Published in final edited form as:

J Surg Res. 2019 January ; 233: 413–419. doi:10.1016/j.jss.2018.08.031.

Resuscitative Endovascular Balloon Occlusion of the Aorta: Assessing Need in an Urban Trauma Center

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Abstract

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) has emerged as a bridge to definitive hemostasis in select patients with noncompressible torso hemorrhage. The number of patients who might benefit from this procedure, however, remains incompletely defined. We hypothesized that we could quantify the number of patients presenting to our center over a 2-year period who may have benefited from REBOA.

Methods: All patients presenting to our trauma center from 2014 to 2015 were included. Potential REBOA patients were identified based on anatomic injuries. We used ICD-9 codes to identify REBOA-amenable injury patterns and physiology. We excluded patients with injuries contraindicating REBOA. We then used chart review by two REBOA-experienced independent reviewers to assess each potential REBOA candidate, evaluate the accuracy of our algorithm, and to identify a cohort of confirmed REBOA candidates.

Results: Four thousand eight hundred eighteen patients were included of which 666 had injuries potentially amenable to REBOA. Three hundred thirty-five patients were hemodynamically unstable, and 309 patients had contraindications to REBOA. Sixty-four patients had both injury patterns and physiology amenable to REBOA with no contraindications, and these patients were

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Authors' contributions: R.P.D. participated in study design, data analysis, and writing of the article. D.N.H. participated in study design, data analysis, and writing of the article. B.P.S. participated in study design. D.J. participated in data collection. M.J.S. and P.M.R. participated in study design. Z.Q. participated in study design, data analysis, and writing of the article. J.W.C. participated in study design, data analysis, and writing of the article.

Disclosure

No authors have conflicts to declare.

Meetings at which this was presented: 13th Annual Academic Surgical Congress, January 30-February 1, 2018, Jacksonville, Florida

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jss.2018.08.031>.

identified as potential REBOA candidates. Of these, detailed independent two physician chart review identified 29 patients (45%) as confirmed REBOA candidates (interrater reliability kappa = 0.94, $P < 0.001$).

Conclusions: Our database query identified patients with indications for REBOA but overestimated the number of REBOA candidates. To accurately quantify the REBOA candidate population at a given center, an algorithm to identify potential patients should be combined with chart review.

Study type: Therapeutic study, level V.

Keywords

REBOA; Resuscitative endovascular balloon occlusion; Needs assessment; Hemorrhage control

Introduction

Noncompressible torso hemorrhage is the leading cause of potentially preventable death in both military and civilian trauma patients.^{1,2} Recent analyses have reported that between 8.2% and 17.1% of torso injuries in both civilian and military populations result in noncompressible torso hemorrhage.^{3,4} In these series, most deaths result from major arterial injuries indicating a capability gap directly addressed by resuscitative endovascular balloon occlusion of the aorta (REBOA). REBOA is now part of the armamentarium of trauma and acute care surgeons⁵ as an adjunct in the management of noncompressible abdominal and pelvic hemorrhage and represents an alternative to resuscitative thoracotomy (RT) in this select population. However, the optimal application of REBOA is still being defined.⁶

Aided by the development of a new, readily available lowprofile endovascular catheters recently approved by the FDA (https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170411.pdf), REBOA programs are being developed at many institutions across the globe.⁷ In addition, to comply with hospital credentialing policies and the need to train and certify providers, basic endovascular courses are now offered,^{8,9} making REBOA increasingly available to the acute care surgeon.

When adopting new technologies, it is important to understand the need for such a device across a range of different patient populations as part of the due diligence espoused by the IDEAL collaboration.¹⁰ Currently there are two studies that attempt to answer the question of how many patients may benefit from REBOA.^{11,12} The first is a gap analysis using both anatomic and physiologic variables from the United Kingdom (UK). The majority of injuries were from blunt traumatic mechanisms, with less than 1% as result of gun violence.¹¹ The second is an analysis of the UK military trauma registry using anatomical criteria only. Although there is a larger number of penetrating trauma victims, the majority of the patients sustained nonpenetrating blast injury.¹² Although these studies contribute greatly to the knowledge and understanding of the need for REBOA, what remains unclear is how many patients may benefit across the United States including urban environments where gun violence is more prevalent than the rest of the world.¹³ The push to establish institutional REBOA programs is clear,⁷ but institutional need and quantification of how many patients

might benefit from the procedure given the current indications¹⁴ remains unknown. Although initial reports of REBOA use indicate favorable outcomes, particularly when deployed before arrest from exsanguination, the scope of this need remains incompletely defined. More specifically, previously published database queries used to determine the need for REBOA have not validated this projected need based on both identified injuries and physiologic data after initial presentation. Finally, REBOA does have inherent risks and requires both initial training and skills maintenance. Therefore, such an assessment can help institutions weigh the pros and cons of establishing a program.

