Who Would Have Benefited from the Prehospital Use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)? An Autopsy Study

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BACKGROUND: Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been increasingly used as part of damage control resuscitation for patients with non-compressible truncal hemorrhage. We hypothesized that there might be a select group of patients that could have benefited from prehospital placement of the REBOA.

STUDY DESIGN: This was a retrospective cohort study including patients who presented to a Level I trauma center with cardiac arrest between January 2014 and March 2018. The findings of a full autopsy were reviewed for the details of internal injuries. A patient was determined to be a REBOA candidate if the patient sustained abdominal organ injuries or pelvic fractures and no associated severe head injuries. The candidate group was compared with the non-candidate group based on prehospital vital signs and other patient characteristics. A multiple logistic regression analysis was performed to identify certain prehospital factors associated with candidacy for prehospital REBOA.

RESULTS: A total of 198 patients met our inclusion criteria. Of those, 27 (13.6%) patients were deemed REBOA candidates. Median Injury Severity Score was 22 (interquartile range 17 to 29). Patients in the candidate group were more likely to have a Glasgow Coma Scale score $\geq$9 (48% vs 15%; $p = 0.012$), oxygen saturation >90% (56% vs 35%; $p = 0.03$), and systolic blood pressure <90 mmHg (48% vs 26%; $p = 0.04$) in the field. Logistic regression showed that these 3 clinical parameters of prehospital vital signs were significantly associated with REBOA candidacy.

CONCLUSIONS: Our data suggest that >10% of trauma patients who presented with cardiac arrest could have benefited from prehospital REBOA. Additional prospective studies are warranted to validate the use of field vital signs in selecting candidates. (J Am Coll Surg 2019;229:383−388. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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Hemorrhage remains the major cause of preventable death after trauma.[1] Although prehospital intervention, such as extremity tourniquets and innovative hemostatic agents, are shown to be effective in controlling bleeding from the extremities, there are scarce options available for non-compressible truncal hemorrhage (NCTH), which represents a major subset of hemorrhagic death.[2,3] In patients with NCTH, mortality approaches 50% in the civilian setting and nearly 80% in the military trauma setting; even with considerably short transportation times, only 25% are even considered to be survivable.[4]

During the last decade, resuscitative endovascular balloon occlusion of the aorta (REBOA) has rapidly emerged as a viable option for hemorrhagic control in patients who present with hemodynamic instability due to

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Abbreviations and Acronyms

EMS	= Emergency Medical Services
GCS	= Glasgow Coma Scale
NCTH	= non-compressible truncal hemorrhage
REBOA	= resuscitative endovascular balloon occlusion of the aorta
SBP	= systolic blood pressure

NCTH.[5] Resuscitative endovascular balloon occlusion of the aorta is currently considered as an alternative intervention to resuscitative thoracotomy and is being performed for various indications worldwide, such as in the patient with life-threatening hemorrhage below the diaphragm or arriving in traumatic cardiac arrest.[6,7] However, in the US, the context of its use has been explicitly limited to the inpatient hospital setting, and several case reports of prehospital use have been presented in the deployed military setting,[8] as well as civilian trauma cases in Europe.[9]

Therefore, we intended to explore whether a certain proportion of patients who presented to our trauma center with cardiac arrest might have benefited from prehospital use of REBOA. We also sought to determine whether there were any significant clinical factors associated with candidacy that might be useful in refining the clinical decisional algorithm for performing REBOA.

