TECHNOLOGY REVIEW (MINI-HTA)

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA (REBOA)

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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EXECUTIVE SUMMARY

Background

Haemorrhage is the leading cause of preventable death following trauma. Truncal and junctional haemorrhages are often described within the trauma literature as non-survivable injuries contributing for almost 90% of catastrophic haemorrhage fatalities. Management of trauma haemorrhage depends on a multifactorial approach of timely surgical intervention, fluid resuscitation and blood transfusion therapy. Even in well-organised trauma systems, there is an inevitable delay between injury and the ability to stop the bleeding. The majority of preventable deaths occur during this vulnerable period, and before any opportunity for definitive surgical haemostasis. Haemorrhage from non-compressible sites not related to trauma, such as a ruptured abdominal aortic aneurysm (rAAA), the gastrointestinal tract, the post-partum uterus and traumatic disruption of thoracic, abdominal, or pelvic viscera exhibit similar challenges for immediate direct bleeding control. There is, therefore, a pressing need for early interventions that can temporarily control bleeding until definitive haemostasis is achieved. The current standard interventions for damage control measure involve invasive modalities such as emergency room thoracotomy and aortic cross-clamping. Resuscitative endovascular balloon occlusion of aorta (REBOA) is a less invasive method of haemodynamic control in haemorrhagic settings relative to resuscitative thoracotomy (RT) with cross clamping of the aorta. Since REBOA device was approved by Food and Drug Administration (FDA) in 2017, it has been widely used in trauma centres across United State (US), UK, Europe and Japan. To date, the technology has not yet been made available in Ministry of Health hospitals in Malaysia. This technology review was requested by the Head of Department and Senior Consultant of General Surgery from Kuala Krai Hospital, Kelantan, to assess the evidence on the use of REBOA as a haemorrhage control and resuscitation adjunct in management of non-compressible haemorrhages.

Objective/ aim

The objective of this systematic review was to assess the efficacy / effectiveness, safety, economic and organisational implications of REBOA as adjunctive measure in management of non-compressible haemorrhages.

Results and conclusion

A total of 4518 titles were identified through the Ovid interface and PubMed, and 15 were identified from references of retrieved articles. After removal of duplicate articles,

2973 titles were screened. A total of 309 abstracts were found to be potentially relevant and were screened using the inclusion and exclusion criteria. Of these, 45 relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, only 13 full text articles were eligible to be included for qualitative synthesis. The 13 selected full text articles comprised of six systematic reviews (SR), five cohort studies, one pre and post intervention study and one economic evaluation study.

Based on retrievable evidence, REBOA had shown to improve systolic blood pressure (SBP) by an estimation of 50mmHg in major haemorrhage from both traumatic and non-traumatic sources. Survival benefit beyond 28 days was evident among non-compressible torso haemorrhage patients who experience delays in surgical intervention more than one hour and compared to those who underwent RT. REBOA was significantly associated with improved survival to discharge in patients with isolated abdominal injury or pelvis/lower extremity injury. REBOA did not confer any long-term survival advantage when used in traumatic cardiac arrest compared with standard of care. Based on limited evidence, the utilisation of prophylactic REBOA among obstetric patients with morbidly adherent placenta had shown to lower the amount of intraoperative haemorrhage and lower the requirement of blood products transfusion.

There was a good level of retrievable evidence that showed the risk of complications with the use of REBOA was 5%. The most common complications included arterial disruption, dissection, pseudoaneurysms, haematoma, thromboembolic problems, and extremity ischaemia. These complications had resulted in limb loss and/or the need for patch angioplasty, complex arterial reconstructions or bypass. The emergent placement carried higher risk of complications compared to prophylactic placement. Other main risk factors were high body mass index, thrombocytopaenia, emergency procedures, big size of the introducer, and use of anti-platelet drugs. Complications seemed to reduce significantly with 7-Fr catheter

Based on a cost utility analysis from the perspective of NHS UK, the use of REBOA was not cost-effective (ICER £44,617.44 per QALY) exceeding WTP threshold of £30,000.

A formal REBOA curriculum improves knowledge and comfort with critical aspects of this procedure. Simulation-based training of REBOA had shown to be effective in improving the knowledge and competency of REBOA placement. This knowledge persisted at six months, though subjective comfort deteriorated among those without REBOA placement in the interim. REBOA refresher training should be considered at six-month intervals in the absence of clinical REBOA cases.

