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Resuscitative endovascular balloon occlusion of the aorta for control of noncompressible truncal hemorrhage in the abdomen and pelvis

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Abstract

BACKGROUND: Noncompressible truncal hemorrhage is a leading cause of potentially preventable death in trauma and acute care surgery patients. These patients are at high risk of exsanguination before potentially life-saving surgical intervention may be performed. Temporary aortic occlusion is an effective means of augmenting systolic blood pressure and perfusion of the heart and brain in these patients. Aortic occlusion temporarily controls distal bleeding until permanent hemostasis can be achieved. The traditional method for temporary aortic occlusion is via resuscitative thoracotomy with cross clamping of the descending aorta. While effective, resuscitative thoracotomy is highly invasive and may worsen blood loss, hypothermia, and coagulopathy by opening an otherwise uninjured body cavity. Resuscitative endovascular balloon occlusion of the aorta (REBOA) achieves temporary aortic occlusion using an occlusive balloon catheter that is introduced into the aorta via endovascular access of the common femoral artery. For this reason it is thought that REBOA could provide a less-invasive method for temporary aortic occlusion. Our purpose is to describe our experience with the implementation of REBOA at our Level 1 trauma center.

METHODS: A retrospective case series describing all cases of REBOA performed at a prominent level 1 trauma center between October 2011 and September 2015. The study inclusion criteria were any patient that received a REBOA procedure in the acute phases after injury. There were no exclusion criteria. Data were collected from electronic medical records and the hospital's trauma registry.

RESULTS: A total of 31 patients underwent REBOA during the study period. The median age of REBOA patients was 47 (interquartile range [IQR] = 27 to 63) and 77% were male. A majority (87%) of patients sustained blunt trauma. The median injury severity score was 34 (IQR = 22 to 42). The overall survival rate was 32% but varied greatly between subgroups. Balloon inflation resulted in a median increase in systolic blood pressure of 55-mm Hg (IQR 33 to 60), in cases where the data

were available (n = 20). A return to spontaneous circulation was noted in 60% of patients who had arrested before REBOA (n = 10). Overall, early death by hemorrhage was 28% with only 2 deaths in the emergency department before reaching the operating room.

CONCLUSIONS: REBOA is an effective method for achieving temporary aortic occlusion in trauma patients with noncompressible truncal hemorrhage. Balloon inflation correlated with increased blood pressure and temporary hemorrhage control in a vast majority of patients.
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Hemorrhage remains the leading cause of potentially preventable deaths in traumatically injured patients.[1–4] Hemorrhage can be broadly categorized as compressible (ie, amenable to control with direct pressure or tourniquet application) or noncompressible (ie, solid organ injury). Patients with noncompressible truncal hemorrhage (NCTH) have very high-mortality rates, ranging from 18% to 50%,[5–7] are at high risk of exsanguination before potentially life-saving surgical interventions can be performed. These critically injured patients are at high risk of progression to cardiovascular collapse if rapid hemorrhage control cannot be obtained.

Historically, resuscitative thoracotomy (RT) with clamping of the thoracic aorta has been performed in patients with cardiovascular collapse from NCTH. Aortic cross clamping provides for increased afterload with improved cardiac and cerebral perfusion as well as temporary inflow control to slow hemorrhage arising below the diaphragm. The use of RT is typically a reactive procedure that is reserved for patients with loss of vital signs. Although RT is effective, this procedure is maximally invasive and may worsen blood loss, hypothermia, and coagulopathy by opening an otherwise uninjured body cavity. Despite the physiologic benefits of aortic cross clamping, the performance of RT results in a significant physiologic insult to the patient and a relatively poor survival rate of 0% to 15%.[8–15]

In recent years, there has been a renewed interest in the utilization of resuscitative endovascular balloon occlusion of the aorta (REBOA) as minimally invasive alternative to open aortic cross clamping to provide temporary aortic occlusion.[16–19] This technique involves placement of an occlusion balloon via a sheath placed into the common femoral artery. Balloon occlusion of the aorta has been shown to mitigate hemorrhage and augment systolic blood pressure (SBP) and perfusion of the heart and brain.[8,9,20] REBOA allows for the same physiologic result as open aortic cross clamping through a less invasive, endovascular approach. Because of its minimally invasive nature, REBOA can be performed as a proactive (rather than reactive) measure in patients with refractory hemorrhagic shock from intra-abdominal/pelvic bleeding. Our purpose is to describe our initial experience with the implementation of REBOA at our American College of Surgeons–verified Level 1 Trauma Center.