METHODS

We conducted a retrospective cohort study from January 2014 to March 2018. The study was approved by the IRB at the University of Southern California. We included trauma patients that were transported to the Los Angeles County, University of Southern California Medical Center, a Level I trauma center, with no signs of life on arrival to the emergency department. Patients without any signs of life in the field, confirmed by the Emergency Medical Service (EMS) personnel, or expired patients who did not undergo a full internal autopsy were excluded from the analysis. Prehospital data were obtained from the Los Angeles County Department of Health Services and included patient demographic characteristics, mechanism of injury, and prehospital vital signs. Our trauma registry was queried for inpatient data, including vital signs on admission, diagnostic images and procedures performed, and patient outcomes. Finally, findings in a full internal autopsy were reviewed to determine the candidacy for the use of prehospital REBOA. Subsequently, our study patients were divided into 2 groups: candidates and non-candidates. We defined a REBOA candidate as the following: abdominal organ injuries and/or pelvic fractures as a source of NCTH and no associated severe head injuries (Abbreviated Injury Scale score $\geq$3).[10]

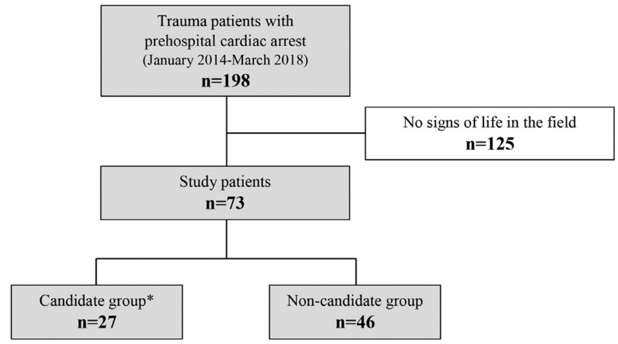

Figure 1. Patient inclusion and exclusion criteria flow diagram. *Patients with abdominal organ injuries and/or pelvic fractures and no associated severe head injuries (Abbreviated Injury Scale score $\geq$3).

Descriptive statistics, including patient characteristics such as age, sex, Injury Severity Score, mechanism of injury, and patient outcomes, were reported as medians and interquartile ranges for continuous variables and as proportions and frequencies for categorical variables. Between the candidate and non-candidate group, prehospital and inpatient data were compared using univariate analysis. Chi-square or Fisher's exact test was used for categorical variables and Student's t-test or Mann-Whitney test was used for continuous variables, as appropriate. Finally, a multivariate logistic regression analysis was performed to identify prehospital clinical factors significantly associated with the candidacy for REBOA as determined by the aforementioned criteria. The variables that were selected were those noted to be significantly different in univariate analysis. We considered $p < 0.05$ to be significant. Analysis was performed using SAS Studio Software for Windows, version 3.6 (SAS Institute) and R, version 3.5.1.

RESULTS

During our study period, a total of 198 patients sustained prehospital cardiac arrest after trauma (Fig. 1). Of those, 73 patients had any signs of life in the field, documented by prehospital EMS. Based on autopsy findings, 27 (13.6%) patients were considered to be candidates for prehospital REBOA. This group was mostly males (88.9%), and the median age was 33 years. The injury pattern was mostly blunt (63.0%) and mean transportation time was 20 minutes. A large majority of these patients sustained high-grade (grade $\geq$3) abdominal solid organ injuries and/or pelvic fractures, with 85% having significant abdominal injury and 65% having significant