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials – October 2020, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to October 2020, EBM Reviews - Health Technology Assessment – 4th Quarter 2016, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 31 October 2020.

ABBREVIATION

AAST	The American Association for the Surgery of Trauma
BEST	Basic Endovascular Skills for Trauma
CASP	Critical Appraisal Skills Programme
CI	Confidence Interval
CPR	Cardiopulmonary Resuscitation
ESTARS	Endovascular Skills for Trauma and Resuscitative Surgery
EVTM	Endovascular Resuscitation and Trauma Management
FAA	Femoral Arterial Access
FDA	Food and Drug Administration
ICER	Incremental Cost Effectiveness Ratio
OR	Odds Ratio
rAAA	ruptured Abdominal Aortic Aneurysm
REBOA	Resuscitative Endovascular Balloon Occlusion of Aorta
RE-START	REBOA Education for Shock Trauma Acute ResusciTation
ROBIS	Risk of Bias in Systematic Reviews
RT	Resuscitative Thoracotomy
RTACC	Resuscitative Thoracotomy with Aortic Cross-Clamping
SBP	Systolic Blood Pressure
SR	Systematic Review
QALY	Quality Adjusted-Life Year
WTP	Willingness to Pay

1.0 BACKGROUND

Haemorrhage is the leading cause of preventable death following trauma. Truncal and junctional haemorrhages are often described within the trauma literature as non-survivable injuries contributing for almost 90% of catastrophic haemorrhage fatalities.[1-3] One local study reported that blunt trauma accounted for majority of trauma in Malaysia with intra-abdominal injury as significant anatomic mortality predictor from haemorrhage [OR 3.948 ; 95% Confidence Interval (CI) 2.331, 6.686, p<0.001]. Haemorrhage was attributed to 24.3% of trauma mortality in this study.[4] Management of trauma haemorrhage depends on a multifactorial approach of timely surgical intervention, fluid resuscitation and blood transfusion therapy.[5] Death can occur quickly due to severe blood loss. Even in well-organised trauma systems, there is an inevitable delay between injury and the ability to stop the bleeding. The majority of preventable deaths occur during this vulnerable period, and before any opportunity for definitive surgical haemostasis. Haemorrhage from non-compressible sites not related to trauma, such as a ruptured abdominal aortic aneurysm (rAAA), the gastrointestinal tract, the post-partum uterus and traumatic disruption of thoracic, abdominal, or pelvic viscera exhibit similar challenges for immediate direct bleeding control. There is, therefore, a pressing need for early interventions that can temporarily control bleeding until definitive haemostasis is achieved. The current standard interventions for damage control measure involve invasive modalities such as emergency room thoracotomy and aortic cross-clamping.

Resuscitative endovascular balloon occlusion of aorta (REBOA) is a less invasive method of haemodynamic control in haemorrhagic settings relative to resuscitative thoracotomy (RT) with cross clamping of the aorta. It was first described by Hughes in 1954 when an intra-aortic balloon catheter tamponade was used in two moribund Korean War casualties with uncontrolled intra-abdominal haemorrhage.[6] Recent champions of the endovascular resuscitation and trauma management (EVTM) concept have re-introduced REBOA to modern clinical practice.[7] It has received a great deal of attention in recent years for its applicability and promise in adult trauma settings. The utility of REBOA has expanded, and the technique has been used to elevate central blood pressure, perfusion to the brain and heart, and systemic afterload while halting hemorrhage below the level of inflation in cases of haemorrhagic shock in a variety of clinical settings.[8-10] Five major clinical settings that REBOA has been applied include traumatic abdomino-pelvic haemorrhage, haemorrhage arising from rAAA, pelvic haemorrhage during (or expected during) pelvic or sacral tumour surgery, postpartum haemorrhage and upper gastrointestinal haemorrhage.[11] Contraindications to REBOA include penetrating neck/chest trauma and blunt cardiac/aortic injury where the use of resuscitative thoracotomy is more favorable. Since REBOA device was approved by U.S. Food and Drug Administration (FDA) in 2017, it has

been widely used in trauma centres across United State (US), UK, Europe and Japan.[8, 12] To date, the technology has not yet been made available in Ministry of Health hospitals in Malaysia. This technology review was requested by the Head of Department and Senior Consultant of General Surgery from Kuala Krai Hospital, Kelantan, to assess the evidence on the use of REBOA as a haemorrhage control and resuscitation adjunct in management of non-compressible haemorrhages.