Patients and Methods

We retrospectively identified all patients that underwent REBOA at The Texas Trauma Institute, an American College of Surgeons–verified Level 1 Trauma Center in Houston, Texas between October 2011 and September 2015. Inclusion criteria were all patients that underwent REBOA during the study period. No patients that underwent REBOA were excluded from the study. Demographic data, mechanism of injury, injury severity score (ISS), Abbreviated Injury Scale, admission vital signs/laboratory values, morbidity, mortality, and discharge disposition were all obtained from trauma registry data. The change in SBP before and after REBOA inflation was obtained from chart review of nursing documentation and review of the performing surgeon's procedure notes. Zone of occlusion was determined by review of digital radiographs obtained at the time of REBOA insertion.

All surgeons performing REBOA during the study period had received formal training in technique. Two of the surgeons were trained at the Endovascular Skills for Trauma and Resuscitative Surgery course.[21] The remaining trauma surgeons were trained via a modified version of the Advanced Surgical Skills for Exposure in Trauma course. Each surgeon was required to demonstrate proficiency with the technical aspects of REBOA placement before clinical use. The zones of aortic occlusion (see Fig. 1) are defined as follows: zone 1 is from the takeoff of the left subclavian artery to the celiac artery, zone 2 is from the celiac artery to the lowest renal artery, and zone 3 is from the takeoff of the lowest renal artery to the aortic bifurcation. Zones 1 and 3 are the preferred zones of occlusion and
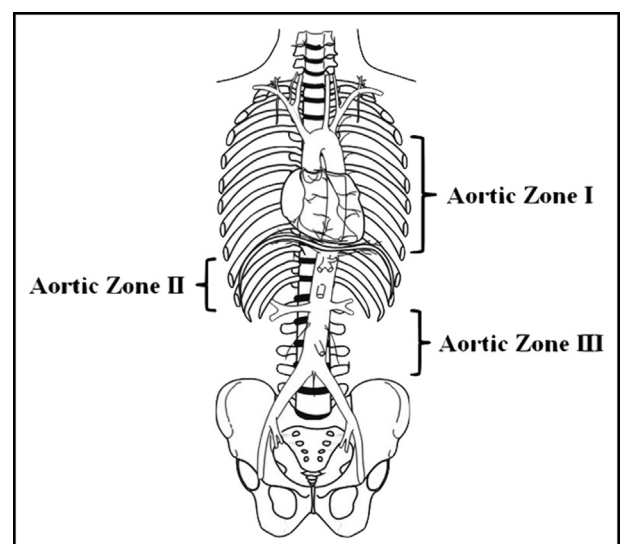
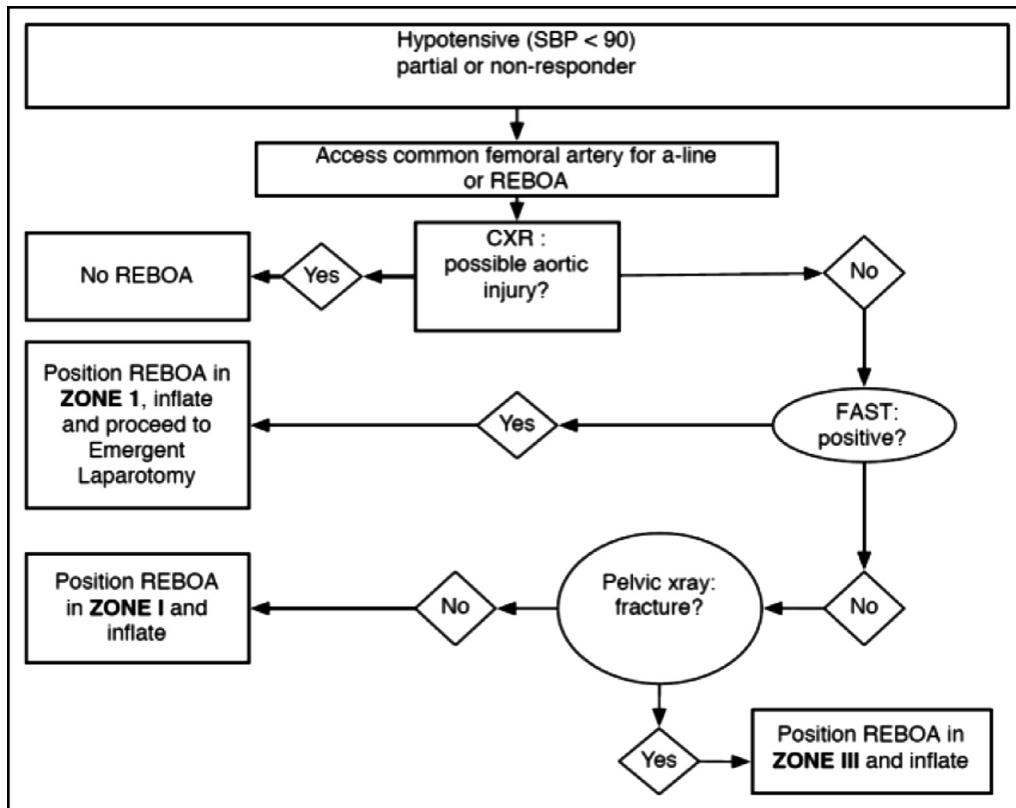**Figure 1**   Aortic zones of occlusion.