Table 1. Patient Characteristics and Injury Severity in Study Groups

Variable	Total (n = 73)	Candidate group (n = 27)	Non-candidate group (n = 46)	p Value
Demographic characteristic				
Sex, male, n (%)	64 (87.7)	24 (88.9)	40 (87.0)	0.39
Age, y, median (IQR)	38 (30−58)	33 (28−52)	42 (24−65)	0.018
Race/ethnicity, n (%)				
Asian	3 (4.1)	1 (3.7)	2 (4.3)	0.31
African American	24 (32.9)	9 (33.3)	15 (32.6)	0.19
White	9 (12.3)	2 (7.4)	7 (15.2)	0.33
Latino	39 (53.4)	15 (55.6)	24 (52.2)	0.09
Mechanism of injury, n (%)				0.15
Blunt	46 (63.0)	17 (63.0)	29 (63.0)	0.29
Penetrating	28 (38.4)	10 (37.0)	18 (39.1)	0.08
Prehospital vital				
Systolic blood pressure <90 mmHg, n (%)	25 (34.2)	13 (48.1)	12 (26.1)	0.04
Glasgow Coma Scale score ≥9, n (%)	20 (27.4)	13 (48.1)	7 (15.2)	0.012
Oxygen saturation >90%, n (%)	31 (42.5)	15 (55.6)	16 (34.8)	0.03
Respiratory rate, median (IQR)	7 (2−15)	6 (2−12)	8 (2−16)	0.27
Heart rate >120 beats/min, n (%)	70 (95.9)	26 (96.3)	44 (95.7)	0.38
Transport time, min, median (IQR)	21 (16−29)	20 (17−29)	21 (16−31)	0.23
Injury severity				
Injury Severity score, median (IQR)	27 (23−34)	22 (17−29)	29 (25−38)	0.07
Head AIS ≥3, n (%)	37 (50.7)	0 (0)	37 (80.4)	<0.001
Neck AIS ≥3, n (%)	27 (37.0)	0 (0)	27 (58.7)	<0.001
Chest AIS ≥3, n (%)	32 (43.8)	1 (3.7)	31 (67.4)	<0.001
Abdomen AIS ≥3, n (%)	37 (50.7)	23 (85.2)	14 (30.4)	0.06
Pelvis AIS ≥3, n (%)	28 (38.4)	17 (65.4)	11 (23.9)	0.08
Field intubation performed, n (%)	42 (57.5)	16 (59.3)	26 (56.5)	0.052
Resuscitative thoracotomy performed, n (%)	55 (75.3)	19 (70.4)	36 (78.3)	0.06
REBOA placed, n (%)	4 (5.5)	2 (7.4)	2 (4.3)	0.057
Disposition after emergency department, n (%)				
Operating room	20 (27.4)	12 (44.4)	8 (17.4)	<0.001
Laparotomy	18 (24.7)	10 (37.0)	8 (17.4)	<0.001
Thoracotomy	4 (5.5)	1 (3.7)	3 (6.5)	0.02
Craniotomy	2 (2.7)	0 (0)	2 (4.3)	0.04
Other	4 (5.5)	3 (11.1)	1 (2.0)	0.03
Angioembolization	1 (1.4)	1 (3.7)	0 (0)	0.16
ICU	1 (1.4)	1 (3.7)	0 (0)	0.16
Morgue	52 (71.2)	13 (48.1)	39 (84.5)	<0.001
Mortality (overall)	68 (93.2)	25 (92.3)	43 (93.5)	0.09

AIS, Abbreviated Injury Scale; IQR, interquartile range; REBOA, resuscitative endovascular balloon occlusion of the aorta.

pelvic trauma (eTable 1). Additionally, 2 other patients had injuries to the mesentery of the small bowel, causing intra-abdominal hemorrhage; 3 had injuries to the femoral artery; 4 had injuries to the abdominal aorta; and 5 had IVC injuries. There were no significant differences in patient characteristics and severity of injury between the candidate and non-candidate groups (Table 1). The mortality rate was similarly high for both candidate and non-candidate groups (92.3% vs 93.5%; p = 0.09). The transport time to the emergency department was similar, with a median of approximately 20 minutes for both groups. Of the 27 candidate patients who presented without signs of life, 19 had a resuscitative thoracotomy performed, 2 had a REBOA catheter placed, and 11 had return of spontaneous circulation, and 11 of this group underwent various hemorrhage-control procedures, including exploratory laparotomy and angioembolization.

