

A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock

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Jonathan James Morrison: stock options, Pryor Medical; grant, CardioMed Device Consultants and Quintiles Consulting; patent, STELA Medical. Jonathan L. Eliason: stock options, Pryor Medical; consultant, Theorem Medical. The remaining authors have nothing to disclose.

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BACKGROUND:	Torso hemorrhage remains a leading cause of potentially preventable death within trauma, acute care, vascular, and obstetric practice. A proportion of patients exsanguinate before hemorrhage control. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an adjunct designed to sustain the circulation until definitive hemostasis. A systematic review was conducted to characterize the current clinical use of REBOA and its effect on hemodynamic profile and mortality.
METHODS:	A systematic review (1946–2015) was conducted using EMBASE and MEDLINE. Original studies on human subjects, published in English language journals, were considered. Articles were included if they reported data on hemodynamic profile and mortality.
RESULTS:	A total of 83 studies were identified; 41 met criteria for inclusion. Clinical settings included postpartum hemorrhage (5), upper gastrointestinal bleeding (3), pelvic surgery (8), trauma (15), and ruptured aortic aneurysm (10). Of the 857 patients, overall mortality was 423 (49.4%); shock was evident in 643 (75.0%). Pooled analysis demonstrated an increase in mean systolic pressure by 53 mm Hg (95% confidence interval, 44–61 mm Hg) following REBOA use. Data exhibited moderate heterogeneity with an I^2 of 35.5.
CONCLUSION:	REBOA has been used in a variety of clinical settings to successfully elevate central blood pressure in the setting of shock. Overall, the evidence base is weak with no clear reduction in hemorrhage-related mortality demonstrated. Formal, prospective study is warranted to clarify the role of this adjunct in torso hemorrhage. (<i>J Trauma Acute Care Surg.</i> 2016;80: 324–334. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)
LEVEL OF EVIDENCE:	Systematic review, level IV.
KEY WORDS:	Resuscitative endovascular balloon occlusion of the aorta; REBOA; hemorrhage control; resuscitation; trauma surgery.

The natural history of uncontrolled hemorrhage is of cardiovascular collapse with consequent cerebral and myocardial hypoperfusion, ultimately leading to death.¹ Hemorrhage originating from within the torso is particularly challenging because the bleeding focus generally cannot be controlled without a hemostatic intervention, such as surgery or angioembolization.² Although torso hemorrhage is best described within the trauma literature, the concept extends beyond this to a number of other pathologies frequently encountered in medicine. Hemorrhage arising from the gastrointestinal tract,³ postpartum uterus,⁴ a ruptured abdominal aortic aneurysm (rAAA),⁵ and traumatic disruption of thoracic, abdominal, or pelvic viscera⁶ can all be characterized as forms of torso hemorrhage.

Where hemorrhage is controlled expeditiously, patients often recover with little to no morbidity.⁷ However, in patients where hemorrhage is either unrecognized or torrential, exsanguination and death frequently occur before definitive hemostasis.⁸ As a result, torso hemorrhage is a leading cause of potentially preventable death in trauma, obstetric, vascular, and acute care practice.

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a maneuver where a compliant balloon is advanced into the aorta and then inflated, thereby obstructing flow into the distal circulation. This has the effect of increasing

cardiac afterload and proximal aortic pressure, resulting in an increase in myocardial and cerebral perfusion.^{9–11}

While this technique was originally described in the 1950s,¹² it is only since the maturation of endovascular techniques in the 1990s that balloon occlusion in hemorrhage has seen greater clinical use.^{13,14} However, because of the complexities of endovascular intervention and uncertainties relating to its efficacy, REBOA has not entered mainstream clinical practice.¹⁵

The aim of this systematic review was fourfold: first, to examine the clinical setting and use of REBOA in the prevention of cardiovascular collapse in patients either at risk of or in established hemorrhagic shock; second, to identify common arterial access methods, imaging modalities, and deployment techniques used to facilitate REBOA; third, to report the hemodynamic profile associated with REBOA use in hemorrhagic shock; and finally, to examine the reported mortality and morbidity associated with REBOA as a clinical technique.

PATIENTS AND METHODS

This systematic review uses the methodology established by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Group.¹⁶

Submitted: July 12, 2015, Revised: October 3, 2015, Accepted: October 16, 2015, Published online: October 30, 2015.

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DOI: 10.1097/TA.0000000000000913

Search Strategy and Selection Criteria

The EMBASE and MEDLINE databases were searched for relevant articles published from January 1946 to October 2015 inclusive, using the Ovid medical search engine. The key words used in the search were composed of combinations of “Aortic Balloon Occlusion/Tamponade” AND “Hemorrhage/Hemorrhage Control/Resuscitation/Shock.” The search was limited to original studies on human subjects, published in English language journals (Fig. 1).

