Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage

**Laura J. Moore, MD, Megan Brenner, MD, Rosemary A. Kozar, MD, PhD, Jason Pasley, DO,
Charles E. Wade, PhD, Mary S. Baraniuk, PhD, Thomas Scalea, MD,**
and **John B. Holcomb, MD,** *Houston, Texas*

AAST Continuing Medical Education Article

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint providership of the American College of Surgeons and the American Association for the Surgery of Trauma. The American College Surgeons is accredited by the ACCME to provide continuing medical education for physicians.

AMA PRA Category 1 Credits™

The American College of Surgeons designates this journal-based CME activity for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Of the *AMA PRA Category 1 Credit™* listed above, a maximum of 1 credit meets the requirements for self-assessment.

Credits can only be claimed online

AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

100+*years*

Objectives

After reading the featured articles published in the *Journal of Trauma and Acute Care Surgery*, participants should be able to demonstrate increased understanding of the material specific to the article. Objectives for each article are featured at the beginning of each article and online. Test questions are at the end of the article, with a critique and specific location in the article referencing the question topic.

Claiming Credit

To claim credit, please visit the AAST website at http://www.aast.org/ and click on the "e-Learning/MOC" tab. You must read the article, successfully complete the post-test and evaluation. Your CME certificate will be available immediately upon receiving a passing score of 75% or higher on the post-test. Post-tests receiving a score of below 75% will require a retake of the test to receive credit.

System Requirements

The system requirements are as follows: Adobe® Reader 7.0 or above installed; Internet Explorer® 7 and above; Firefox® 3.0 and above, Chrome® 8.0 and above, or Safari™ 4.0 and above.

Questions

If you have any questions, please contact AAST at 800-789-4006. Paper test and evaluations will not be accepted.

Disclosure Information

In accordance with the ACCME Accreditation Criteria, the American College of Surgeons, as the accredited provider of this journal activity, must ensure that anyone in a position to control the content of *J Trauma Acute Care Surg* articles selected for CME credit has disclosed all relevant financial relationships with any commercial interest. Disclosure forms are completed by the editorial staff, associate editors, reviewers, and all authors. The ACCME defines a 'commercial interest' as "any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." "Relevant" financial relationships are those (in any amount) that may create a conflict of interest and occur within the 12 months preceding and during the time that the individual is engaged in writing the article. All reported conflicts are thoroughly managed in order to ensure any potential bias within the content is eliminated. However, if you perceive a bias within the article, please report the circumstances on the evaluation form.

Please note we have advised the authors that it is their responsibility to disclose within the article if they are describing the use of a device, product, or drug that is not FDA approved or the off-label use of an approved device, product, or drug or unapproved usage.

Disclosures of Significant Relationships with Relevant Commercial Companies/Organizations by the Editorial Staff

Ernest E. Moore, Editor: PI, research support and shared U.S. patents Haemonetics; PI, research support, TEM Systems, Inc. Ronald V. Maier, Associate editor: consultant, consulting fee, LFB Biotechnologies. Associate editors: David Hoyt and Steven Shackford have nothing to disclose. Editorial staff: Jennifer Crebs, Jo Fields, and Angela Sauaia have nothing to disclose.

Author Disclosures

Megan Brenner: consultant and stock options, Pryor Medical. Rosemary Kozar: speaking fees, American College of Surgeons. Charles E. Wade: board membership, Trauma Products, Inc. and Decisio; consultant, Astrazeneca and Haemonetics; grants, ABS, NTI, Optiscan, Masimo, Haemonetics, and CoreMed Acorda; patents: University of Texas; royalties: University of Texas; stock, Decisio. John B. Holcomb: board Membership, Tenaxis, SeTRAC, Decisio, ATS; grants/research funding, Haemonetics, KCI, and BiO2 Medical; speaking fees: University of Alabama, City of Milwaukee, ATracc, ASH meeting, RESS/AHA 2013, TRansFuse 2014, South Padre Island Trauma Symposium, Thrombosis and Hemostasis Summit of NA; royalties, North American Rescue. The remaining authors have nothing to disclose.

Reviewer Disclosures

The reviewers have nothing to disclose.

Cost

For AAST members and *Journal of Trauma and Acute Care Surgery* subscribers there is no charge to participate in this activity. For those who are not a member or subscriber, the cost for each credit is $25.

BACKGROUND:	Hemorrhage remains the leading cause of death in trauma patients. Proximal aortic occlusion, usually performed by direct aortic cross-clamping via thoracotomy, can provide temporary hemodynamic stability, permitting definitive injury repair. Resuscitative endovascular balloon occlusion of the aorta (REBOA) uses a minimally invasive, transfemoral balloon catheter, which is rapidly inserted retrograde and inflated for aortic occlusion, and may control inflow and allow time for hemostasis. We compared resuscitative thoracotomy with aortic cross-clamping (RT) with REBOA in trauma patients in profound hemorrhagic shock.
METHODS:	Trauma registry data was used to compare all patients undergoing RT or REBOA during an 18-month period from two Level 1 trauma centers.
RESULTS:	There was no difference between RT (n = 72) and REBOA groups (n = 24) in terms of demographics, mechanism of injury, or Injury Severity Scores (ISSs). There was no difference in chest and abdominal Abbreviated Injury Scale (AIS) scores between the groups. However, the RT patients had lower extremity AIS score as compared with REBOA patients (1.5 [0–3] vs. 4 [3–4], $p < 0.001$). Of the 72 RT patients, 45 (62.5%) died in the emergency department, 6 (8.3%) died in the operating room, and 14 (19.4%) died in the intensive care unit. Of the 24 REBOA patients, 4 (16.6%) died in the emergency department, 3 (12.5%) died in the operating room, and 8 (33.3%) died in the intensive care unit. In comparing location of death between the RT and REBOA groups, there were a significantly higher number of deaths in the emergency department among the RT patients as compared with the REBOA patients (62.5% vs. 16.7%, $p < 0.001$). REBOA had fewer early deaths and improved overall survival as compared with RT (37.5% vs. 9.7%, $p = 0.003$).
CONCLUSION:	REBOA is feasible and controls noncompressible truncal hemorrhage in trauma patients in profound shock. Patients undergoing REBOA have improved overall survival and fewer early deaths as compared with patients undergoing RT. (*J Trauma Acute Care Surg*. 2015;79: 523–532. Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.)
LEVEL OF EVIDENCE:	Therapeutic study, level IV.
KEY WORDS:	Aortic balloon occlusion; hemorrhagic shock; trauma; resuscitative thoracotomy; resuscitation.