We sought to assess the need for REBOA in our center and to develop a generalizable methodology to identify the number of patients with anatomic injuries and presenting physiology amenable to REBOA, with the intention of characterizing the accuracy of our algorithm compared to traditional chart review. We hypothesized that a database query could accurately quantify the potential number of patients with indications for REBOA at our level I institution over a 2-year period.

Materials and methods

The John Paul Pryor Shock Trauma and Resuscitation Center at the University of Pennsylvania is a large level I academic trauma center with approximately 2700 contacts annually and a 21% penetrating trauma rate. This was a retrospective study of all injured patients who presented to and were treated for a diagnosis of trauma (ICD-9 injury codes 800–995 excluding 930–939.9) at our center between 2014 and 2015. After approval from the University of Pennsylvania Institutional Review Board (IRB), we queried our institutional trauma database. We were granted a waiver of informed consent and a waiver of HIPAA authorization from the IRB. This registry contains up to 84 ICD-9 code diagnoses for each patient contact. An algorithm was created to identify patients that presented to our trauma system who may have been REBOA candidates based on their injury pattern and initial presenting physiology (potential REBOA). In keeping with a recently published joint statement by the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP), we sought to identify patients with subdiaphragmatic exsanguinating hemorrhage not responsive to resuscitation or transiently responsive to resuscitation as potential REBOA candidates.¹⁵

We grouped patient injuries into four major categories (Figure) and identified all the patients presenting during the study period with these injury patterns using ICD-9 codes (see Supplement for list of ICD-9 codes). Because REBOA is traditionally described in patients in hemorrhagic shock, we subsequently identified all patients who arrived with an initial presenting systolic blood pressure of < 90 mmHg. Because only the initial blood pressure on arrival is available in our database, we also used blood transfusion in the trauma bay as a surrogate for persistent hypotension and hemodynamic instability.

After these patients were identified, they were cross-referenced with patients who presented with one of the four major injury patterns. We excluded those with contraindications for REBOA based on available guidelines and algorithms: patients with major vascular neck

injuries, thoracic injuries, axillary injuries, and upper extremity amputation (see Supplement for list of ICD-9 code exclusions).¹⁴ This gave us a group of potential REBOA candidates.

For the purposes of this study, patients who responded to initial resuscitation, defined as appropriate response in systolic blood pressure after two units of packed red blood cells, were not considered to be REBOA candidates. Likewise, patients who had documented initial concerning physical examination findings indicative of major thoracic injuries were excluded. For patients with lower extremity vascular injuries, ICD-9 codes do not differentiate injuries to the proximal superficial femoral artery (SFA) from more distal injuries. Proximal SFA injuries may not be amenable to tourniquet application, so we chose to include this ICD-9 code as a search term to identify those with proximal injuries who received a resuscitative thoracotomy or who expired without intervention yet may have been a candidate for REBOA. Patients suffering from junctional vascular injuries and proximal lower extremity vascular injuries were included as potential REBOA candidates. To assess the ability of this algorithm to accurately identify REBOA candidates, chart review was used to evaluate the initial presentation and resuscitation of these patients thereby determining whether each patient was indeed a REBOA candidate. This gave us a group of confirmed REBOA candidates. Two independent reviewers experienced in REBOA performed this review to adjudicate algorithm-identified cases.

For each confirmed REBOA candidate, the following data points were collected: patient demographics (gender, race, age), presenting vitals (heart rate, systolic blood pressure, Glasgow Coma Scale, respiratory rate, temperature), mechanism of injury (blunt, penetrating), injury severity score, and whether or not the patient underwent a resuscitative thoracotomy. Specific injury patterns and interventions, obtained from operative records, were also collected.

Data for nonparametric continuous variables were expressed as median [interquartile range (IQR)], and categorical values were expressed as n (%). Kappa statistic was used to determine interrater reliability between the physicians performing independent chart review. Stata v14.0 (College Station, TX) was used for all statistical analysis.