Two reviewers (J.J.M. and R.E.G.) independently screened the abstracts for suitability. Publications were excluded where non-hemorrhage-related pathology was reported or ineligible study types (e.g., letters and reviews) were identified. Following abstract screening, the remaining publications were subjected to a full-text eligibility assessment.

The full-text assessment consisted of two reviewers independently assessing the publication to determine suitability

for inclusion. Level I to IV evidence was considered, and particular attention was paid to the reporting of hemodynamic performance, balloon type, balloon deployment technique, complications, and mortality. During the full-text assessment, articles were excluded if little or no clinical data were reported on the subject of balloon occlusion. For example, if a study made reference to the use of balloon occlusion within a broader context but did not report clinical data specific to that adjunct, it was excluded.

Where articles undergoing full-text review identified additional relevant studies that had not been previously identified, the additional relevant studies were also reviewed and included if eligible. If disagreement was encountered at any stage of the publication inclusion/exclusion process, an independent third reviewer (J.O.J.) arbitrated a final decision.

Data Extraction

A data extraction form was developed *a priori* to record key data points from the included studies. Publication-specific data included the year of publication, study type, number of subjects, and the clinical setting. The level of aortic occlusion was reported by aortic zone, as previously defined.⁹ Specifically, Zone I consists of the thoracic aorta. Zone III includes the infrarenal aorta, and Zone II resides between the Zones I and III; Zone II is rarely used clinically as an occlusion site for REBOA. Mortality was reported as a proportion of the study cohort undergoing balloon occlusion.

Complications relating to the insertion and deployment of the aortic balloon catheter were recorded as free text. Systolic blood pressure (SBP, mm Hg) was extracted where reported, specifically pre-REBOA and post-REBOA balloon deployment. Hemorrhagic shock was defined as a mean (or individual) reported SBP of less than 90 mm Hg. A clinical description of hemorrhagic shock was used in lieu of numerical data where clearly stated. Total time of aortic occlusion was also recorded. Finally, balloon type, method of arterial access (percutaneous or cutdown), and the method of deployment (e.g., clinical or image guided) were recorded.

Data Synthesis, Risk of Bias, and Heterogeneity Assessment

The key characteristics of the eligible studies in terms of study type, clinical setting, aortic zone of occlusion, mortality, and morbidity were extracted as described earlier and summarized in a tabular format. The risk of bias was assessed for each study using the Cochrane Collaboration's tool for assessing risk of bias. This tool assesses six domains (selection, performance, detection, attrition, reporting, and other) and rates the risk of bias in each as “high,” “low,” or “unclear.”

A pooled analysis of SBP was performed to characterize the hemodynamic profile associated with REBOA use. The difference in means between pre-REBOA and post-REBOA pressures was analyzed using a continuous random-effects model. The level of heterogeneity was reported using I^2 rather than the Q value because a low study number was anticipated. Single-patient case reports were not included in this analysis. Results were reported in a forest plot, and the

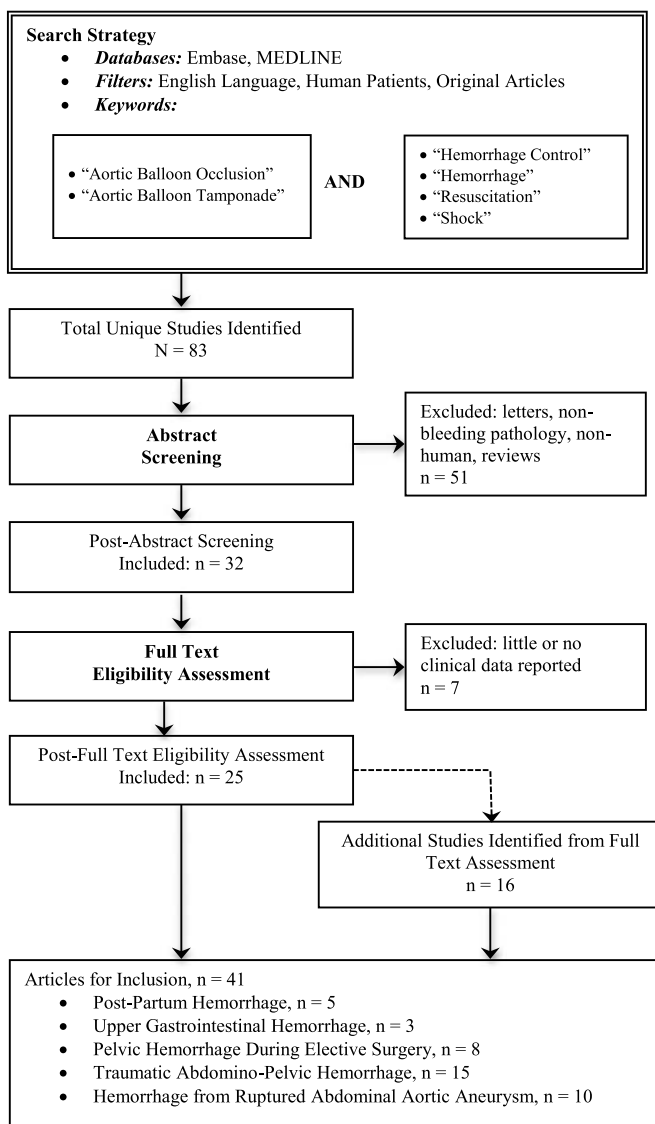


Figure 1. Literature search results.

data analysis was performed using Open MetaAnalyst (Brown University, Providence, RI).