Hemorrhage continues to be the leading cause of potentially preventable death in trauma patients.[1–4] Noncompressible torso hemorrhage (NCTH) occurs from vascular disruption of axial torso vessels, solid organ injury, pulmonary parenchymal injury, and/or injury to the bony pelvis.[5] It is currently estimated that NCTH accounts for 60% to 70% of deaths following otherwise survivable injuries.[1,2] In both military and civilian populations, NCTH is a significant contributor to hemorrhage-related deaths with mortality rates more than 40%. NCTH arising from the abdomen is the leading cause of preventable death on the battlefield.[6] A recent evaluation of the National Trauma Data Bank reported a 45% mortality rate from civilian Level 1 trauma centers for patients with NCTH.[7] In addition, delay in time to laparotomy in patients with major abdominal hemorrhage is a significant contributor to patient mortality, with every 3-minute delay increasing mortality by 1%.[8] Often, these patients present in extremis requiring resuscitation and emergent intervention for hemorrhage control. If hemorrhage is not treated promptly, patients rapidly progress to cardiovascular collapse and death. The bottom line is that rapid hemorrhage control is a cornerstone of current therapy.

The concept of aortic occlusion in the setting of NCTH originating from the abdomen and pelvis is neither new nor novel. Multiple previous case series have documented the advantages of aortic occlusion in patients with hemorrhagic shock and significant intra-abdominal hemorrhage from solid organ injury, disruption of a named axial vessel, and/or pelvic fracture with ring disruption.[9–12] Physiologically, occlusion of the aorta during hemorrhagic shock results in increases in coronary blood flow, cardiac output, mean arterial pressure,

carotid blood flow, and partial oxygen pressure of the brain.[13–15] In the setting of trauma, the means by which aortic occlusion has classically occurred is in the setting of resuscitative thoracotomy with aortic cross-clamping (RT). The technique of RT is maximally invasive, and survival rates remain less than 10% in modern series.[16,17]

Much like RT, resuscitative endovascular balloon occlusion of the aorta (REBOA) supports proximal aortic pressure and minimizes hemorrhage, allowing for resuscitation and surgical repair of hemorrhage. Currently available aortic occlusion balloons were initially developed for use in the setting of ruptured abdominal aortic aneurysms (AAAs), a clinical scenario that is similar to NCTH in trauma. The treatment of ruptured AAAs also started with thoracotomy as a means to obtain proximal aortic control years ago and has now progressed to the use of intra-aortic balloons. The utility and effectiveness of REBOA has been well established in the setting of ruptured AAAs.[18–20] However, their effectiveness and utility in the trauma population have not been well documented. Several recent case series reporting on the use of REBOA in the trauma population have demonstrated that REBOA is a technically feasible method for rapid aortic occlusion for the treatment of NCTH arising from the abdomen or pelvis.[21,22] The purpose of our study was to compare RT with REBOA in trauma patients with profound hemorrhagic shock caused by NCTH.

PATIENTS AND METHODS

Trauma registry data were used to identify all adult patients (age ≥ 16 years) undergoing RT or REBOA during an 18-month

period beginning January 01, 2012, from two Level 1 trauma centers (Texas Trauma Institute, Memorial Hermann Hospital, University of Texas–Houston, and R Adams Cowley Shock Trauma Center, University of Maryland–Baltimore). Patients undergoing RT with penetrating chest trauma or suspected or confirmed intrathoracic hemorrhage were excluded from the study because these patients are not considered candidates for REBOA. The presence of these exclusion criteria was determined by chart review of all RT patients. Demographic data, mechanism of injury, Injury Severity Score (ISS), Abbreviated Injury Scale (AIS), admission vital signs/laboratory values, mortality, and outcomes were obtained from the trauma registry for all study patients. Early deaths were defined as those occurring within 24 hours of hospital admission. The Denver Multiple Organ Failure (MOF) score was used to define organ failure.[23]

The 18-month study period selected reflects a time of transition in practice for both of our centers. Trauma surgeons at both institutions were trained in the insertion of REBOA between August 2012 and March 2013. Three of the trauma surgeons were trained at the Endovascular Skills for Trauma and Resuscitative Surgery (E-STARS) course.[24] The remaining trauma surgeons were trained via a modified version of the Advanced Surgical Skills for Exposure in Trauma (ASSET)[25] course or via the Basic Endovascular Skills for Trauma (BEST)

course.[26] All surgeons were required to demonstrate proficiency with the technique in the skills laboratory before use in their respective trauma centers. Indications for REBOA placement at both institutions included refractory hemorrhagic shock caused by NCTH to include penetrating abdominal trauma and blunt trauma. A decision algorithm for REBOA insertion that was used at both institutions during the study period is depicted in Figure 1. The decision to use RT or REBOA was at the discretion of the attending trauma surgeon. The presence or suspicion of a major intrathoracic injury is considered to be an absolute contraindication for REBOA insertion at both institutions. The choice of aortic zone of occlusion was determined by the attending trauma surgeon based on the results of the digital chest x-ray (CXR) and pelvic film, mechanism of injury, and Focused Assessment with Sonography for Trauma (FAST) examination. If the CXR result was negative and the FAST examination result was positive, a Zone I occlusion was performed. If the FAST examination result was negative and a pelvic fracture was present, then a Zone III occlusion was performed. Occlusion in Zone II was avoided in all cases (Fig. 2).

Summary statistics of age, sex, type of injury, ISS, base deficit, and initial systolic blood pressure are presented by REBOA or emergency department (ED) thoracotomy group.
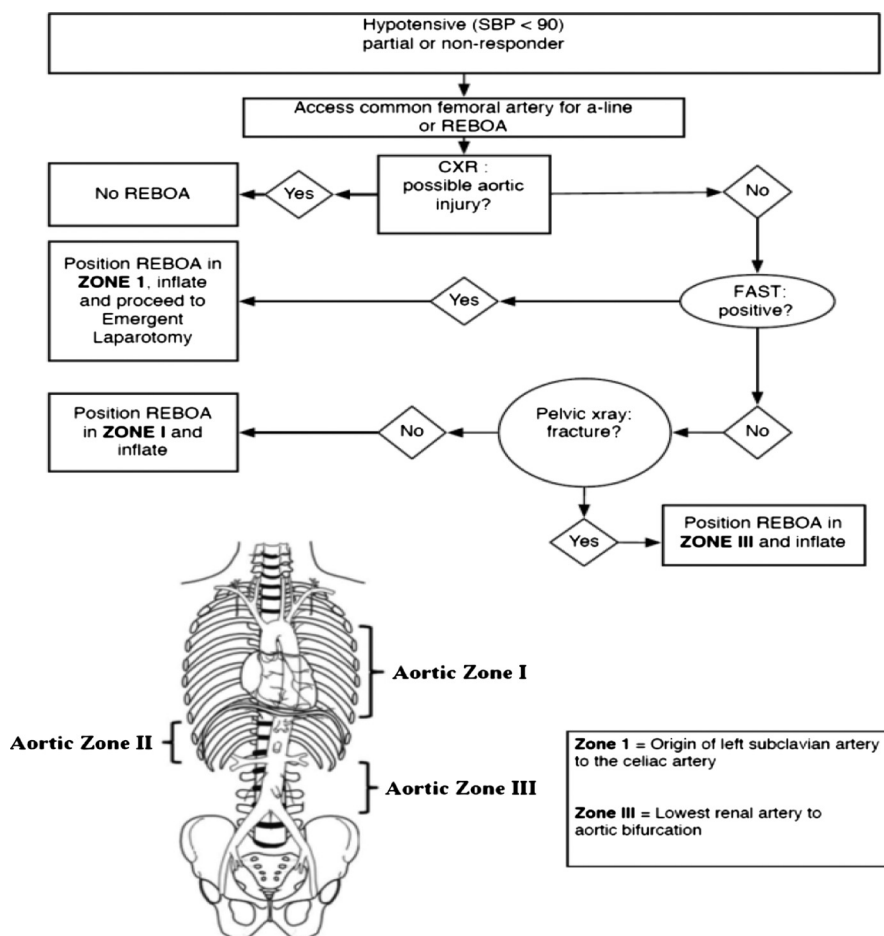