Table 2. Multivariate Logistic Regression for Resuscitative Endovascular Balloon Occlusion of the Aorta Candidacy

Variable	Odds ratio	95% CI	p Value
Systolic blood pressure <90 mmHg	4.31	1.77–12.28	0.003
Glasgow Coma Scale score ≥9	7.28	2.36–22.43	0.001
Oxygen saturation >90%	3.20	1.33–11.45	0.011

Prehospital variables were then compared between the 2 groups. Patients in the non-candidate group were more likely to have a decreased Glasgow Coma Scale (GCS) score. Only 15% of them had a GCS score ≥9 in the field. Similarly, there were significant differences in other elements of prehospital vital signs. Patients in the candidate group were more likely to be hypotensive (systolic blood pressure [SBP] <90 mmHg), and patients in the non-candidate group were more likely hypoxic (oxygen saturation [SpO_2] ≤90%) in the field. A multivariate logistic regression model yielded an odds ratio of 3.20 for those with GCS ≥9 to be prehospital REBOA candidates, an odds ratio of 4.31 for those with an SBP <90 mmHg, and an odds ratio of 7.28 for those with an SpO2 of >90% (Table 2). Of note, having ≥2 of these 3 criteria (GCS ≥9, SBP <90 mmHg, SpO_2 ≥90%) had a positive predictive value of 100% for being considered a REBOA candidate.

DISCUSSION

In this study at a high-volume Level I trauma center, we have performed an extensive review of autopsy results in patients who developed prehospital cardiac arrest and found that >10% of study patients sustained NCTH in the abdomen and/or pelvis without associated severe head or thoracic injuries. In other words, these patients could have potentially benefited from the use of REBOA in the prehospital setting. Although this is not the first study to focus on reporting the incidence of injuries for which REBOA could have been indicated, our study examined more detailed autopsy results in conjunction with prehospital clinical variables.[10] Our results might support the current practice of using prehospital REBOA in the military trauma setting, as well as civilian trauma setting.

The context of REBOA use in the US has been in the inpatient hospital setting explicitly. A recent Joint Statement by the American College of Surgeons Committee on Trauma and American College of Emergency Physicians vaguely defines the indications for use of REBOA, given the adventitious nature of the device; data are still being collected to better delineate ideal scenarios for its use. The statement gives indications as clinical findings of refractory shock or witnessed cardiac arrest due to suspected NCTH or severe junctional or proximal lower extremity hemorrhage. It also recommends against transportation of patients with a REBOA in place, given the difficulty in management of the device, particularly in the context of failure or prolonged transport time.[11] Ongoing discussions by US Military Joint Trauma System Committee on Tactical Combat Causality Care have allowed for REBOA placement in select cases in the austere deployed setting, as described in the most recently published Joint Trauma System Clinical Practice Guidelines.[12] Placement at the point of injury has been suggested, especially in scenarios where the likelihood that survival to the next level of care is untenable without such an intervention. This military committee recommends placing the REBOA catheter in patients with "an injury pattern that suggests abdominopelvic NCTH, an SBP <90 mmHg, and an unsatisfactory response to the first whole unit of blood."[13] In the deployed or austere setting, transfer of patients with a REBOA in place might be feasible as long as a capable trauma or vascular surgeon is available for troubleshooting and imminent definitive surgery.[11]

Although the prehospital REBOA has been suggested for rural civilian settings, particularly in Europe,[14,15] to date it has been used primarily by the US military through highly specialized medical teams that employ REBOA-trained physicians, such as the Air Force Special Operations Surgical Team. Manley and colleagues[16] and Northern and colleagues[8] described successful lifesaving placement of the REBOA by Special Operations Surgical Team in 4 and 20 service members, respectively, who were all 2 to 3 hours from the nearest Role 2 facility. In this series and similar studies, placement decision was made by a physician provider who determined its need using various methods, including physical examination with clinical findings such as abdominal distention and mechanism of trauma, and even focused assessment with sonography for trauma examinations in the setting of hemodynamic instability.[17] However, the skills of the providers in the prehospital setting vary, with paramedic-trained providers participating in the vast majority of austere civilian and military trauma; Special Operations Surgical Team-level skill is not always available in the setting in which REBOA might be required to sustain a patient until definitive surgical management.