RESULTS

Figure 1 illustrates the literature search and assessment results. A total of 83 unique studies were identified and underwent abstract screening. Thirty-two of these studies were deemed appropriate for and underwent full-text review. Of these, seven studies reported little or no clinical data, leaving 25 studies for inclusion following full-text review. Reference review of these 25 studies identified an additional 16 eligible studies, which were not identified during the key word search. These studies were predominantly older in publication date but were still eligible for inclusion. Therefore, 41 articles were selected, including 18 case reports, 19 case series, and 4 retrospective cohort studies. All of these studies were deemed to be at high risk of bias. In total, 857 patients treated with REBOA were included (Fig. 1, Table 1).^{12–14,17–55}

Clinical Setting

REBOA has been used for the management of hemorrhage in five major clinical settings: (1) postpartum hemorrhage (PPH) (5 studies), (2) upper gastrointestinal (UGI) hemorrhage (3 studies), (3) pelvic hemorrhage during pelvic/sacral tumor surgery (8 studies), (4) traumatic abdominopelvic hemorrhage (15 studies), and (5) hemorrhage arising from rAAA (10 studies) (Table 1).

In all studies, REBOA was used as a hemorrhage control and resuscitation adjunct, to prevent cardiovascular collapse.^{12–14,17–55} In 31 (75.6%) of 41 studies, REBOA was deployed in patients already in established hemorrhagic shock and at significant risk of circulatory arrest. In these studies, REBOA was performed as an emergent procedure to achieve vascular control proximal to the bleeding focus and to provide circulatory support to bridge patients to definitive hemorrhage control, either using operative or angioembolic techniques.

The remaining 10 studies reported results from the prophylactic balloon placement in hemodynamically stable patients at risk of significant hemorrhage.^{30,31,35,36,42,44,46–48} The majority of these patients were undergoing the resection of pelvic and sacral tumors,^{30,31,35,42,46–48} which are frequently large, highly vascular lesions and their location generally necessitates lateral or prone patient positioning for surgical access. Consequently, in the event of major bleeding, pelvic inflow is often inaccessible. In these studies, the preoperative placement of a REBOA catheter enabled remote vascular control to be achieved as required. Similarly, in high-risk obstetric cases, prophylactic balloon placement has been effectively used before definitive surgical control of PPH.^{36,44}

Arterial Access, Imaging, and Deployment Techniques

Of the 41 studies, 39 (95.1%) reported data pertaining to arterial access and REBOA balloon deployment (Table 2). The femoral artery was the most commonly reported access site (32 studies or 92.3% of the patients) for REBOA, followed by the brachial artery (five studies or 7.7% of the patients). There were two solitary reports of the use of the axillary and

carotid arteries. The antegrade brachial route was predominantly used in the setting of rAAA to allow retrograde femoral approach for endovascular repair.

Of the 10 studies where prophylactic arterial access was obtained in anticipation of major hemorrhage, percutaneous access (vs. surgical cutdown) was more commonly used and reported in 9 (90%) of the 10 publications, involving 149 patients (76.8%). This is in contrast to the remaining 29 studies, where patients were in hemorrhagic shock and percutaneous access was used in 20 studies (69%), involving 122 patients (56.4%). In the remaining nine publications, surgical cutdown was used in six studies, and a mixture of techniques used was reported in three studies.

Only one study reported in detail the problems that were encountered with arterial access, and all these access attempts were undertaken in hypotensive patients.⁴⁰ In this report, surgical cutdown was the most reliable access method with 91.7% (11 of 12 attempts) success rate (one attempt resulted in accidental venous cannulation performed on a patient undergoing simultaneous cardiopulmonary resuscitation). Of the 12 reported percutaneous attempts, only five (41.7%) were successful. Reasons for failure included obesity, incorrect introducer sheath size, and lack of a pulsatile artery. Importantly, ultrasonography was not used to guide any of these attempts.