Results

Four thousand eight hundred eighteen trauma patients were captured in our institutional database from 2014 to 2015. In total, 666 patients had injury patterns potentially amenable to REBOA. The three most common injury patterns leading to inclusion were pelvic injuries, liver injuries, and spleen injuries. Three hundred nine patients had contraindications to REBOA and were excluded (Figure). Three hundred thirty-five patients had abnormal presenting physiology, of which 186 patients received blood transfusions in the trauma bay during their initial resuscitation and 149 patients had an initial systolic blood pressure < 90 mmHg.

We identified 64 patients (1.3% of patients, 79.7% male, 53% penetrating mechanism of injury, median ISS 19 [IQR 14–28]) who had an injury pattern and physiology amenable to REBOA with no contraindications based on injury locations.

Review of these 64 potential REBOA patients by two independent REBOA-experienced physicians identified 29 patients (45% of those identified by algorithm) as confirmed REBOA candidates. The interrater reliability between the two reviewers was kappa 0.94, $P < 0.001$. Of all trauma patients, 0.6% of patients were confirmed REBOA candidates.

The demographics of the confirmed REBOA cohort are displayed in Table 1. The cohort primarily comprised hypotensive, severely injured patients. Twenty-four percent of the cohort underwent resuscitative thoracotomy. The injury patterns of the 29 confirmed REBOA candidates are presented in Table 2. Pelvic indications for REBOA at our center were low. However, we found that penetrating vascular indications were high. Sixty-nine percent of the cohort had an indication for zone 1 occlusion. More than half of the group had a massive transfusion activated, and the median number of packed red blood cells was greater than 10 units at both 4 and 24 h. The specific injuries and operative interventions of the REBOA candidates are detailed in Table 3. Mortality in the confirmed REBOA group was 48.3%.

Discussion

In this single-center, retrospective study we attempted to assess the accuracy of a database query for quantifying the number of patients who presented to our trauma center with injuries and physiology amenable to REBOA. Previous REBOA needs assessments based on database review alone have not validated this projected need with chart review and thus may represent either overassessment or underassessment of the actual utility of REBOA. We found that registry review alone based on ICD-9 codes significantly overestimated the number of true REBOA candidates even when adding transfusion requirement as a surrogate for persistent hemodynamic instability. Only by pairing chart review with this registry data analysis were we able to identify the number of true REBOA candidates over a 2-year period. In general, these were severely injured patients with subdiaphragmatic, penetrating injuries who demonstrated either a transient response or no response to resuscitation. These patients consumed a large number of blood products and had nearly 50% mortality. However, these select patients represented only 0.6% of trauma patients presenting to our level I center.

REBOA has seen a large amount of interest in the past decade as a means of achieving temporary in-flow control in critically injured patients with torso hemorrhage. Unlike pharmaceutical development, which may take years of investigation to bring a product to market, medical devices and their associated procedures are often rapidly incorporated into practice.^{16,17} Such rapid implementation is generally accompanied by a broad clinical interest and enthusiastic adoption followed by investigative efforts into the technology, its specific indications, uses, and outcomes.¹⁸ Part of these efforts generally focus on correct patient selection and application. To ensure both patient safety and quality assurance, it is critical that a “needs assessment”¹⁹ is undertaken before deploying new medical technology such as REBOA.

Because we combined our algorithm with a detailed chart review, we believe we have a true representation of need for this procedure at our institution. By omitting a chart review or not

taking into account patient physiology, other studies may overestimate the number of true candidates. The overestimation of potential need was recently highlighted by Joseph et al. who found that on autopsy, less than half of a cohort of patients who underwent resuscitative thoracotomy may have benefited from REBOA.²⁰ Conversely, an algorithm-based needs assessment may identify patients who may benefit from early femoral vascular access.

By pairing an algorithm based on ICD-9-coded anatomic injuries and physiologic patient data with a detailed chart review, we identified a small percentage of patients (0.6%) who would potentially benefit from REBOA annually. This rate is comparable to the published UK civilian experience, which found 0.55% of over 72,000 patients to be candidates. This analysis did not include a chart review of identified REBOA candidates and is likely an overestimation. The similarity in need, however, is interesting given the stark difference in injury mechanisms—in the UK study, 91% of their potential REBOA candidates were victims of blunt trauma mechanism, whereas more than 70% of our patients suffered from penetrating mechanisms of injury.