Figure 2   REBOA algorithm.

zone 2 is considered to be a no occlusion zone and thus should be avoided.

The Texas Trauma Institute algorithm used to determine patient suitability for REBOA insertion is depicted in Fig. 2. We used the steps for insertion of REBOA as described by Stannard et al[22] Patients with a SBP of less than 90-mm Hg have an 18 gauge arterial line placed into the common femoral artery in the emergency department. A chest x-ray (CXR) is then performed to evaluate for aortic injury or major intrathoracic hemorrhage as the source of the patients hypotension. Patients with a CXR that is concerning for thoracic aortic or other major thoracic injury are not candidates for REBOA placement. If the CXR does not suggest a major intrathoracic injury then a Focused Abdominal Sonogram for Trauma (FAST) examination is performed to evaluate for the presence of intra-abdominal hemorrhage. If the FAST examination is positive, then a zone 1 deployment is performed. If the FAST examination is negative, then a pelvic x-ray is performed. If a pelvic fracture is identified then a zone 3 deployment is performed. *Patients with hemodynamic instability attributed to an obvious catastrophic head injury (visible brain matter or transcranial gunshot wound) were not considered candidates for REBOA.* For all REBOA cases, we used the Cook Medical Coda balloon which was deployed via a 14 French sheath placed in the common femoral artery. Summary statistics of patient age, ISS, Abbreviated Injury Scale, and SBP are displayed as median

with interquartile range (IQR). Wilcoxon rank-sum was used to compare continuous variables.

Results

Over the course of the 48-month study period, a total of 31 patients underwent REBOA. The median age of REBOA patients was 47 years of age (IQR 27 to 63). Seventy-seven percent of the patients were male and 87% had a blunt mechanism of injury. The median ISS was 34 (IQR = 22 to 42) and the overall survival rate was 32%. Of the 31 patients, 10 patients had cardiopulmonary resuscitation (CPR) in progress at the time of REBOA insertion.

Of the 21 deaths, 2 (9.5%) occurred in the ER, 7 (33%) occurred in the operating room, and the remaining 12 (42.5%) occurred in the shock trauma intensive care unit. Most of deaths were due to either nonsurvivable head injury (43%) or multiple organ failure (28.5%). When comparing nonsurvivors to survivors, the median ISS for survivors was 29 (IQR 22 to 43) compared with 34 (IQR 22 to 41.5) in nonsurvivors ($P = .74$). Of the 10 survivors, the median ICU length of stay was 7 days (IQR 6 to 14) and median hospital length of stay was 22 days (IQR 17 to 40). *The rate of multiple organ failure among survivors was 6.5%.* Thirty percent of the survivors were discharge home, 30% were discharged to a rehabilitation hospital, and the remaining 40% were discharged to a nursing facility.
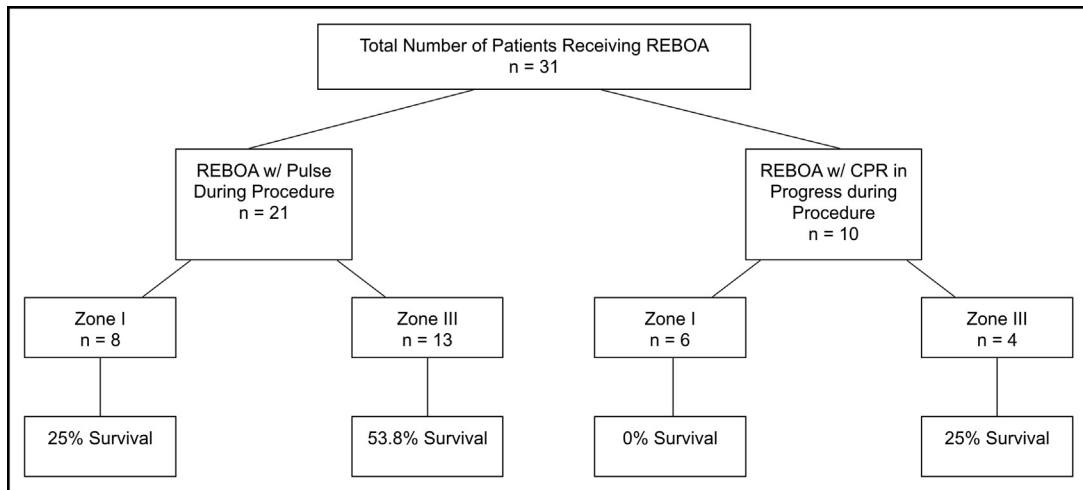
Figure 3   Breakdown of study patients.