Fluoroscopy was used to aid and confirm correct REBOA balloon deployment and placement in 20 studies (64.4% of the patients). Six studies (21.4% of the patients) reported a mixture of imaging use, including plain radiography and ultrasonography, while 11 studies (14.2% of the patients) reported balloon placement and deployment success using only clinical measures (Table 2). Clinical methods were varied and ranged from the loss of a pulse oximetry trace in the lower extremity to the loss of a left brachial pulse for guiding both balloon placement and inflation. A technique frequently replicated in rAAAs involved the use of left brachial access to pass a balloon catheter down the aorta, inflating it in the aneurysmal sac with pullback to lodge the balloon in the AAA neck.⁵⁰

Effect on SBP in Hemorrhagic Shock

Of the 28 studies describing patients in established hemorrhagic shock, there were six cohort studies reporting pre-REBOA and post-REBOA SBP values.^{13,14,19,22,34,45} Figure 2 presents the heterogeneity analysis of these data using a continuous random-effects model. Overall, REBOA deployment in hemorrhagic shock was found to increase SBP by a mean value of 53 mm Hg (95% confidence interval, 44–61 mm Hg). The data exhibited moderate heterogeneity with an I^2 of 35.5.

Overall REBOA Balloon Occlusion Time

Ten studies reported overall REBOA balloon occlusion times. Of the five studies examining Zone I occlusion times, 27 patients had a median occlusion time of 63 minutes (interquartile range, 33–88 minutes).^{13,19,22,51,53} The remaining six studies examined 23 patients undergoing Zone III occlusion, with a median occlusion time of 45 minutes (interquartile range, 30–105 minutes),^{13,14,29,33,45,52} inclusive of 2 patients with unusually long occlusion times of 6 hours

TABLE 1. Summary of the Reports Pertaining to Balloon Occlusion

References	Year	Study Type	n	Aortic Zone	Shock	Risk of Bias	Mortality	Aortic Occlusion–Related Morbidity
PPH								
44	1995	Case report	1	III	N	Not applicable	Nil	Nil
49	2003	Case report	1	III	Y	Not applicable	Nil	Nil
52	2004	Case report	1	III	Y	Not applicable	Nil	Nil
36	2009	Case report	1	III	N	Not applicable	Nil	Nil
45	2012	Case series	6	III	Y	High	Nil	Aortic injury × 1
UGI hemorrhage								
53	2001	Case report	1	I	Y	Not applicable	Nil	Nil
41	2010	Case report	1	I	Y	Not applicable	Nil	Nil
37	2014	Case report	1	I	Y	Not applicable	Nil	Nil
Pelvic hemorrhage during elective pelvic and sacral tumor surgery								
35	2007	Case series	5	III	N	High	Nil	Nil
48	2008	Case series	12	III	N	High	Nil	Nil
46	2009	Case report	1	III	N	Not applicable	Nil	Nil
47	2010	Case series	9	III	N	High	Nil	Nil
42	2010	Cohort study	120	III	N	High	Nil	Fem A embolism × 3; puncture site hematoma × 5
31	2010	Case report	1	III	N	Not applicable	Nil	Nil
30	2013	Cohort study	45	III	N	High	Nil	Fem A thrombosis × 3
23	2014	Case report	1	III	N	Not applicable	Nil	Nil
Traumatic abdominopelvic hemorrhage								
12	1954	Case series	2	I	Y	High	2/2 (100%)	Nil
40	1986	Case series	15	I	Y	High	13/15 (86.7%)	Failed percutaneous access × 5; failed cutdown × 1
29	1986	Case report	1	III	Y	Not applicable	Nil	Nil
34	1989	Case series	21	I	Y	High	14/21 (66.7%)	Fem A thrombosis × 1
51	2001	Case report	1	I	Y	Not applicable	Nil	Nil
14	2010	Case series	13	III	Y	High	7/13 (53.8%)	Balloon rupture × 1; Fem A thrombosis × 1
13	2013	Case series	6	I × 4; III × 2	Y	High	2/6 (33.3%)	Nil
28	2013	Case series	5	III	Y	High	Unknown	Nil
33	2014	Case report	1	III	Y	Not applicable	Nil	Nil
20	2014	Case report	1	III	N	Not applicable	Nil	Nil
22	2015	Case series	7	I	Y	High	1/7 (14.3%)	Nil
19	2015	Case series	14	I	Y	High	9/14 (64.3%)	Nil
17	2015	Cohort study	452	—	Y	High	343/452 (75.9%)	Unknown
18	2015	Case series	24	I	Y	High	10/24 (41.7%)	Renal failure × 3, access complication and amputation × 3
55	2015	Cohort study	24	I × 19; III × 5	Y	High	15/24 (62.5%)	Nil
Hemorrhage from rAAAs								
39	1964	Case series	1	III	Y	Not applicable	Nil	Nil
25	1972	Case report	1	III	Y	Not applicable	Nil	Nil
24	1977	Case series	5	III	Y	High	3/5 (60.0%)	Nil
54	2000	Case series	9	I	Y	High	Unknown	Nil
50	2003	Case series	11	III	Y	High	3/11 (27.3%)	Balloon rupture × 3; embolic complications × 2
21	2005	Case report	1	I	Y	Not applicable	Nil	Nil
43	2006	Case series	3	I	N	High	Nil	Nil
38	2009	Case series	19	I	Y	High	Unknown	Embolic complication × 1
26	2009	Case series	12	I	Y	High	1/12 (8.3%)	Nil
32	2014	Case report	1	I	Y	Not applicable	Nil	Nil

N, no; Y, yes.