Figure 1. REBOA algorithm. Reproduced with permission from Wolters Kluwer/Lippincott Williams & Wilkins. Source: Stannard et al.[27]
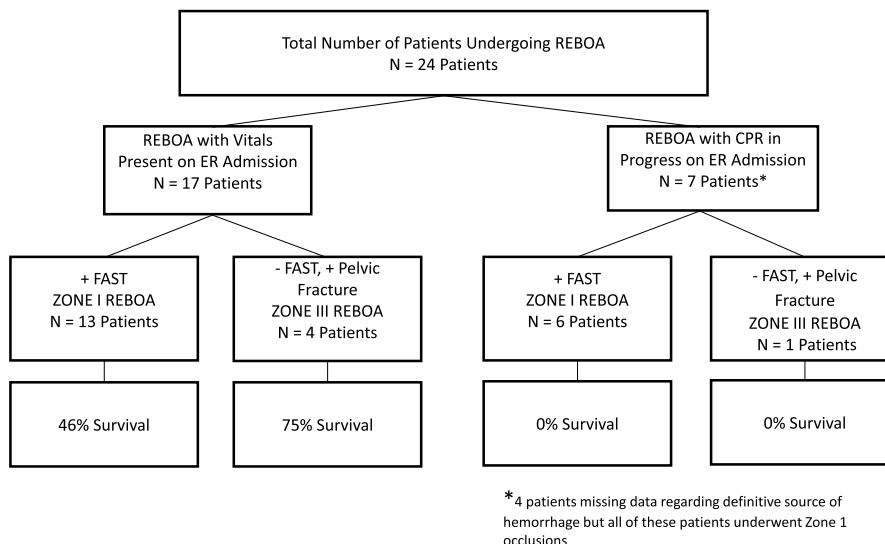
Figure 2. Breakdown of REBOA patients by zones of occlusion.

These data are heterogeneous in nature; therefore, statistical tests for comparison included the Wilcoxon rank-sum for continuous scale variables (medians, 25th and 75th percentiles) and the Fisher's exact test for categorical variables.

RESULTS

During the 18-month study period, we identified a total of 92 patients who underwent RT at both institutions. Of these 92, we identified 72 patients who underwent RT for exsanguinating hemorrhage originating from the abdomen or pelvis and 24 patients who underwent REBOA for the same indication. A summary of the descriptive characteristics of the two study groups is displayed in Table 1. There was no significant difference between the RT and REBOA patients in terms of sex, age, mechanism of injury, ISS, admission base deficit, or admission blood pressure. Of note, 21.3% (n = 16) of patients in

the RT group were assigned an ISS of 75, while only 6.3% (n = 1) were assigned an ISS of 75 in the REBOA group. There was no difference in chest AIS score and abdominal AIS score between the RT and REBOA groups. However, the RT patients had lower extremity AIS score as compared with REBOA patients (1.5 [0–3] vs. 4 [3–4], $p < 0.001$). Among the patients undergoing RT, 27 patients had vital signs present on ED admission and 45 patients had absent or missing vital signs on ED admission. Among patients undergoing RT, 25 patients had sources of hemorrhage that would have been controlled with Zone 1 occlusion, 6 had sources of hemorrhage that would have been controlled with Zone III occlusion, and 41 patients had an unknown source of hemorrhage (Table 2).

During the course of the 18-month study period, there was a relative decrease in the use of RT and a relative increase in the use of REBOA (Fig. 3). The overall survival rate for patients in the REBOA group was 37.5% compared with 9.7% in the RT group, but a larger percentage of REBOA patients had vital signs present on admission as compared with the RT group (71% vs. 38%). Of the 72 RT patients, 45 (62.5%) died in the ED, 6 (8.3%) died in the operating room, and 14 (19.4%) died in the intensive care unit (ICU). Of the 24 REBOA

TABLE 1. Descriptive Characteristics of the Study Population

Overall (N = 96)		RT (n = 72)	REBOA (n = 24)
Age	n	72	23
	Median (P25–P75)	30.5 (23.5–48)	41 (24–62)
Male	n (%)	63 (87.5)	19 (79.2)
Blunt	n (%)	32 (44.4)	16 (66.7)
ISS	n	71	19
	Median (P25–P75)	34 (27–59)	28 (17–43)
Chest AIS score	n	72	24
	Median (P25–P75)	3 (3–4)	3.5 (3–4)
Abdomen AIS score	n	72	24
	Median (P25–P75)	3 (2–4)	3 (2–4)
Extremity AIS score	n	72	24
	Median (P25–P75)	1.5 (0–3)	4 (2.5–4)
No. patients with ISS of 75	n	16	1
	%	21.3%	6.3%