There were 14 zone 1 insertions and 17 zone 3 (Fig. 3). When documented (n = 20, 65%), balloon inflation resulted in a median increase in SBP of 55-mm Hg (IQR 33 to 60). When broken down by zone of occlusion, the median increase in SBP for zone I occlusions (n = 7) was 65-mm Hg (IQR 52 to 72) and for zone 3 occlusions (n = 13) was 45-mm Hg (IQR 30 to 60). Among the 10 patients that were undergoing CPR at the time of REBOA insertion, 6 (60%) had a return of spontaneous circulation after balloon inflation.

The sources of hemorrhage identified in zone 1 occlusions are depicted in Fig. 4. Among the 14 patients with a zone 1 insertion, 2 (14%) died in the ER and the remaining were taken to the operating room (OR) for laparotomy. Four patients died in the operating room with half of these intraoperative deaths attributed to refractory hemorrhagic shock and the other half to nonsurvivable head injuries. Of the 8 zone 1 patients that survived to ICU admission, 6 died. Half of these deaths ascribed to multiple organ failure and the other half to nonsurvivable head injuries.

The sources of hemorrhage identified in zone 3 occlusions are depicted in Fig. 5. Among the 17 patients with a zone 3 placement, none died in the emergency room. Of these 17, 12 (70%) were taken to the OR for pelvic packing ± exploratory laparotomy for other injuries, and 5 (30%) were taken from the ED to interventional radiology for angiography. Among the 5 patients taken to angiography, 80% underwent embolization for pelvic hemorrhage. Of the 12 patients that were taken to the operating room, 3 (25%) died in the operating room due to refractory hemorrhagic shock. One of these intraoperative deaths was due to a grade V liver injury and the other 2 were attributed to noncontrollable pelvic hemorrhage. Of the 14 zone 3 patients that survived to ICU admission, 6 died in the intensive care unit with half of the deaths attributed to multiple organ failure and the other half attributed to nonsurvivable head injuries.

The highest survival rate (54%) was observed in patients undergoing zone 3 deployment with vital signs present during REBOA insertion (Fig. 3). The lowest survival rate (0%) was observed in patients undergoing zone 1 deployment with CPR in progress. Of the 10 patients that were CPR in progress at the time of REBOA, 1 survived to hospital discharge.

There were no complications attributed to vascular access for REBOA insertion in this series. One survivor did require a lower extremity amputation but this was attributed to traumatic injury rather than REBOA insertion. In addition, there were no spinal cord deficits noted among the survivors.

Comments

This clinical series represents the largest single center series from the United States on the contemporary use of REBOA as an adjunct for patients with hemorrhagic shock arising below the diaphragm. Although there has been a
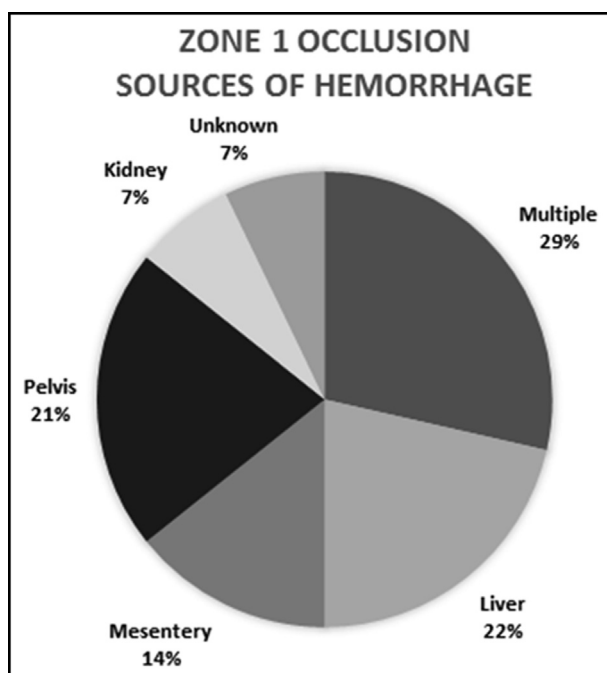