TABLE 2. REBOA Insertion Technique and Deployment Method

					Access Technique, n		Deployment Method, n		
Reference	n	Arterial Insertion	Shock	Balloon Type	Perc	Cutdown	Clinical	Fluoro	Other
PPH									
44	1	Femoral	N	8.5 Fr Aortic (Cook)	1	0	0	1	0
49	1	Femoral	Y	10 Fr Aortic (BVM Medical)	0	1	1	0	0
52	1	Femoral	Y	IABP (Datascope Corp.)	1	0	0	1	0
36	1	Femoral	N	30-mm Aortic (Forte Co. Ltd/)	1	0	0	1	0
45	6	Femoral	Y	30-mm Aortic (NuMED)	6	0	6	0	0
UGI hemorrhage									
53	1	Femoral	Y	IABP (unknown)	0	1	1	0	0
41	1	Femoral	Y	14-mm Angioplasty (Bard, Inc.)	1	0	1	0	0
37	1	Femoral	Y	8 Fr Fogarty (Edwards)	1	0	1	0	0
Pelvic hemorrhage during elective pelvic and sacral tumor surgery									
35	5	Femoral	N	Sizing (NuMED)	5	0	5	0	0
48	12	Femoral	N	Sizing (AGA Medical)	12	0	0	0	0
46	1	Femoral	N	—	1	0	1	0	0
47	9	Femoral	N	—	9	0	9	0	9
42	120	Femoral	N	Maxi LD (Cordis)	120	0	0	120	0
31	1	Femoral	N	—	—	—	0	1	0
30	45	Femoral	N	—	0	45	0	45	0
23	1	Femoral	N	—	1	0	0	1	0
Traumatic pelvic and abdominal hemorrhage									
12	2	Femoral	Y	10 Fr Dotter-Lukas	0	2	2	0	0
40	15	Femoral	Y	Percluder (Intervascular)	5	11	—	—	—
29	1	Brachial	Y	No 8/22 Fogarty (Edwards)	0	1	1	0	0
34	21	Femoral	Y	Percluder (Intervascular)	8	13	1	0	0
51	1	Carotid	Y	5 Fr Moiyen (Goodtec)	1	0	0	1	0
14	13	Femoral	Y	20-mm Berstein (Boston)	13	0	13	0	13
13	6	Femoral	Y	Coda (Cook Medical)	3	3	3	0	3
28	5	Femoral	Y	Fogarty	0	5	0	5	0
33	1	Femoral	Y	IABP (Senko Medical)	1	0	0	1	0
20	1	Femoral	Y	Coda (Cook Medical)	1	0	0	1	0
22	7	Femoral	Y	—	7	0	0	0	7
19	14	Femoral	Y	Block Balloon (Senko Medical)	14	0	14	0	0
18	24	Femoral	Y	IAOB (Senko Medical)	23	1	0	24	0
Control of hemorrhage from rAAAs									
39	1	Brachial	Y	—	0	3	0	3	0
25	1	Axillary	Y	No 8/22 Fogarty (Edwards)	0	1	1	0	1
24	5	Brachial	Y	No 8/22 Fogarty (Edwards)	0	5	0	5	0
54	9	Brachial	Y	40 mm Aortic (Meditech)	0	9	0	9	0
50	11	Brachial	Y	No 8/22 Fogarty (Edwards)	0	11	11	0	11
21	1	Femoral	Y	—	1	0	0	1	0
43	3	Femoral	N	—	3	0	0	3	0
38	19	Femoral	Y	46-mm Reliant (Medtronic)	19	0	0	19	0
26	12	Femoral	Y	46-mm Reliant (Medtronic)	12	0	0	12	0
32	1	Femoral	Y	34-mm Amplatzer (St Jude)	1	0	0	1	0

N, no; Y, yes.

and 10 hours.^{33,52} No study reported the need for significant balloon manipulation.