The prehospital provider often faces the difficult task of determining whether time should be taken to perform advanced interventions, such as endotracheal intubation, cricothyroidotomy, or needle thoracostomy, rather than transport the patient as expediently as possible to the nearest trauma facility. This question is complicated and requires a complex answer; the situation, time of transportation, and level of skill of the provider must all be considered when protocolizing the use of advanced measures. It is important to note that although clinical judgement and experience can never be fully replaced, providing easy clinical metrics to support decision making can augment clinician confidence in performing these invasive procedures, particularly in the setting where delayed transportation without immediate intervention will result in mortality.

Given the lack of diagnostic adjuncts, such as ultrasound, in the civilian prehospital setting, the EMS provider must rely on clinical examination to determine whether the REBOA would be indicated before arrival at a trauma center. de Schoutheete and colleagues[18] proposed the "MIST" (mechanism with high-energy trauma, injury either diagnosed with focused assessment with sonography for trauma or lack of control lower limb hemorrhage with direct compression or tourniquet, signs of SBP <90 mmHg followed by treatment with partial aortic occlusion) algorithm. It is important to note that focused assessment with sonography for trauma is operator- and situation-dependent, and the provider will not be able to determine conclusively whether the patient has a thoracic aortic injury or precluding head or neck injury. Additionally, many prehospital providers will not have access to ultrasonography, and patients with possible prolonged transportation times can face the serious risk associated with continued ischemia, such as irreversible damage to abdominal viscus, spinal cord ischemia, and limb ischemia.[19] It is also important to note that time spent obtaining arterial access by the inexperienced provider can result in significant diminishing returns.[20]

Therefore, we sought to determine what, if any, unifying characteristics the prehospital provider normally determine in the field would be significantly associated with candidacy for the use of REBOA. Our results suggest that the 3 variables in prehospital vital signs (SBP <90 mmHg, GCS ≥ 9, and $SpO_2 > 90\%$) can be used to capture those patients who have an injury pattern that might be amenable to advanced prehospital hemorrhagic control measures, such as REBOA. The importance of these measures is that they are easily obtained by the prehospital providers, and our results show that only 2 of the 3 are required, with the positive predictive value approaching 100% (eTable 1). This is important in the event that 1 of the 3 measures cannot be obtained reliably, which is often true during the rapid transportation associated with the prehospital setting.

There are several limitations to this study. First, we need to emphasize that we only included a select group of patients for the analysis. The study was designed such that only cardiac arrest patients with injury patterns suggestive of hemorrhagic shock were selected and others were excluded, such as severe head injury. Of note, indications and contraindications for REBOA placement continues to be controversial, and in actual clinical practice, REBOA might be considered in patients with suspected severe traumatic brain injury in the context of exsanguinated NCTH.[21] Second, our study is not designed to make a strong recommendation for the use of REBOA in patients who meet the prehospital vital sign criteria (SBP, GCS, and SpO_2). Although it is well described that delay in hemorrhagic control is significantly associated with poor patient outcomes, a future prospective study is warranted to compare patient outcomes between those with and without prehospital REBOA. Certainly, these patients should still be transported expediently to the nearest trauma center with or without temporary hemorrhagic control. Additionally, the cutoffs chosen for logistic regression, although common, are arbitrary and will need to be validated in future study. Third, it is important to note that the transportation times in our study were relatively short, at approximately 20 minutes, and the clinical criteria for prehospital REBOA that we proposed in this study cannot be generalized to areas where transportation times can exceed 30 to 45 minutes, such as the austere deployed setting or rural communities. Various emerging REBOA techniques, including partial or intermittent inflation/deflation of the balloon, might be required in these scenarios.[22-24] It is also important to note that we could not reliably capture data about EMS dispatch time in the current study. Therefore, no accurate conclusions can be made about time from injury to arrival at the trauma center. Finally, as we only included the patients who underwent a full internal autopsy, there might be a significant selection bias in our study. It is unknown how many patients who only underwent an external autopsy sustained internal injuries that were amenable to the use of REBOA.