TABLE 2. Comparison of Nonsurvivors Between RT and REBOA

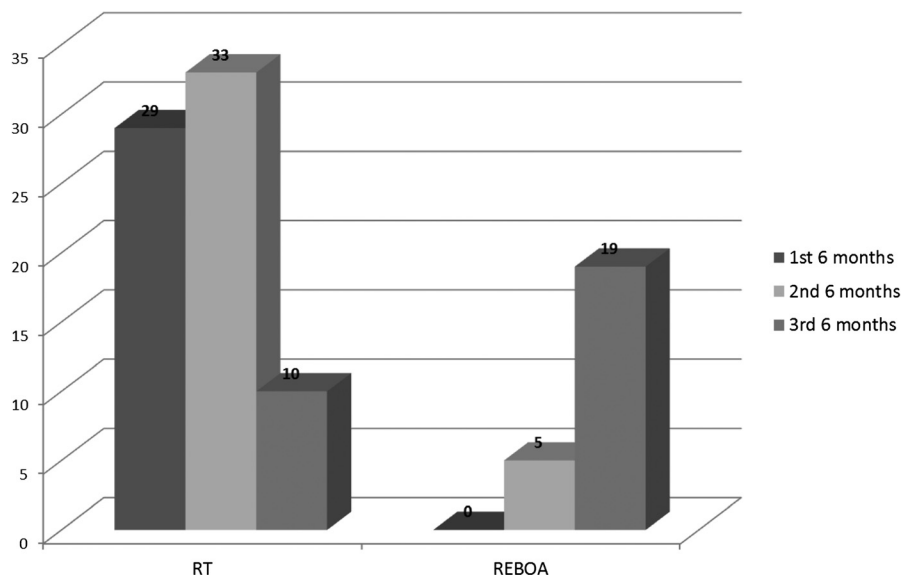| Among Deaths (n = 80)		RT Deaths (n = 65)	REBOA Deaths (n = 15)	p
All Deaths	% (n)	90.3 (65)	62.5 (15)	0.003
Died in ED	% (n)	69.2 (45)	26.7 (4)	<0.001
Died in OR	% (n)	9.2 (6)	20 (3)	0.69
Died in ICU	% (n)	21.6 (14)	53.3 (8)	0.17
Age	Median (P25–P75)	31 (24–46)	40.5 (24–66)	0.41
Male	% (n)	87.7 (57)	73.3 (11)	0.22
Blunt	% (n)	44.6 (29)	73.3 (11)	0.08
ISS	Median (P25–P75)	35.5 (22–67)	34 (20–45.5)	0.39

Figure 3. Graphic depiction of the number of RT and REBOA during the 18-month study period.

patients, 4 (16.6%) died in the ED, 3 (12.5%) died in the operating room, and 8 (33.3%) died in the ICU. In comparing location of death between the RT and REBOA groups, there were a significantly higher number of deaths in the ED among the RT patients as compared with the REBOA patients (62.5% vs. 16.7%, $p < 0.001$). Table 3 compares the causes of death in the ICU in the RT and REBOA groups. Of the 14 RT patients who survived to ICU admission, 10 (71.4%) died of hemorrhage within 24 hours of ICU admission, 2 died of multiple-organ failure, and 2 died from head injuries. The majority of deaths in the REBOA group (53.3%) occurred in the ICU. Among the REBOA patients who died in the ICU, one died of multiple-organ failure, and the remaining seven died of head injuries.

Zone I occlusion was used in 19 patients (79.1%), and Zone III occlusion was used in 5 patients (21%). A breakdown of the REBOA patients by zones of occlusion is presented in Figure 3. No Zone II occlusions were performed. Of the 20 patients who survived REBOA insertion in the ED, 15 (75%) underwent exploratory laparotomy, 4 (20%) underwent angiography with embolization, and 1 (5%) underwent exploratory laparotomy followed by angiography with embolization.

A comparison of RT survivors and REBOA survivors is presented in Table 4. There was no difference in the survivors between the two groups in terms of demographics, admission base deficit, or ISS. Of note, while the numbers are small, a majority of the REBOA survivors (77.8%) were discharged home, while a majority of the RT patients were discharged to

either a rehabilitation hospital (57.1%) or a skilled nursing facility (14.4%). There were no REBOA-related complications in this series of patients.

DISCUSSION

The concept of transient aortic occlusion followed by surgical intervention for hemorrhage control is not new. Proximal aortic occlusion, historically performed by direct aortic cross-clamping via thoracotomy, can provide temporary hemodynamic stability by augmenting cardiac afterload and provide inflow control, permitting definitive injury repair. In 1976, Ledgerwood et al.[9] reported their experience with aortic occlusion via resuscitative thoracotomy with thoracic aortic cross-clamping in the operating room before laparotomy in patients with hemorrhagic shock and massive hemoperitoneum with a survival rate of 24%. This was followed in 1979 by a report from Mattox et al.[28] of the use of RT in conjunction with laparotomy in the ED in 51 patients with intra-abdominal hemorrhage with a reported survival rate of 0%. Moore et al. reported their experience with this technique from Denver General Hospital in 1984 with an overall survival rate of 31%.[10] Finally, Wiencek and Wilson[12] reported on 26 patients with thoracotomy and aortic cross-clamping before laparotomy with a survival rate of 19%. In these case series, the authors noted the following: (1) aortic

TABLE 3. Comparison of Cause of ICU Death Among Groups

	RT ICU Deaths (n = 14)	REBOA ICU Deaths (n = 8)
Early death from hemorrhage, % (n)	71.4 (10)	0 (0)
Multiple organ failure, % (n)	14.3 (2)	12.5 (1)
Head injury, % (n)	14.3 (2)	87.5 (7)

TABLE 4. Comparison of Survivors Between RT and REBOA

Among Survivors (n = 16)		RT Alive (n = 7)	REBOA Alive (n = 9)	p
Survivors	% (n)	9.7% (7)	37.5% (9)	0.003
Age	Median (P25–P75)	29 (21–51)	43 (25–59)	0.71
Male	% (n)	85.7% (6)	88.9% (8)	1.00
Blunt	% (n)	42.9% (3)	55.6% (5)	1.00
ISS	Median (P25–P75)	29 (16–34)	26 (17–29)	0.56

occlusion quickly restored the blood pressure ensuring blood flow to the heart and brain,[9,10,12,28] (2) aortic occlusion before laparotomy avoided catastrophic cardiovascular collapse that often occurs at laparotomy,[9,10] and (3) obtaining proximal aortic control before entering the "hematoma" decreased total blood loss.[9]