Mortality

There were no episodes of mortality reported among studies on PPH, UGI bleeding, or with the use of balloon occlusion during pelvic and sacral surgery.^{30,31,35–37,41,42,44–49,52,53}

The majority of these studies reported on the prophylactic use of REBOA. The largest burden of mortality is reported in studies examining REBOA use in traumatic injury and rAAA, which ranges between 8.0% and 86.7%.^{12–14,17–19,22,24,26,34,50,55}

In the study with the highest mortality, Low et al.,⁴⁰ in 1986, reported the survival of 2 (13.3%) of 15 trauma patients who had sustained gunshot wounds to the heart, liver, and

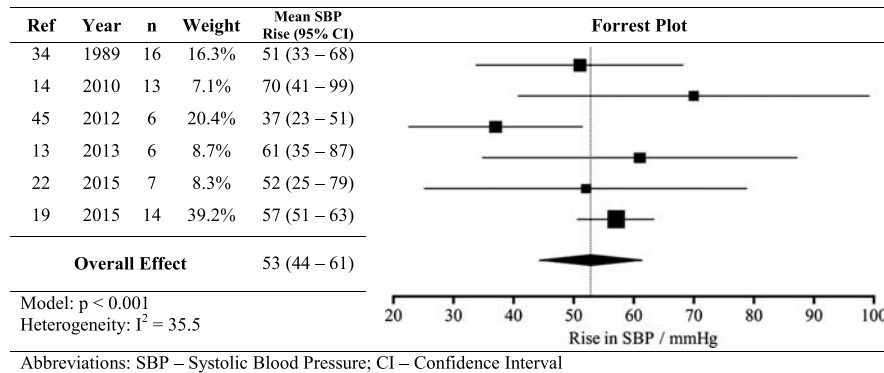


Figure 2. Heterogeneity analysis of the hemodynamic effects of REBOA in hemorrhagic shock using a continuous random-effects model.

aorta. Detail on the injury pattern of the fatalities is scant, but six patients were in cardiac arrest with cardiopulmonary resuscitation ongoing.

Following from this early report, a further series using the same balloon catheter (Percluter) was examined by Gupta et al.³⁴ in 1989 and reported a survival of 7 (33.3%) of 21 patients. Within the fatalities, five were already in circulatory arrest, and of the nine who presented with a spontaneous circulation, all had sustained a major visceral or vascular injury. Overall, the authors of the publication felt that the REBOA balloon catheter was a useful adjunct in rescuing patients presenting in extremis, supporting them to laparotomy. Subsequently, during the past decade, several case series have emerged from groups in Europe, United States, and Japan.

In 2010, a French group used Zone III REBOA in 13 hypotensive patients with pelvic fractures¹⁴ with a mean Injury Severity Score (ISS) of 48 ± 16 and a pre-REBOA mean SBP of 41 ± 26 mm Hg. Of these 13 patients, 6 (46.2%) survived. All seven fatalities resulted from hemorrhagic shock with four deaths caused by a failure of hemorrhage control and three caused by organ failure later in the intensive care unit. Brenner et al.¹³ built on this experience and published a series of six patients from the United States. They reported an overall survival of four (66.7%) of six patients. The two deaths in this series were related to traumatic brain injuries, rather than a primary hemorrhage-related event.

The largest experience of REBOA as an adjunct in trauma injury management comes from Japan. Three recent case series reporting on a total of 45 patients describe 26 survivors (57.8%). REBOA was used to complement a variety of other clinical interventions including angioembolization,²² resuscitative thoracotomy (RT),¹⁸ and conventional abdominal surgery.¹⁹ A key difference identified between fatalities and survivors, in addition to injury burden, was occlusion time (minutes), which was substantially longer in fatalities (224 ± 52 vs. 46 ± 15 , $p = 0.002$).¹⁹

Recently, Norii et al.¹⁷ reported the Japanese experience with REBOA, using the Japanese Trauma Data Bank, which included a comparison with a matched non-REBOA population. Between 2004 and 2011, 452 bluntly injured patients underwent REBOA as part of their management. The REBOA cohort ($n = 452$) had sustained a high injury burden, as measured by a mean ISS of 36, and consequently had a high overall mortality of 343 patients (76%). When this cohort was adjusted for

injury burden and presenting physiology using Trauma and Injury Severity Score (TRISS) methodology, both survivor and nonsurvivor cohorts achieved their predicted survival rates of 71% and 35%, respectively.

These investigators went further and used a statistical methodology called propensity score matching to generate two groups, one that received REBOA ($n = 351$) and another with similar preintervention characteristics managed without REBOA ($n = 1,456$). Patients treated with REBOA sustained a mortality higher than those without as demonstrated by an odds ratio of survival of 0.30 (95% confidence interval, 0.23–0.40).

The most current report is a cohort study from the United States using patients with infradiaphragmatic exsanguination who underwent either REBOA ($n = 24$) or RT ($n = 72$) as part of their management.⁵⁵ Both groups were well matched in terms of demography, mechanism of injury, or injury burden. The REBOA group had fewer early deaths and improved overall survival as compared with the RT group (37.5% vs. 9.7%, $p = 0.003$).

In patients receiving REBOA for the management of hemorrhage from an rAAA, mortality ranged from 8% to 60% (Table 1).^{24,26,50} The study with the highest mortality was from Ng and Oschner,²⁴ who in 1977, reported the survival of two (40.0%) of five patients treated with transbrachial Fogarty catheter aortic occlusion. Of the three deaths, one occurred intraoperatively and two postoperatively because of a myocardial infarction and cerebral hypoxia. Overall, the balloon was thought to be critical in establishing early hemorrhage control.