Morrison *et al.* studied the potential need for REBOA in UK military combat casualties. They utilized anatomical injury patterns alone and found that nearly 20% of their study population may have benefited from REBOA. Although the injury patterns in our study population were very different, when using anatomic criteria alone, 15% of our population had injuries amenable to REBOA. Our study highlights that using anatomical criteria alone may overestimate the need for REBOA. We recommend individual needs assessments should incorporate both anatomic and physiologic criteria.

Critics of the use of REBOA may highlight that the overall need in any given trauma population is low. Our study shows that annually, 0.6% of our patient population would have potentially benefited from REBOA. This compares to approximately 1.5% of patients per year at our center who would undergo a resuscitative thoracotomy. Of these, the REBOA group represents those whose only requirement for thoracotomy was to achieve proximal inflow control of the aorta in the setting of massive torso hemorrhage. Importantly, those undergoing thoracotomy also includes victims with thoracic injuries, a widely agreed upon contraindication to REBOA. In our urban trauma center, we found that we had relatively few indications for a zone 3 occlusion and even fewer indications for pelvic fractures and often cited indication for REBOA placement.^{21,22} In addition, only 3% and 4% of our patient population either presented hypotensive or required a blood transfusion during their initial resuscitation. Both REBOA and thoracotomy are rarely performed but potentially life-saving interventions that have shown similar survival figures in the available data.²³ Although we confirmed that 29 patients presenting to our center over a 2-year period were REBOA candidates, any improvement in survival or changes in resuscitation requirements and organ failure in these patients remain open research questions. Our study also underscores that REBOA is a relatively uncommon procedure and highlights the need for both training and skills maintenance.

Our study has several important limitations. The result of our needs assessment is representative of our specific institutional population and patient needs and may not be widely generalizable. However, a similar methodology used to define our REBOA cohort

can be used to define individual institutional needs. It is possible that our needs assessment is an overestimation of our institutional needs; however, in contrast to the UK study, we have attempted to minimize this risk by performing a concurrent chart review. Furthermore, we do place REBOA catheters at our institution, and the two reviewers are both physicians trained in REBOA placement. This may have introduced some bias into our results. The authors believe we have minimized this bias, however, by having two blinded reviewers from different disciplines (surgery and emergency medicine) perform the chart review. Another important limitation of this study is that we have identified a cohort of patients who may have been candidates for REBOA, but it is not clear that all patients identified would have undergone REBOA based on variations in provider training, resource availability, and patient factors not captured in the registry or on chart review. As such, all confirmed REBOA candidates may not have actually undergone REBOA. Our analysis may also suffer from some referral bias as we are one of several level I trauma centers in our urban area, and our patient population may not be reflective of other urban patient populations with different transport times and injury demographics. In addition, because we did not perform chart review on the patients who were not identified as REBOA candidates based on anatomic and physiologic criteria built into our algorithm, some additional potential REBOA candidates may have been present within the 4818 total database patients but were missed due to coding or other clerical errors.

Conclusion

A needs assessment for REBOA is helpful in quantifying institutional need and can be accurately performed by combining ICD-9 identified injuries, physiologic data, and chart review. Future direction should focus on identifying patient factors that may predict the use of REBOA.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgment

D.N.H. is currently supported by a training grant through the National Heart, Lung, and Blood Institute (K08HL131995). REBOA simulation equipment was provided to the University of Pennsylvania by Prytime Medical Devices, Inc.

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Fig –.
Flow diagram of patients included in the study.

Table 1 –

Characteristics of confirmed REBOA candidates and presenting physiology.

Patient Characteristics	REBOA Candidates(n = 29)
Demographics	
Male	26 (89.7)
Female	3 (10.3)
Age	28 [22–51]
Mechanism	
Penetrating	21 (72.4)
Blunt	8 (27.6)
ISS	22 [17–34]
Initial vitals	
GCS	14 [3–15]
SBP	84 [62–114]
HR	86 [41–113]
RR	18 [14–22]
Temperature (°C)	36.3 [36.1–36.5]
Resuscitative thoracotomy	7 (24.1)

Data are expressed as n (%) or as median [interquartile range]. REBOA = resuscitative endovascular balloon occlusion of the aorta; ISS = Injury Severity Score; GCS = Glasgow Coma Scale; SBP = systolic blood pressure; HR = heart rate; RR = respiratory rate.