The use of REBOA in the setting of hemorrhagic shock was first reported in 1954 during the Korean War by Lieutenant Colonel Carl Hughes.[29] Interest in the use of an intra-aortic occlusion balloon as a means to provide proximal aortic occlusion did not reemerge until the recent military conflicts in Iraq and Afghanistan. The Joint Theater Trauma System has recently released a clinical practice guideline recommending REBOA as an adjunct to control life-threatening hemorrhage as a selective alternative to RT in surgically capable theater facilities.[30] In addition, the increased availability and familiarity with endovascular skills have also played a role in the resurgence of REBOA. Aortic occlusion balloons are now routinely used in both open and endovascular repairs of AAAs. In addition, the use of REBOA in the setting of ruptured AAA has been shown to be highly effective at controlling hemorrhage until definitive repair can be performed and has been associated with an improved survival following ruptured AAA.[31–33] The clinical scenario of hemorrhagic shock from a ruptured AAA is similar to what one might observe in a trauma patient presenting in extremis from massive hemoperitoneum. There are also reports of the use of REBOA in the setting of postpartum hemorrhage,[34] pelvic surgery,[35–38] and hepatobiliary surgery.[39] In the setting of trauma, there are several case series reporting the use of REBOA for control of abdominal and pelvic hemorrhage. Gupta et al.[40] reported on the use of REBOA in 21 hemodynamically unstable patients with penetrating abdominal trauma. In this series, REBOA was inserted in patients with refractory hemorrhagic shock after 15 minutes to 20 minutes of fluid resuscitation. Eleven patients (50%) survived initial laparotomy, but only seven (33%) survived to hospital discharge. More recently, Martinelli et al.[22] reported on their experience with the use of REBOA in 13 patients with hemorrhagic shock from pelvic fractures. In this series, there was a significant improvement in patients' systolic blood pressure after insertion of REBOA (41 mm Hg after REBOA vs. 111 mm Hg after REBOA, $p = 0.001$) and a survival rate of 46%. In our initial case series of the use of REBOA in six patients with both blunt and penetrating trauma, we reported a survival rate of 66%.[21] Our reported experience with REBOA differs from that reported by both Gupta et al. and Martinelli et al. In the Gupta series, balloons were inserted in both the ED and the operating room after a 15-minute to 20-minute period of aggressive resuscitation.[40] In the Martinelli series, REBOA insertions were performed by a senior experienced interventional radiologist under fluoroscopy, not by the attending trauma surgeon.[22] In our series, the attending trauma surgeon placed the REBOA in the ED with digital x-ray capability only.

A detailed description of the technique of REBOA insertion is beyond the scope of this article; however, a technical description has been previously published by Stannard et al.[27] From a technical standpoint, trauma and acute care surgeons already possess the technical skills required to perform REBOA. Placement of REBOA can be divided into the following steps: (1) femoral arterial access, (2) balloon selection and positioning,

(3) balloon Inflation, (4) balloon deflation, and (5) sheath removal.[27] Obtaining arterial access and the use of plain radiographs to determine device placement are standard practices for trauma surgeons. The additional endovascular skills required for sheath and wire insertion along with optimal balloon positioning can be easily and rapidly acquired with additional training.[24,26] When using REBOA, the trauma surgeon must decide on which zone of occlusion should be used. The aortic zones of occlusion include Zone I (origin of the left subclavian artery to the celiac artery), Zone II (celiac artery to the lowest renal artery), and Zone III (lowest renal artery to the aortic bifurcation). Inflation of REBOA in Zone I is akin to thoracic aortic clamping that would be performed during resuscitative thoracotomy. As a rule, Zone I occlusion should be used in patients with suspicion of intra-abdominal hemorrhage (i.e., positive FAST examination result), and Zone III occlusion should be used in patients with suspected hemorrhage from a confirmed pelvic fracture. In the current series, the majority of our patients had a Zone I inflation (79%), with Zone III inflation reserved for those patients with exsanguinating hemorrhage caused by isolated pelvic ring disruption (21%). We did not have any Zone II occlusions in this series.

Our purpose with this study was to compare RT with REBOA in patients with hemorrhagic shock caused by NCTH originating from the abdomen and/or pelvis. We demonstrated that REBOA is not only feasible in this patient population but also associated with an improved survival rate. Review of the current published literature reports survival rates ranging from 0% to 16.7% for patients undergoing RT in the setting of abdominal injury.[16] The published survival rates for REBOA in the setting of abdominal or pelvic hemorrhage range from 33% to 66%, which is comparable with the 37% survival rate in this study.[21,22,40,41] There are several potential explanations for the improved survival rates observed in the REBOA group. One potential explanation is the minimally invasive nature of REBOA as compared with RT. While both REBOA and RT essentially provide equivalent aortic occlusion and similar physiologic results (increased blood pressure, increase myocardial and cerebral perfusion, proximal control to minimized hemorrhage), the means by which the aorta is occluded are drastically different. The performance of RT has obvious associated morbidity for the patient including uncontrolled hemorrhage from the thoracotomy site and hypothermia, which result from opening a second body cavity. In addition, in patients with an unfavorable body habitus or difficult exposure, clamping of the esophagus rather than the aorta can occur. In addition, physiologic markers such as serum lactate, pH, and PCO_2 have been shown to improve significantly in animal models using REBOA in the setting of hemorrhagic shock.[13,15,42] White et al.[13] compared 60 minutes of aortic occlusion with either RT or REBOA in a swine model of hemorrhagic shock, demonstrating that the use of REBOA was associated with less acidosis, a lower serum lactate, and lower fluid requirements compared with the use of RT. Finally, it has been our observation that the decision to perform an RT often does not occur until the patient has loss of vital signs. This is likely caused by the extremely invasive nature of RT. In contrast, we have observed that the decision to perform REBOA often occurs before loss of vital signs. This is likely caused by the relatively less invasive nature of REBOA and may contribute to the improved survival seen in this series. As evidenced by this

series of patients, 71% of patients undergoing REBOA had vital signs present at ED admission as compared with only 38% in the RT group.

Another notable difference between the RT and REBOA groups was the location of death among nonsurvivors. The majority of RT deaths occurred in the ED, while only a minority of the REBOA deaths occurred in the ED. In fact, the majority of deaths in the REBOA group occurred in the ICU, and none of the ICU deaths in the REBOA group were attributed to hemorrhage. Among the REBOA patients who died in the ICU, one died of multiple-organ failure, and the remaining seven died of head injuries. This is in contrast to the ICU deaths that occurred in the RT group. Of the 14 RT patients who survived to ICU admission, the majority died of hemorrhage within 24 hours of ICU admission. The remaining ICU deaths in the RT group were attributed to either multiple-organ failure or head injury. From these data, one can conclude that patients who undergo REBOA are experiencing fewer early deaths caused by hemorrhage and they are surviving long enough to make it to the ICU where the majority succumbs to death from head injuries. In addition, RT patients who make it to the ICU are still succumbing to early death from hemorrhage. While we do not have data regarding the source of ongoing hemorrhage in the RT patients, trauma surgeons are all too familiar with the deadly triad of acidosis, hypothermia, and coagulopathy that commonly occurs in patients who undergo RT. Often, this bleeding from the chest occurs in the setting of a previously normal CXR result. This likely is a significant contributor to the high number of ICU deaths caused by hemorrhage observed in the RT group.

To be clear, there are still clinic situations in which resuscitative thoracotomy is indicated. Of the 92 RTs performed at these institutions during the 18-month study period, 22% were performed for suspicion of a major intrathoracic injury as the source for cardiovascular collapse. Any patient with a suspected or confirmed major intrathoracic injury and cardiovascular collapse should still undergo RT because this procedure allows for access to thoracic vasculature for direct clamping, release of cardiac tamponade, and/or temporizing management of cardiac or hilar injuries. The use of REBOA should be confined to those patients with suspected or documented exsanguinating hemorrhage arising from below the diaphragm.

