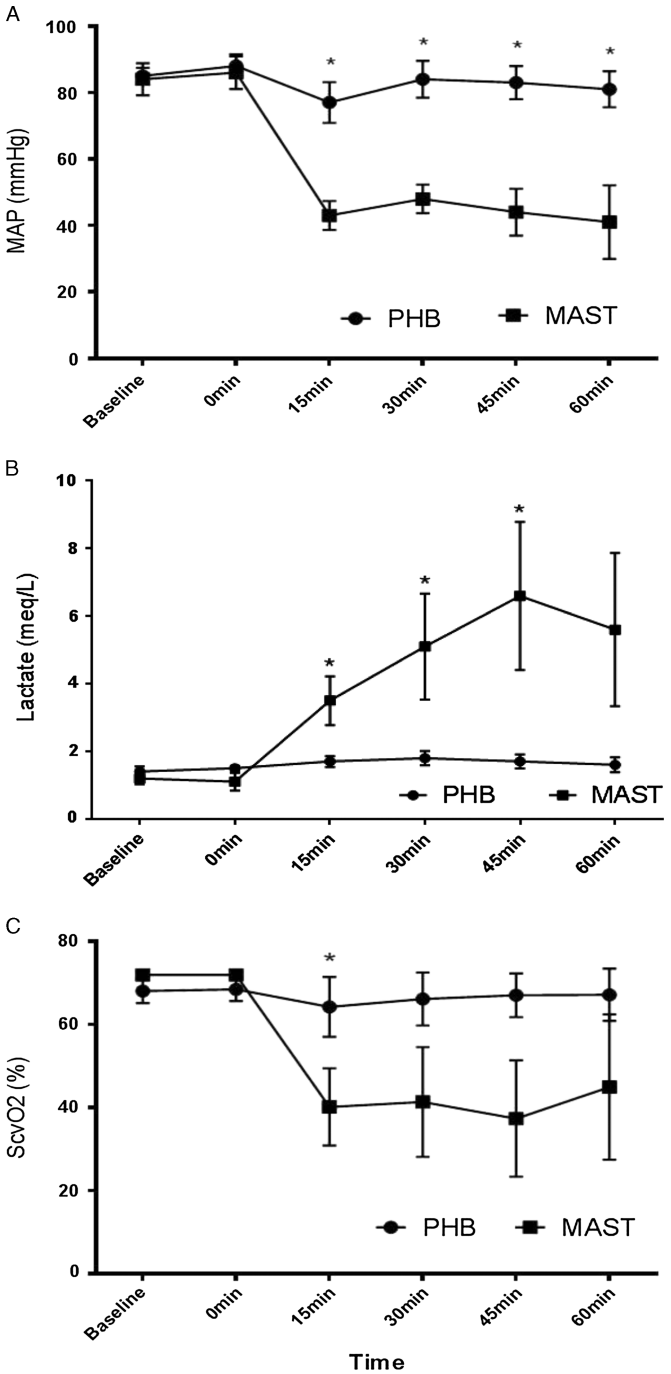

Figure 4. *A,* MAP overtime changes during PHB and MAST application. *B,* Lactate level overtime changes during PHB and MAST application. *C,* $ScvO_2$ overtime changes during PHB and MAST application. Points marked with asterisks represent significant differences ($p < 0.05$) between PHB and MAST subjects.

device by immediately resuscitating the animals with colloid to increase mean arterial and thus hydrostatic pressure. The performance of the PHB device in this setting indicates that it would be successful in staunching hemorrhage at later time points of application. The finding that the PHB completely stopped femoral artery pulsations distal to its application hints that it may be useful in multivessel pelvic injury including venous injury as well as in the setting of coagulopathy.

The use of a hemorrhage control device such as the PHB described in this study should be viewed as a potential adjunct to innovative and evolving strategies such as REBOA. While REBOA is demonstrating much promise in preclinical and clinical reports, its application requires skill, time, and the delivery of a viable patient. The use of a device such as the PHB in the initial echelon of prehospital care may enhance survival and provide an additional critical time for the application of REBOA or time to explore other options such as interventional radiology. The use of an inflatable member as a part of the PHB also may allow care providers flexibility by altering inflation pressures to judge the level or degree of hemostasis. Because of the lateral mechanics produced by the device with both belt tightening and bladder inflation, it is also likely capable of serving the purpose of pelvic fracture stabilization, although this was not tested.

A recently U.S. Food and Drug Administration (FDA) approved device called the Abdominal Aortic Tourniquet (AAT) has similarities to the PHB. In human volunteer testing, the device has been demonstrated to be able to occlude abdominal aortic flow.[25] However, it has not been tested for application on the pelvis and has not undergone testing in animal hemorrhage models such as the one described in this study.

Future studies will examine the use of PHB in later time points and in mixed vessel injury types. Also planned are future studies examining the use of the PHB in abdominal vascular trauma because the same device has demonstrated its ability to stop aortic flow in animals. Design options for the PHB include adjustable bladder arrangements allowing bladder inflation over separate quadrants of the abdomen or the abdomen as a whole. The device could be configured for application to both the abdomen and the pelvis if required. Additional studies will be required to examine the effects of such prolonged compression on reperfusion physiology and oxygen transport as well.

Lastly, the PHB device described in this pilot study may be considered an option for post-partum hemorrhage as a temporizing hemostasis measure until other obstetrical techniques can be deployed. While not a significant problem in the United States, post-partum hemorrhage represents a significant source of maternal mortality in developing countries.[26]

There are several limitations to this study. First and foremost, the subjects studies were swine averaging 42 kg in weight and not adult humans who will weigh considerably more and of course have anatomic differences in pelvic shape and depth of the pelvic arteries. This potential limitation is being evaluated in a separate institutional review board–approved study in which the PHB in human adult volunteers is being shown to halt flow in the popliteal artery as a surrogate to iliac artery occlusion (data not published). In addition, in this study, only a lethal arterial injury was studied, but hemorrhage from complex pelvic fractures may often include major venous bleeding as well. It is likely that the PHB would be effective in this regard, but further testing will be required.

CONCLUSION

In this pilot study of lethal pelvic arterial hemorrhage, a prototype pelvic hemostasis belt was able to rapidly staunch

hemorrhage despite increasing hydrostatic pressure produced by volume resuscitation. Survival and major hemodynamic indices such as MAP, lactate levels, and central venous hemoglobin oxygen saturation were also preserved when compared with control groups receiving volume resuscitation with and without application of MAST. The results warrant further study of the use of such a device as a hemorrhage control adjunct in tandem as a bridge to other techniques such as REBOA and other angioembolization strategies.

AUTHORSHIP

M.H.T. and K.R.W. contributed to the literature search, study design, data collection, data analysis, data interpretation, writing, and critical revision. G.T.D. and B.M.M. contributed to data collection, data analysis, and critical revision. H.B.A. and J.L.E. contributed to data interpretation and critical revision.

DISCLOSURE

K.R.W. and G.T.D. have intellectual property on the use of pelvic hemostasis belt assigned to the University of Michigan.

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