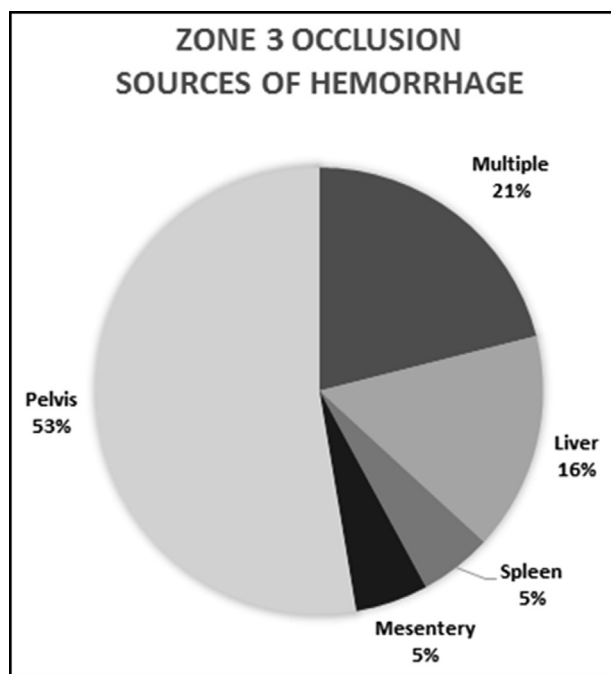**Figure 4**   Sources of hemorrhage among zone 1 occlusions.

Figure 5 Sources of hemorrhage among zone 3 occlusions.

recent resurgence in the use of REBOA, the concept of aortic balloon occlusion is not new. In a 1954 case series, Lieutenant Colonel Carl Hughes first described the use of aortic balloon occlusion in 3 soldiers with intra-abdominal hemorrhage during the Korean War.[16] With the recent conflicts in Iraq and Afghanistan, there has been a renewed interest in the use of aortic balloon occlusion as an adjunct to hemorrhage control. The Joint Theater Trauma System Clinical Practice Guideline released in June 2014 has recommended REBOA for use as an alternative to RT in patients with severe hemorrhagic shock due to NCTH, including patients in cardiac arrest.[23] Renewed clinical interest combined with recent technological advances and familiarity with endovascular techniques has led to the increased utilization of REBOA.

In the contemporary literature there are several case series documenting the use of REBOA in trauma patients. In a 1989 series of 21 patients sustaining penetrating abdominal trauma, Gupta et al[24] reported insertion of REBOA after 15 minutes of refractory hemorrhagic shock. In this series, only 50% of the patients survived to laparotomy and 33% survived to hospital discharge. Brenner[18] published a combined case series from Houston and Baltimore, with an overall survival rate of 66%, reporting no deaths from hemorrhage. Irahara reported on the REBOA experience in 14 traumatically injured patients in Japan with a survival rate of 36%.[25] In a more recent multicenter series combining the experiences from the Texas Trauma Institute in Houston and the R. Adams Cowley Shock Trauma Center in Baltimore, Moore et al[17] compared survival in patients with NCTH arising below the diaphragm undergoing RE-BOA (n = 24) to those patients undergoing resuscitative thoracotomy (n = 72). Over 18 months, we documented

the decreased utilization of RT and increased utilization of REBOA at both institutions. In this series, the overall survival rate for REBOA was 37.5% compared with 9.7% in the resuscitative thoracotomy group ($P = .003$). Finally, in another Japanese series of 24 patients, Saito et al[26] reported a 30-day survival rate of 29.2%.

> The optimal utilization of REBOA continues to evolve. In our Level One Trauma center patients that are hypotensive (defined as a systolic blood pressure <90 mm Hg) with suspected truncal hemorrhage arising from below the diaphragm are considered to be candidates for REBOA. Patients that are hypotensive on arrival to our ER are initiated on massive transfusion protocol. Prior to placement of REBOA we require a chest x-ray to rule out a thoracic aortic injury or pulmonary hilar vascular injury as the source of the patient's hypotension. Patient's that remain hypotensive despite rapidly receiving 2 units of packed red blood cells and 2 units of fresh frozen plasma are considered to be non-responders. If the chest x-ray is negative for significant mediastinal findings, then a rapid evaluation to determine the source of truncal hemorrhage is performed. This includes a FAST exam to evaluate for the presence of pericardial fluid and intraperitoneal blood. If the patient has a positive abdominal FAST exam, then Zone 1 balloon inflation is pursued. If the FAST exam is negative but the patient has a pelvic fracture, then a pelvic binder should be placed in conjunction with a Zone 3 balloon inflation is pursued. In our institution, if a patient arrives in extremis (SBP < 50 mm Hg) or has loss of vital signs without a penetrating chest injury the decision to utilize REBOA vs Resuscitative Thoracotomy remains at the discretion of the attending trauma surgeon. If common femoral arterial access has already been established, then rapid placement of REBOA is pursued. If common femoral arterial access is not easily obtained, then resuscitative thoracotomy should be performed. After balloon inflation, an assessment of the patient's hemodynamic response to inflation should be performed. As noted in the results, patient's with vital signs at the time of balloon inflation uniformly experienced an increase in their systolic blood pressure. Among those patients that were CPR in progress at the time of REBOA inflation 60% had return of spontaneous circulation. After securing the balloon the patient should be taken to either the operating room or the angiography suite for definitive hemorrhage control based upon the suspect source of hemorrhage.