This registry study is limited by its retrospective nature in that we have not been able to clearly identify certain variables including time from ED presentation to performance of either RT or REBOA. The definitive source of hemorrhage among patients who expired in the ED is missing in 41 patients. This is likely caused by the fact that patients arriving in the ED in extremis are never stable enough to go for definitive imaging and may expire before laparotomy. The time required to perform an RT or REBOA was not able to be ascertained in a retrospective fashion from the medical records. Brenner et al.[26] recently published the time to insert REBOA in the simulation laboratory and found that all of the REBOA trainees were able to insert the balloon in less than 5 minutes. REBOA insertions in the trauma resuscitation area are currently being videotaped at one of the institutions. When reviewing these insertions, there are some instances when the REBOA insertion is performed in less than 3 minutes, while other insertions took up to

15 minutes if arterial access was difficult to obtain. In the event that obtaining arterial access is taking an unreasonable amount of time, we would advocate moving to RT. In addition, obtaining accurate ISS and AIS score in patients who die in the ED is difficult, as complete imagining or exploration is frequently not conducted. In addition, other markers of severity of illness such as base deficit, serum pH, and lactate are missing from large numbers of patients, particularly those patients from both groups who arrived as cardiopulmonary resuscitation in progress. Finally, while the data do not reflect a statistical difference in overall severity of illness as demonstrated by ISS and AIS score between the RT and REBOA groups, given the small sample size, it is possible that the RT patients were more critically ill on presentation than the REBOA patients. There were more patients in the RT group that arrived with cardiopulmonary resuscitation in progress as compared with the REBOA group. This may contribute to the lower survival rate observed in the RT group.

CONCLUSION

Noncompressible hemorrhage from the abdomen and pelvis remains the leading cause of death from hemorrhage in both military and civilian trauma patients. The use of REBOA in patients with noncompressible hemorrhage from the abdomen and pelvis is feasible and effectively controls hemorrhage. In addition, patients undergoing REBOA seems to have at least equivalent overall survival and fewer early deaths as compared with patients undergoing RT.

AUTHORSHIP

L.J.M., T.S., and J.B.H. designed of the study. L.J.M., M.B., and J.P. acquired the data. L.J.M., M.B., R.A.K., C.E.W., and M.S.B. analyzed and interpreted the data. All authors drafted and revised the manuscript.

DISCLOSURE

The authors have no conflicts of interest.

REFERENCES

1. Kauvar DS, Lefering R, Wade CE. Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. *J Trauma.* 2006;60(Suppl 6):S3–S11.
2. Kauvar DS, Wade CE. The epidemiology and modern management of traumatic hemorrhage: US and international perspectives. *Crit Care.* 2005;9(Suppl 5):S1–S9.
3. Martin M, Oh J, Currier H, Tai N, Beekley A, Eckert M, Holcomb J. An analysis of in-hospital deaths at a modern combat support hospital. *J Trauma.* 2009;66(Suppl 4):S51–S60.
4. Kelly JF, Ritenour AE, McLaughlin DF, McLaughlin DF, Bagg KA, Apodaca AN, Mallak CT, Pearse L, Lawnick MM, Champion HR, et al. Injury severity and causes of death from Operation Iraqi Freedom and Operation Enduring Freedom: 2003–2004 versus 2006. *J Trauma.* 2008;64 (Suppl 2):S21–S26.
5. Morrison JJ, Rasmussen TE. Noncompressible torso hemorrhage: a review with contemporary definitions and management strategies. *Surg Clin North Am.* 2012;92(4):843–858.
6. Eastridge BJ, Mabry RL, Seguin P, Seguin P, Cantrell J, Tops T, Uribe P, Mallett O, Zubko T, Oetjen-Gerdes L, Rasmussen TE, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg.* 2012;73(6 Suppl 5):S431–S437.

7. Kisat M, Morrison JJ, Hashmi ZG, Efron DT, Rasmussen TE, Haider AH. Epidemiology and outcomes of non-compressible torso hemorrhage. *J Surg Res.* 2013;184(1):414–421.

8. Clarke JR, Trooskin SZ, Doshi PJ, Greenwald L, Mode CJ. Time to laparotomy for intra-abdominal bleeding from trauma does affect survival for delays up to 90 minutes. *J Trauma.* 2002;52(3):420–425.

9. Ledgerwood AM, Kazmers M, Lucas CE. The role of thoracic aortic occlusion for massive hemoperitoneum. *J Trauma.* 1976;16(08):610–615.

10. Millikan JS, Moore EE. Outcome of resuscitative thoracotomy and descending aortic occlusion performed in the operating room. *J Trauma.* 1984;24(5):387–392.

11. Sankaran S, Lucas C, Walt AJ. Thoracic aortic clamping for prophylaxis against sudden cardiac arrest during laparotomy for acute massive hemoperitoneum. *J Trauma.* 1975;15(4):290–296.

12. Wiencek RG, Wilson RF. Injuries to the abdominal vascular system: how much does aggressive resuscitation and prelaparotomy thoracotomy really help? *Surgery.* 1987;102(4):731–736.

13. White JM, Cannon JW, Stannard A, Markov NP, Spencer JR, Rasmussen TE. Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock. *Surgery.* 2011;150(3):400–409.

14. Dunn EL, Moore EE, Moore JB. Hemodynamic effects of aortic occlusion during hemorrhagic shock. *Ann Emerg Med.* 1982;11(5):238–241.

15. Spence PA, Lust RM, Chitwood WR, Iida H, Sun YS, Austin EH. Transfemoral balloon aortic occlusion during open cardiopulmonary resuscitation improves myocardial and cerebral blood flow. *J Surg Res.* 1990; 49(3):217–221.

16. Rhee PM, Acosta J, Bridgeman A, Wang D, Jordan M, Rich N. Survival after emergency department thoracotomy: review of published data from the past 25 years. *J Am Coll Surg.* 2000;190(3):288–298.

17. Rabinovici R, Bugaev N. Resuscitative thoracotomy: an update. *Scand J Surg.* 2014;103(2):112–119.

18. Ten Bosch JA, Cuypers PW, van Sambeek M, Teijink JAW. Current insights in endovascular repair of ruptured abdominal aortic aneurysms. *EuroIntervention.* 2011;7(7):852–858.

19. Berland TL, Veith FJ, Cayne NS, Mehta M, Mayer D, Lachat M. Technique of supraceliac balloon control of the aorta during endovascular repair of ruptured abdominal aortic aneurysms. *J Vasc Surg.* 2013;57(1):272–275.