CONCLUSIONS

Our study proposes the potential role of REBOA in the prehospital setting. The use of simple clinical variables obtained by the prehospital provider can identify the injury pattern that would be amenable to REBOA placement, which can be lifesaving.

Author Contributions

Study conception and design: R Henry, Matsushima, RN Henry, Wong, Warriner, Strumwasser, Foran, Inaba, Rasmussen, Demetriades

Acquisition of data: R Henry, Matsushima, Wong, Foran

Analysis and interpretation of data: R Henry, Matsushima, RN Henry, Warriner, Strumwasser, Inaba, Rasmussen, Demetriades
Drafting of manuscript: R Henry, RN Henry, Wong
Critical revision: Matsushima, Warriner, Strumwasser, Foran, Inaba, Rasmussen, Demetriades

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eTable 1. List of 27 Candidates for Resuscitative Endovascular Balloon Occlusion of the Aorta

Patient no.	Field SBP, mmHg	Field GCS score	Field SpO_2, %	Injury mechanism	Description of major injury	Disposition after ED
1	167	12*	92*	Motor vehicle accident	Grade IV spleen, grade III liver, pelvic fracture	Morgue
2	128	14*	96*	Motorcycle accident	Grade II liver, grade II kidney, pelvic fracture	Operating room
3	52*	3	78	Motor vehicle accident	Pelvic fracture, abdominal aortic injury, IVC injury	Morgue
4	50*	3	93*	Gunshot wound	Grade IV liver, grade IV kidney, mesenteric laceration	Morgue
5	126	9*	95*	Motor vehicle accident	Grade IV spleen, pelvic fracture	IR suite
6	62*	6	98*	Motor vehicle accident	Grade IV liver, grade II spleen, pelvic fracture	Morgue
7	76*	12*	94*	Gunshot wound	Grade III liver, femoral artery injury	Operating room
8	64*	9*	82	Motor vehicle accident	Grade III liver, pelvic fracture	Morgue
9	94	14*	94*	Stab wound	Grade III spleen	Operating room
10	82*	15*	95*	Motor vehicle accident	Grade IV liver	Morgue
11	112	13*	100*	Blunt assault	Grade II liver, grade III kidney, pelvic fracture	Operating room
12	74*	5*	99*	Gunshot wound	Grade IV kidney, abdominal aortic injury, IVC injury	Morgue
13	140	13*	97*	Motor vehicle accident	Pelvic fracture, femoral artery injury	Operating room
14	68*	12*	73	Gunshot wound	Grade IV spleen, pelvic fracture	Operating room
15	52*	10*	88	Gunshot wound	Grade II liver, grade III kidney, mesenteric laceration	Morgue
16	196	15*	99*	Motor vehicle accident	Grade I liver, grade III kidney	Operating room
17	96	13*	94*	Motor vehicle accident	Pelvic fracture, iliac artery, and vein injury	Morgue
18	98	12*	94*	Stab wound	Grade II liver, grade III kidney	Operating room
19	78*	11*	94*	Motorcycle accident	Pelvic fracture, iliac vein injury	Morgue
20	94	14*	95*	Blunt assault	Grade IV spleen, IVC injury	Operating room
21	88*	12*	86	Gunshot wound	Grade IV liver, IVC injury	Morgue
22	72*	6	93*	Motorcycle accident	Femoral artery injury, abdominal aortic injury	Morgue
23	68*	9*	90	Gunshot wound	Grade IV liver	Operating room
24	76*	12*	82	Motor vehicle accident	Pelvic fracture	Morgue
25	144	13*	97*	Blunt assault	Grade II kidney, grade II spleen	ICU
26	80*	12*	92*	Stab wound	Grade IV liver	Morgue
27	58*	9*	85	Motor vehicle accident	Pelvic fracture, IVC, and abdominal aortic injury	Morgue

*Abnormal value.
ED, emergency department; GCS, Glasgow Coma Scale; IR, interventional radiology; SBP, systolic blood pressure; SpO_2, oxygen saturation.