The survival rate of 32% observed in the present series of patients is consistent with other reports in the literature.[17,19,25,26] As expected, the lowest survival rates were observed in those patients that arrived with CPR in progress and indications for a zone 1 occlusion (ie, positive intra-abdominal FAST examination). Of these 10 patients that arrived with CPR in progress, 60% had return of spontaneous circulation with balloon inflation. Although the mortality rate is still high among patients arriving with CPR in progress, it is important to highlight that half of these patients survived beyond 24 hours and died of nonsurvivable head injuries. The highest survival rate (53.8%) was seen in those patients that had vital signs present on arrival and REBOA inflated

at zone 3 for pelvic hemorrhage. The management of patients with hemorrhagic shock from severe pelvic fractures has continued to pose a clinical challenge. Mortality rates in these patients remain high, even at experienced level 1 centers with multidisciplinary clinical pathways.[27–29] The mainstays of treatment have been pelvic packing, angioembolization, and early pelvic stabilization. Although ongoing experience with REBOA is needed, we believe that deployment of RE-BOA in zone 3 may prove to be the optimal tool for early hemorrhage control in this patient population.

After balloon inflation, a significant increase in SBP was observed in all patients that had vital signs present. The increase in SBP was most notable for zone 1 occlusions, ranging from 40- to 80-mm Hg with a median increase of 65-mm Hg. In a recent systematic review of REBOA use in 6 cohort studies for hemorrhagic shock, Morrison et al[20] reported a mean increase in SBP of 53-mm Hg. This increase in SBP after REBOA inflation has also been observed in numerous animal studies.[9,30,31] Also of note, among the patients that were undergoing CPR at the time of REBOA insertion, 60% had return of spontaneous circulation after balloon inflation. *All of these patients were undergoing active resuscitation with blood products via massive transfusion protocol at the time of CPR as well as resuscitation with Advance Cardiac Life Support during balloon insertion. These findings further support the efficacy of balloon inflation as an adjunct to improve SBP.*

> Selecting the optimal zone of initial occlusion continues to be an area of ongoing clinical research. In this series, 47% of the Zone 3 occlusions in this series were ultimately attributed to multiple sources of hemorrhage (pelvis plus an additional intra-abdominal source) as well as liver, spleen, and/or mesenteric hemorrhage. Per our algorithm, Zone 3 occlusions should be reserved for patients with a pelvic fracture and negative FAST exam. All of the patients in this series that had Zone 3 occlusions had a negative FAST exam with a pelvic fracture present. The limitations of FAST exam are recognized with one recent series reporting a false negative rate of 49% for patients with blunt abdominal trauma.[32] While it is difficult to determine in which source(s) of hemorrhage was responsible for the patient's hypotension this brings to question whether or not inflation in Zone 3 could have been potentially detrimental. Given the findings of this series and the known potential for false negative rates one could argue that Zone 1 deployment should be utilized for all patients with repositioning to Zone 3 only after definitively ruling out other non-pelvis sources of hemorrhage.

In this study, all REBOA insertions were performed by trauma surgeons using digital x-rays to confirm appropriate placement. While a detailed description of the technique of REBOA insertion is beyond the scope of this article, the technical aspects of REBOA insertion are certainly within the realm of the acute care surgeon. REBOA insertion involves (1) obtaining common femoral artery access; (2) inserting the balloon over a wire at the appropriate level; (3) inflating the balloon; (4) deflating the balloon; and (5) removing the arterial sheath. *The initial steps (1 through 3) can be accomplished in the emergency department using digital x-ray.* Flouroscopy is not required and is not used for REBOA placement at our institution. Obtaining arterial access is the critical step of this procedure. It has become our practice to place an 18 gauge arterial line in the common femoral artery for all trauma patients with a SBP less than 90-mm Hg. This ensures that we have arterial access for continuous blood pressure monitoring and offers the benefit of having readily available arterial access that can be rapidly upsized to a larger sheath to allow for RE-BOA placement if needed. One of the current drawbacks of the commercially available REBOA catheters is the relatively large size of the sheaths required for deployment and the long guidewires (260 cm) required for balloon insertion. These devices were initially designed for use in endovascular repairs in patients with abdominal aortic aneurysms, a very different patient population than the typical young trauma patient. As a result, the 14 French sheaths often result in occlusion of the ipsilateral common femoral and iliac arteries. In addition, these sheaths must be removed via cut-down on the common femoral artery with subsequent surgical repair of the vessel and clearance of any proximal or distal thrombus that has formed. Recently, the United States Food and Drug Administration has approved a new guidewire free REBOA device that can be deployed via a 7 French sheath (ER REBOA catheter, Prytime Medical, Arvada, CO). Although no clinical data are yet available on this device, it offers the theoretical advantage of deployment through a smaller sheath without the need for repair of the common femoral artery during removal. In addition, the ER REBOA device does not require insertion of the long 260-cm guidewire required with the Cook Medical Coda balloon that we used in this series. While we did not have any vascular access related complications in this series, a recent case series from Japan have brought into question the potential for limb loss related to REBOA insertion. In a retrospective review of 24 REBOA insertions for blunt trauma, Norii et al[19] reported 3 cases of lower extremity amputation that were attributed to vascular injury or ischemia from REBOA insertion. Limb complications have not been observed in the 2 recent US case series from Brenner and Moore.[17,18] One potential explanation for the difference in extremity complications between the Japanese and US experience may be related to inherent differences between the trauma systems in the 2 countries. In the Norii series, all REBOA insertions were performed by physicians with additional training in interventional radiology with little or no in-house trauma surgery support. This is in stark contrast to the US series from Houston and Baltimore where 24/7 in-house trauma faculty are performing the REBOA insertions and subsequently removing the sheaths via open cut-down and surgical repair of the common femoral artery. As we continue to gain clinical experience with REBOA and the number of centers using this technique increases, it will