Subsequently, Matsuda et al.⁵⁰ reported the survival of 8 (72.7%) of 11 patients in whom REBOA was used to control hemorrhage in the setting of deep hemorrhagic shock (mean pre-REBOA SBP, 60.9 ± 15.4 mm Hg). Of the three nonsurvivors, two deaths followed REBOA balloon rupture, while the third death occurred after multiple embolic events to the brain, liver, and kidney. In the nine patients whose shock was successfully controlled with REBOA, the operative mortality was 11%.

Finally, Philipsen et al.²⁶ most recently reported the highest procedural survival rate (11 of 12, 92%) in patients in whom REBOA was used to control hemorrhage from an rAAA. The only nonsurvivor experienced a complete rupture of the abdominal aorta. Despite achieving hemodynamic stability following REBOA, the patient failed resuscitation because of

an inability to provide blood transfusions secondary to religious reasons.

Device-Related Mortality

There were three deaths directly associated with balloon related complications.⁵⁰ All patients were being treated for rAAA and had transbrachial aortic occlusion performed. Two balloons ruptured, resulting in precipitous cardiovascular collapse and death. There was also one fatal embolic event following aortic instrumentation and proximal embolization into the cerebral circulation. Based on studies reporting device-related mortality, such events were rare, with an incidence of 3 (0.8%) in 381 patients.

Device-Related Morbidity

Several studies reported episodes of device-related morbidity, including an aortic injury,⁴⁵ femoral arterial complications,^{14,18,30,34,42} and balloon-related embolic events.^{50,55}

The aortic injury occurred in the setting of PPH and was promptly recognized because of hypotension after hysterectomy and balloon deflation.⁴⁵ More proximal aortic balloon occlusion was undertaken, while successful operative exploration and repair was performed. It was suspected that balloon overinflation injured the aorta, which was performed in response to continued vaginal bleeding despite initial balloon inflation.

Five studies reported thrombotic and embolic complications relating to the arterial puncture required for REBOA.^{14,18,30,34,42} A total of 11 arterial injuries required surgical intervention to restore lower extremity perfusion. Unfortunately, this was unsuccessful in three cases, which progressed to lower extremity amputation.¹⁸ Two studies reported nonfatal embolic events that resulted in lower extremity ischemic events.^{38,50} There was one episode of nonfatal balloon rupture, which was managed with prompt balloon replacement.⁵⁰ The overall rate of morbidity within the reporting literature is 3.7% (14 complications in a population of 381). The overall procedure-related arterial injury, amputation, and nonfatal embolic event rates are 2.9%, 0.8%, and 0.5%, respectively. While complications tended to occur in the emergency setting, there was no association between a particular REBOA device, technique, or specialty.

An important concern regarding the use of aortic occlusion is the potential for paraplegia secondary to spinal cord ischemia. Although a theoretical mechanism for paralysis following REBOA is plausible, there are no instances of lower extremity paralysis reported within the presented literature.

DISCUSSION

The current review is the first systematic analysis of the literature on the subject of REBOA. A total of 41 studies, reporting on 857 patients have been identified spanning 70 years of published literature. REBOA seems to effectively elevate central blood pressure in the setting of hemorrhagic shock; however, evidence suggestive of a reduction in mortality is lacking.

The major limitation of the current review is the quantity and quality of the available evidence, which is limited. The majority of the evidence identified consists of case reports and case series (Grade IV evidence) with only four cohort studies

identified (Grade III evidence). The SBP analysis demonstrates moderate heterogeneity, and all studies are at significant risk of bias, underestimating the true mortality and morbidity. These findings should prompt efforts to improve on this by stimulating formal prospective evaluation.

The reappraisal of REBOA has largely been motivated by the significant burden of combat injury stemming from the wars in Iraq and Afghanistan.⁵⁶ These conflicts have reaffirmed the substantial and potentially preventable mortality sustained from torso hemorrhage.^{57,58} Military trauma care and the associated commitment to combat casualty care research have been a powerful driver in the reevaluation of REBOA as a hemorrhage control adjunct.

REBOA has been used in the management of five common causes of torso hemorrhage: PPH, UGI bleeding, tumor surgery, traumatic hemorrhage, and rAAA, all of which are substantial contributors to global mortality.²⁻⁵ Within the spectrum of management options, REBOA has been used to prevent cardiovascular collapse and circulatory arrest by two main mechanisms: (1) either prophylactically when major hemorrhage is anticipated, where the major utility of REBOA is to provide inflow control to the focus of bleeding and (2) in the setting of established hemorrhagic shock, where REBOA can be used to sustain the central circulation in addition to providing proximal vascular control.