Table 2 –

Characteristics of REBOA candidate injuries.

Clinical Data	REBOA candidates (n = 29)
Injury pattern	
Abdominal solid organ	10 (34)
Junctional vascular	4(14)
Extremity vascular	2(7)
Pelvic fractures	2(7)
Mesenteric vascular	4(14)
Abdominal vascular	3(7)
Unknown	4(14)
Zone of occlusion	
One	20 (69.0)
Three	9(31)
Blood products	
4h	13 [5–21]
24 h	16 [5–27]
MTP	17 (59)

Data are expressed as n (%) or as median [interquartile range]. ISS = Injury Severity Score; MTP = massive transfusion protocol.

Table 3 –
REBOA candidates primary source of bleeding, mechanism of injury, operative intervention, and zone of occlusion.

REBOA candidate	Primary etiology of bleeding	Injury pattern	Primary surgical intervention	Zone of occlusion	Mortality
1	Solid organ	Multisystem blunt trauma, MVC	Laparotomy, control of liver hemorrhage	1	No
2	Solid organ	Multisystem blunt trauma, MVC	RT, laparotomy, splenectomy, nephrectomy, colectomy	1	Yes
3	Solid organ	Multisystem blunt trauma, MVC	Laparotomy, control of liver hemorrhage	1	Yes
4	Solid organ	Multisystem blunt trauma, Fall	Laparotomy, splenectomy, IR pelvic angiogram	1	No
5	Pelvic fracture	Multisystem blunt trauma, Fall	Orthopedic pelvic fixation	3	No
6	Pelvic fracture	Multisystem blunt trauma, MPC	Orthopedic pelvic fixation	3	No
7	Unknown	Multisystem blunt trauma, MVC	Blunt trauma code	1	Yes
8	Unknown	Multisystem blunt trauma, MVC	Negative exploration	1	Yes
9	Junctional vascular	GSW groin	SFA graft, SFV repair, fasciotomy	3	No
10	Junctional vascular	GSW groin	Laparotomy, enterectomy, SFA graft, fasciotomy	1	No
11	Junctional vascular	GSW groin	RT	3	Yes
12	Junctional vascular	GSW groin	SFA graft, SFV repair, fasciotomy	3	No
13	Abdominal vascular	GSW abdomen	RT, laparotomy, enterectomy, ligation iliac vein	1	Yes
14	Abdominal vascular	GSW abdomen	Laparotomy, IVC injury, nephrectomy	1	Yes
15	Abdominal vascular	GSW abdomen	Laparotomy, IVC ligation, aortic repair	1	Yes
16	Solid organ	GSW flank	Laparotomy, nephrectomy, splenectomy	1	No
17	Solid organ	GSW abdomen, lower extremity	Laparotomy, splenectomy, colectomy, popliteal graft	1	No
18	Extremity vascular	GSW lower extremity	RT, SFA graft	3	Yes
19	Extremity vascular	GSW lower extremity	RT, SFA graft, CFV repair, fasciotomy	3	No
20	Mesenteric vascular	GSW abdomen	Laparotomy, colectomy	3	No
21	Mesenteric vascular	GSW abdomen	Laparotomy, damage control	1	Yes
22	Mesenteric vascular	GSW abdomen	Laparotomy, colectomy	1	No
23	Mesenteric vascular	GSW abdomen	Laparotomy, ligation of SMV, colectomy, nephrectomy	1	Yes
24	Solid organ	GSW abdomen	Laparotomy, control of liver hemorrhage	1	Yes
25	Solid organ	GSW abdomen	Laparotomy, nephrectomy, iliac vein repair, fasciotomy	1	No
26	Solid organ	GSW abdomen	Laparotomy, left nephrectomy	1	No
27	Solid organ	GSW abdomen	Laparotomy, nephrectomy, enterectomy	1	No
28	Unknown	GSW right buttock	RT	3	Yes

REBOA candidate	Primary etiology of bleeding	Injury pattern	Primary surgical intervention	Zone of occlusion	Mortality
29	Unknown	GSW abdomen, pelvis	RT	I	Yes

RT = resuscitative thoracotomy; SFA = superficial femoral artery; SFV = superficial femoral vein; CFV = common femoral vein; IVC = inferior vena cava; SMV = superior mesenteric vein; MVC = motor vehicle collision; MPC = motor-pedestrian collision; GSW = gunshot wound.