be important to disclose complications that occur as a result of this technique. Currently, the American Association for the Surgery of Trauma is conducting the AORTA trial which is a prospective, observational study that aims to compare outcomes from open and endovascular aortic occlusion.

This study has several limitations. Due to the retrospective nature of the study, several variables of interest such as time to perform the REBOA procedure and the duration of balloon inflation were not able to be determined in all patients. With the increased utilization of REBOA in our clinical practice, we are continuing to focus on documentation of these variables for future studies.

Conclusions

Resuscitative endovascular balloon occlusion of the Aorta is an effective method for achieving temporary aortic occlusion in trauma patients with noncompressible torso hemorrhage arising from below the diaphragm. Balloon inflation in both zone 1 and zone 3 occlusions results in an increase in SBP. In addition, REBOA inflation during CPR resulted in return of spontaneous circulation in 60% of the patients. Despite the high-injury severity seen in this population, the overall survival rate was 32% with a minority of deaths occurring from hemorrhage. These results suggest that REBOA is an effective tool for the management of hemorrhagic shock due to NCTH arising below the diaphragm.

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Discussion

Discussant

Dr. David Plurad (Sierra Madre, CA): That was very well presented, Clay. I would like to commend you on your bravery as well for your level of training.

I would like to thank the Congress for allowing me to review what is the largest series of REBOA to date in the United States. It's very good to be a trauma surgeon these days. Recent changes in resuscitative protocols have been resuscitated themselves from the past. We have echoes of warnings against too much crystalloid being administered, early administration of whole blood, and we probably have the Roman soldiers to thank for wielding tourniquets as well as they wielded swords.

But I would ask if it is appropriate at this time to resuscitate the idea of resuscitative endovascular occlusion of the aorta? The Japanese experience would suggest that REBOA is associated with an increase in complications and a propensity score matched mortality. Granted, this is based on a large administrative data set using complex statistical methodology, but their experience is extensive, and these data cannot be ignored due to a recent review of data showing that REBOA cannot be associated with increased survival.

The manuscript does not give us a good idea of where exactly REBOA fits in the resuscitative protocol. I would ask those cases where a surgeon was needed; how far away is the ED from the OR at Memorial Hermann? I have the following questions:

What was the overall rate of multisystem organ failure? Was the group's resuscitative protocol hypotensive trauma patients with abdominal injuries? Along those lines, what is the group's resuscitative protocol for unstable pelvic fracture? What is the mean balloon occlusion time in OR and OR to OR times? What is the risk benefit analysis of REBOA in patients who have negative FAST and negative pelvic films?

Dr. Clay Martin (Houston, TX): Thank you very much, Dr. Plurad, for that discussion and some really good questions. I'll start out by addressing the first which was in regard to multisystem organ failure. We didn't keep track of it outside of as a cause of death. As such, it accounted for 29% of our mortality and the overall incidence was 19.4%.

The second question was regarding transfusion protocol. Our first step was to activate massive transfusion protocol, and then if systolic blood pressure did not increase to above 90 millimeters mercury after two units of packed red cells and fresh frozen plasma, they were considered a nonresponder and a candidate for REBOA.

The third question had to do with our protocol for unstable pelvic fractures. The first thing we did was to apply pelvic binder and then make a clinical decision whether to send them to interventional radiology for embolization.