20. Malina M, Holst J. Balloon control for ruptured AAAs: when and when not to use? *J Cardiovasc Surg (Torino).* 2014;55(2):161–167.

21. Brenner ML, Moore LJ, DuBose JJ, Tyson GH, McNutt MK, Albarado RP, Holcomb JB, Scalea TM, Rasmussen TE. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. *J Trauma Acute Care Surg.* 2013;75(3):506–511.

22. Martinelli T, Thony F, Decléty P, Sengel C, Broux C, Tonetti J, Payen JF, Ferretti G. Intra-aortic balloon occlusion to salvage patients with life-threatening hemorrhagic shocks from pelvic fractures. *J Trauma.* 2010; 68(4):942–948.

23. Moore FA, Sauaia A, Moore EE, Haenel JB, Burch JM, Lezotte DC. Postinjury multiple organ failure: a bimodal phenomenon. *J Trauma.* 1996; 40(4):501–510.

24. Villamaria CY, Eliason JL, Napolitano LM, Stansfield RB, Spencer JR, Rasmussen TE. Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) course: curriculum development, content validation, and program assessment. *J Trauma Acute Care Surg.* 2014;76(4):929–935.

25. Kuhls DA, Risucci DA, Bowyer MW, Luchette FA. Advanced surgical skills for exposure in trauma: a new surgical skills cadaver course for surgery residents and fellows. *J Trauma Acute Care Surg.* 2013;74(2): 664–670.

26. Brenner M, Hoehn M, Pasley J, Dubose J, Stein D, Scalea T. Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. *J Trauma Acute Care Surg.* 2014; 77(2):286–291.

27. Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J Trauma.* 2011;71(6):1869–1872.

28. Mattox KL, Allen MK, Feliciano DV. Laparotomy in the emergency department. *JACEP.* 1979;8(5):180–183.

29. Hughes CW. Use of an intra-aortic balloon catheter tamponade for controlling intra-abdominal hemorrhage in man. *Surgery.* 1954;36(1):65–68.

30. Joint Theater Trauma System Clinical Practice Guideline. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock; 2014. Available at: http://www.usaisr.amedd.army.mil/ assets/cpgs/REBOA_for_Hemorrhagic_Shock_16Jun2014.pdf. Accessed August 18, 2014.

31. Mehta M, Taggert J, Darling RC 3rd, Chang BB, Kreienberg PB, Paty PS, Roddy SP, Sternbach Y, Ozsvath KJ, Shah DM. Establishing a protocol for endovascular treatment of ruptured abdominal aortic aneurysms: outcomes of a prospective analysis. *J Vasc Surg.* 2006;44(1):1–8.

32. Karkos CD, Harkin DW, Giannakou A, Gerassimidis TS. Mortality after endovascular repair of ruptured abdominal aortic aneurysms: a systematic review and meta-analysis. *Arch Surg.* 2009;144(8):770–778.

33. Mayer D, Pfammatter T, Rancic Z, Hechelhammer L, Wilhelm M, Veith FJ, Lachat M. 10 years of emergency endovascular aneurysm repair for ruptured abdominal aortoiliac aneurysms: lessons learned. *Ann Surg.* 2009; 249(3):510–515.

34. Harma M, Harma M, Kunt AS, Andac MH, Demir N. Balloon occlusion of the descending aorta in the treatment of severe post-partum haemorrhage. *Aust N Z J Obstet Gynaecol.* 2004;44(2):170–171.

35. Luo Y, Duan H, Liu W, Min L, Shi R, Zhang W, Zhou Y, Tu C. Clinical evaluation for lower abdominal aorta balloon occluding in the pelvic and sacral tumor resection. *J Surg Oncol.* 2013;108(3):148–151.

36. Tang X, Guo W, Yang R, Tang S, Dong S. Use of aortic balloon occlusion to decrease blood loss during sacral tumor resection. *J Bone Joint Surg Am.* 2010;92(8):1747–1753.

37. Honda H, Yoshida T, Shibue C, Baba H. Use of aortic occlusion balloon catheter for sacral giant cell tumor resection [in Japanese]. *Masui.* 2012; 61(6):610–613.

38. Mi C, Lu H, Liu H. Surgical excision of sacral tumors assisted by occluding the abdominal aorta with a balloon dilation catheter: a report of 3 cases. *Spine.* 2005;30(20):E614–E616.

39. Miura F, Takada T, Ochiai T, Asano T, Kenmochi T, Amano H, Yoshida M. Aortic occlusion balloon catheter technique is useful for uncontrollable massive intraabdominal bleeding after hepato-pancreato-biliary surgery. *J Gastrointest Surg.* 2006;10(4):519–522.

40. Gupta BK, Khaneja SC, Flores L, Eastlick L, Longmore W, Shaftan GW. The role of intra-aortic balloon occlusion in penetrating abdominal trauma. *J Trauma.* 1989;29(6):861–865.

41. Soen M, Nishihara I, Fukuda M, Fujiwara S, Akimoto H, Fukumoto H. Evaluation of 38 cases of employing aortic occlusion balloon catheter [in Japanese]. *Masui.* 2005;54(3):265–269.

42. Avaro JP, Mardelle V, Roch A, Gil C, de Biasi C, Oliver M, Fusai T, Thomas P. Forty-minute endovascular aortic occlusion increases survival in an experimental model of uncontrolled hemorrhagic shock caused by abdominal trauma. *J Trauma.* 2011;71(3):720–772.

DISCUSSION

Dr. Timothy C. Fabian (Memphis, Tennessee): The authors are basically attempting a risk-benefit analysis of a minimally-invasive versus a maximally-invasive maneuver of proximal vascular control. Both carry the insult of major ischemia/reperfusion injury. Thoracotomy has the risk of a second large wound into a separate anatomic cavity. REBOA risks femoral artery injury and balloon delivery through the aorta or into a branch vessel. This discussion will focus on feasibility and efficacy.

REBOA is certainly attractive in theory. It can provide proximal vascular control prior to releasing the abdominal wall tamponade with definitive laparotomy. It also avoids the exacerbation of hypothermia produced by two coelomic cavities entered with resuscitative thoracotomy. Thoracotomy is never pleasant in the emergency room. All of your balloon occlusions were performed in the emergency department.

Let me pursue a few technical points. In the manuscript you note that a prior report by Megan Brenner demonstrated that, in the simulation lab, REBOA was routinely accomplished in less than five minutes. While the simulator is quite effective relative to sheath, guide wire and catheter skills instruction, its fidelity relative to inguinal anatomy and the scenario of shock is weak.

I'm not sure the five-minute procedural times are commonly reproduced in the clinical scenario of a crashing patient undergoing intubation, venous access, and the general chaos associated with cardiovascular collapse.