The current literature demonstrates that the vessel most commonly used to access the aorta is the femoral artery. This is in keeping with mainstream practice because the femoral artery is of a good caliber and consistently located in a readily accessible region. Access methods vary between percutaneous and open surgical cutdown, with the latter having the most favorable success rates in hypotensive patients. However, it is important to note that the majority of studies did not report the use of ultrasound-guided punctures, an adjunct that can be used to improve arterial cannulation success rates.^{59,60} Furthermore, femoral artery puncture complications seem to be minimal with only a small number of thrombotic and embolic events reported.

REBOA deployment can be guided by a number of imaging modalities. Fluoroscopy was reported as the most common method, used in more than half of patients. This required either the use of a dedicated interventional radiology suite or a mobile fluoroscopy unit in the emergency department or operating room.⁶¹ Importantly, 16 studies reported a clinical “fluoroscopy-free” method of deployment, with only one serious placement-related complication (an aortic injury).⁴⁵ This is an important finding because the need for fluoroscopy is a major limitation to the use of REBOA in settings with limited medical infrastructure.

The resuscitative component of REBOA is well demonstrated by the current literature, albeit in a relatively small patient population. The current review clearly demonstrates a significant elevation of SBP before and after REBOA deployment. This phenomenon is also well described in animal studies using REBOA,^{62,63} as well as the experience gained at open surgery with the use of extrinsic aortic compression.⁶⁴

The most important question to answer is whether REBOA imparts a survival benefit. Within the trauma literature, which is where most mortality occurs, both nonsurvivors and survivors tended to have a high burden of injury, presenting

with gross physiologic derangements.^{13,14,34,40} The majority of studies lack a control group, with the exception of the studies by Norii et al.¹⁷ and Moore et al.⁵⁵

The Japanese propensity score-matched investigation demonstrated that REBOA treatment was associated with an increase in mortality. This is an important finding, which must be examined critically. The data used in the study were derived from a trauma registry, which recorded little data surrounding the use of REBOA, such as the aortic zone of balloon inflation or timing of occlusion. Propensity score matching is a very powerful technique in the generation of comparable groups, although fundamentally, it cannot account for latent or unmeasured confounding variables.

It is also unclear whether REBOA was used in the context of a formal damage-control protocol, with consistent application or whether it was used as a “last-ditch” attempt at retrieving unsalvageable casualties. However, it is an important study because of the size of population examined and the clear negative outcome associated with REBOA use. It presents a note of caution with the use of this adjunct in trauma care, echoing other opinions.¹⁵

The study by Moore et al.⁵⁵ provides a different perspective, albeit with smaller numbers. Those investigators present a cohort of patients treated using a formal protocol accompanied with rapid access to definitive hemostasis. The latter is likely to be the critical determinant for success in the use of REBOA. These conflicting works highlight the need for formal prospective evaluation, ideally within a trial setting.

Prospective data collection is underway in the form of a American Association for the Surgery of Trauma-sponsored observation study (AORTA)⁶⁵ and a European registry (ABOTrauma Registry)⁶⁶ which should permit the consistent recording of REBOA-specific data such as indications, hemodynamic performance, outcome, cause of death, and morbidity. Several major questions require data to be answered, such as outcome stratified by the degree of hemorrhagic shock, time of deployment, and the influence of REBOA on organ failure and blood product use.

As a complex clinical intervention, the introduction of REBOA into clinical practice should follow the IDEAL recommendations—Idea, Development, Exploration, Assessment and Long-term study.⁶⁷ REBOA is currently between the “development” and “exploration” phase, and the trauma community must engage with a clinical trial to evaluate this adjunct appropriately, before widespread adoption occurs.

CONCLUSION

REBOA has been used as a torso hemorrhage control and resuscitation adjunct in a variety of clinical settings. It has been used to prevent cardiovascular collapse and circulatory arrest in patients either at risk of or in established hemorrhagic shock. The prophylactic use of REBOA in certain clinical contexts such as prevention of PPH or for limiting hemorrhage during oncologic resection does not seem to be associated with mortality or frequent morbidity. For treatment of hemorrhagic shock, however, although effective in elevating central blood pressures, clear evidence supporting REBOA use for improving mortality rates is lacking. This comprehensive review suggests

that formal prospective evaluation of this adjunct is needed to establish the indications, if any, for REBOA in the management of hemorrhagic shock

AUTHORSHIP

J.J.M., R.E.G., J.O.J., T.E.R., and J.L.E. designed this study. J.J.M. and J.O.J. conducted the literature search. J.J.M., R.E.G., and J.O.J. contributed to data collection and analysis. All authors participated in data interpretation and writing.

DISCLOSURE

J.J.M. and J.L.E. are Clinical Advisory Board Members of Pryor Medical, Inc. R.E.G. consults for CardioMed Device Consultants. The Health Services Research Unit receives funding from the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. J.O.J. is in receipt of an NHS Research Scotland fellowship, which includes salary funding.

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