The fourth question I believe was about mean balloon time. That is actually something we wanted to look into, but it turns out that intraoperative data regarding the timing of this procedure are very hard to establish in a retrospective series. You really need someone prospectively gathering those data points at the time. That's something we would really like to look into in the future.

The last question had to do with the decision to inflate in the presence of a negative FAST examination and negative pelvic films. The first thing to do was to perform a diagnostic peritoneal aspirate. And if that was positive, that was confirmatory for abdominal bleeding and a zone 1 occlusion was placed.

Dr. Ronald Stewart (San Antonio, TX): First, Clay, it's an exceptional presentation. A great, great presentation, so thank you.

Pretty much everyone who knows me knows that I'm really a skeptical person. So I think we should be really skeptical about REBOA in general. Actually, I appreciate your conclusions when you say that this is an effective tool in the hands of a well-trained trauma surgeon. I'm also probably somewhat impacted in that we have a Japanese second-year fellow in our acute care surgery program. So the reports from there are not particularly glowing, and since the catheter itself was also being marketed to emergency medicine, it sets the stage up for potential real problems with the approach. Having said all that, that's mainly editorial.

It seems like to me the better approach to your data analysis would have been to not just list the survival rate but compare that to a historical cohort with same ISS or matched injury both physiologic and injury presentation on arrival. Did you do that analysis?

Dr. Clay Martin (Houston, TX): No, sir, we did not.

Dr. Ronald Stewart (San Antonio, TX): So another way to more formally do that, because even though this is the largest series, it's a small number of patients, is maybe to consider a case-control design to look at REBOA. So I would say that would be a good next step.

Then I know no one wants to hear this from me, but I'm going to say for this to really be shown to be effective, it's going to have to be studied in a randomized trial of carefully matched patients because there's probably going to be no other way to sort out whether this is beneficial,

harmful, or neutral without really a rigorous prospective clinical study.

Dr. Daniel Margulies (Los Angeles, CA): Thank you for that presentation. We're all trying to figure out the proper place for REBOA, whether to use it or not and what indications. I think your study really gives us some insight.

What I was wanting to know is what your specific indications for placing them were in your experience because you mentioned the slide in the beginning where it said blood pressure less than 90 and yet you're talking about it as if it's a replacement for thoracotomy in the ED. Most patients who come in with a pressure of 80 don't all get a thoracotomy. With regards to that, you're maybe comparing it to somebody that could be rushed to the operating room and have their bleeding controlled.

So in your critical analysis of these patients with the aorta occluded for some period of time, did you find any detrimental effects from the hypoperfusion during the occlusion? Granted, I understand they were bleeding, but you are occluding the aorta and oftentimes that leads to an acidosis. So I was just wondering if you were able to determine any untoward effect.

Dr. Clay Martin (Houston, TX): No, sir, we did not see anything related to that. But in reference to the comparison with the resuscitative thoracotomy, REBOA, because of its low-complication rate thus far, we believe that it can be an effective proactive measure of preventing cardiovascular collapse and death rather than the reactive measure of resuscitative thoracotomy in crashing patients.

Dr. Daniel Margulies (Los Angeles, CA): So I was asking about the specific indications. Did you follow that, any patient that had a blood pressure under 90? Or was that after transfusion attempt? And I suppose it's probably in the article, but I'm very interested in your specific indications.

Dr. Clay Martin (Houston, TX): As far as I know, we followed the algorithm that was presented. Nonresponders with a systolic BP below 90 with a positive FAST examination received a zone 1 occlusion, and then those with a negative FAST examination going for a pelvic X-ray. If there was evidence of pelvic fracturing, they received a zone 3 occlusion.

Dr. Bryan Morse (Atlanta, GA): Dr. Martin, I want to congratulate you on an excellent talk and even swaying me a little bit off of my stance of being resistant to this technology. I'm starting to see maybe there is a role for it in perhaps blunt trauma.

However, we see a tremendous amount of penetrating injuries, and we really sort of err on the side of getting people to the operating room quickly. I heard you earlier mention that they weren't able to really track time. But maybe as a surrogate, how do you know when this instrument or when REBOA is in place? Does it require extra X-rays? Because it seems like that would be something that kind of slows you down.

Second, did you look at REBOA mortality rates and outcomes specifically in penetrating injury, including complications where you have a gunshot wound like to the aorta and the REBOA device goes out the side of the artery?

How does REBOA help you—and this is a real challenge for us—decompress cardiac tamponade, put a hilar twist on the lung, that sort of thing? Thank you.

Dr. Clay Martin (Houston, TX): In response to the question about aortic injury, that is actually a contraindication of REBOA. If we suspect that the aorta has been injured, we won't run the catheter up there.

As far as the second question about relieving cardiac tamponade, I don't think I have the clinical experience to really speak to that.