In our modest REBOA experience with seven patients the femoral pulse is either very weak or absent. Do you utilize ultrasounds for arterial localization? And how many of your cases were able to have percutaneous femoral access versus open vascular exposure? Your experiences clearly demonstrate the feasibility of REBOA for management of the trauma patient with intraabdominal or pelvic injuries at the current state of endovascular equipment development.

I would now like to finish with the issue of efficacy. You reported a highly significant difference in survival. The last sentence in the manuscript states, "Patients undergoing REBOA have improved overall survival and fewer early deaths as compared to patients undergoing resuscitative thoracotomy." While I suspect this may be true, I don't believe your data really supports that.

There are, indeed, no statistical differences in ISS or mechanism of injury in the total groups or in those that died in these groups, suggesting an apples-to-applies comparison. But as you noted at the end, more importantly, nearly twice as many thoracotomy patients arrived with CPR in progress — 53% versus 29%. I see more of an apples-to-oranges comparison in the two groups. Obviously, the only way to resolve the issue would be a randomized controlled trial and that will never happen.

Regardless of this criticism related to efficacy, I believe you are correct and REBOA should replace resuscitative thoracotomy for proximal vascular control in the management of severe abdominal and pelvic trauma. A very difficult question we face, however, is patient selection. We know the problem with a hypotensive patient with a ruptured AAA, not so much with blunt trauma or penetrating injury.

When is occlusion too much (i.e. unnecessary)? When is it not enough (i.e. unsalvageable)? We need to aim for the sweet spot, when it is just right—easy to say, but difficult to define.

Finally, could you speculate on future technological developments and the impact those will have on the REBOA applications? Thanks for this very important contribution that will almost certainly have a large impact on the management of non-compressible torso hemorrhage and, hopefully, improve patient survival.

Dr. Eileen Bulger (Seattle, Washington): I think as we introduce new technologies and new procedures it is absolutely critical that we evaluate them. And I would encourage you to include additional data, if you have it, in the paper.

Can you comment on whether you have any data alluding to how long it takes to get the REBOA in place compared to the time it takes to get a cross clamp on the aorta with a resuscitative thoracotomy?

Do you have any data on how long the balloons were up in these patients? Whether there were any delays to getting an unstable patient to the operating room for laparotomy because you're taking a lot of time to try to get a REBOA up? Is that an issue? Is that a concern? And what is the complication rate with REBOA in your series?

I think all those things are important things that we need to know as we are adopting this technology. And I would echo, also, the patient selection concerns and the comparison.

Without physiologic data I think it is not fair to compare these patients to resuscitative thoracotomy patients who, again, are largely in cardiac arrest.

Dr. Ramyar Gilani (Houston, Texas): Dr. Moore, I really enjoyed your presentation and I just had a couple of questions that I wanted to ask about your experience.

Our experience has been that because of its minimally invasive nature, REBOA is employed much earlier in the algorithm in a patient who is in shock versus resuscitative thoracotomy. Do you have any data saying how many REBOA patients you had that had actually arrested? And, similarly, how many resuscitative thoracotomy patients were done in patients who had actual pulse but were just hypotensive?

My second question has to do with the similarities to ruptured aneurysms. The real power that we've discovered in treating ruptured aneurysms is in the treatment that remains endovascular for these patients. What happened to these patients after the hemorrhage control maneuver was employed in both groups, if you have any data on that? Thank you.

Dr. Zsolt J. Balogh (Newcastle, Australia): Great paper, Laura. I think it's a bit controversial but going to be a landmark publication. My question is regarding the future.

I think you are going to see a new epidemic of multiple organ failure because we're going to save patients who previously just died. And they're going to be the sickest patient on the ICU.

The other reason we're going to see that is if we are lowering the threshold of using this, causing severe reperfusion injury, basically this is the best way to generate MOF in the lab in rats, can you comment on this, please? Thank you very much, again.

Dr. Paula Ferrada (Richmond, Virginia): Dr. Moore, congratulations on a great paper. I wanted to ask your thoughts regarding training, proficiency, and availability for this novel technique. If you really think REBOA is the future, how do we make this technology available to every and any trauma surgeon locally and globally? Thank you.

Dr. Laura J. Moore (Houston, Texas): Thank you all for your insightful questions and comments. I will try to get to all of these.

Dr. Fabian, with regard to your comment and several other comments about time to performance. The only published literature about time to performance is from Dr. Brenner's paper on timing in the skills lab.

At both UT Houston and at Baltimore we have a video record all of our trauma resuscitations. The team in Baltimore has already started looking at the time it takes for the surgeon to insert REBOA in their institution. We are in the process of doing that as well as Houston.

I can tell you time to performance is variable and is dependent on several factors. If we already have percutaneous arterial access we're able to get the balloon up within about 90 seconds. If you don't have arterial access obviously it takes longer.

If you're having difficulty achieving arterial access, at some point you are going to have to abandon that approach and potentially move on to thoracotomy.

In terms of what percentage of our patients had an ultrasound-guided placement versus a cut down, it's about 50/50 in this series. Our practice in Houston, as well as in Baltimore, has been if a patient arrives pulseless we go straight to a cutdown to achieve arterial access. But if they arrive with a pulse that you can palpate then we use a percutaneous technique, with or without ultrasound, to gain arterial access.

In terms of future applications, Dr. Fabian, I think with our current sheath and catheter sizes it's a little bit challenging to deploy this in other settings. However, in the next 18 months I think we will start to see catheters that will fit through a 6 or 7 French sheath which will, I think, expand the application.

One of the inherent biases to REBOA is its minimally-invasive nature. Several of you asked how many of the REBOA patients were CPR in progress as compared to the thoracotomy group. Half of the thoracotomy patients were CPR in progress; a third of the REBOA patients were CPR in progress. From my personal experience it is a lot easier for me to make a decision to inflate a balloon in a patient with a pulse than it is for me to open that same person's chest to cross clamp the aorta.

In terms of complications, we do not have complication data for this particular series. We can go back and look at that. I know from Houston, alone, we haven't had any significant complications outside of one patient who did have a superficial femoral artery thrombosis that occurred about 24 hours after the REBOA was removed and the artery was repaired.

Dr. Balogh, with regard to your comment about multiple organ failure, we had one multiple organ failure death in our case series of 24 patients. There are some animal data out there showing that aortic occlusion is tolerated for up to 90 minutes, albeit at the expense of an increasing lactate burden. But, again, we don't have a lot of human data on this yet. And certainly that is something that we need to continue to gather data on as we continue to use this in human applications.

Finally, with regard to credentialing and training there currently are not any published standards for credentialing. Some institutions and organizations are starting to offer REBOA training course but at this time the credentialing process has been dependent upon the local institution.

I appreciate your attention and the privilege of the podium.