2.0 OBJECTIVE

The objective of this systematic review was to assess the efficacy / effectiveness, safety, economic and organisational implications of REBOA as adjunctive measure in management of non-compressible haemorrhages.

3.0 TECHNICAL FEATURE

Endovascular balloon occlusion of the aorta is a technique of placing a flexible balloon catheter into the femoral artery (in rare occasion, brachial, carotid or axillary arteries)[13], manoeuvring it into the aorta and inflating a balloon to temporarily occlude the aorta, proximal to an injury for patients in traumatic arrest and haemorrhagic shock states (Figure 1). This action will increase cardiac afterload and proximal aortic pressure, preserving myocardial and cerebral perfusion.[14] It will allow effective resuscitation to be achieved before surgical intervention and definitive haemostasis is possible.

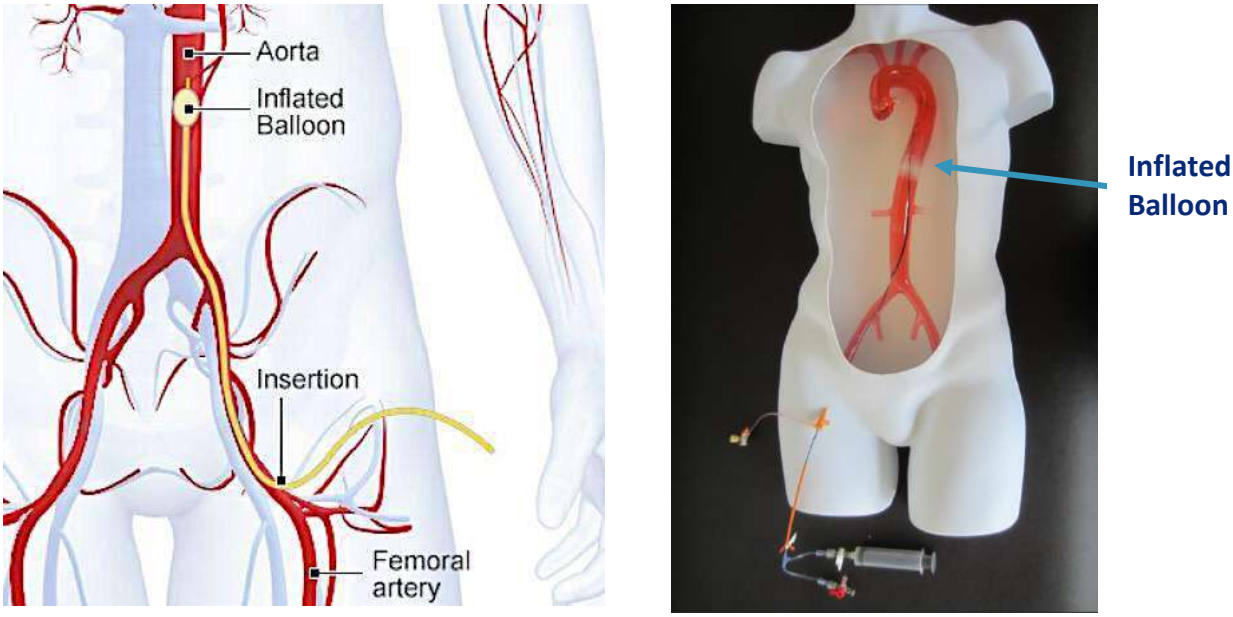

Figure 1: Diagram of REBOA catheter placement and deployment

Device Description [15, 16]

The REBOA catheter is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring. The device consists of a compliant occlusion balloon with an atraumatic distal tip (P-tip®), a dual lumen catheter shaft and a hub with extension lines to provide access to each lumen. The balloon lumen is used to inflate and deflate the balloon. The arterial line lumen is used to monitor blood pressure. The catheter is designed to be used without a guidewire. A peel away sheath is pre-loaded on the catheter shaft to ease insertion of the catheter's P-tip® into an introducer sheath haemostasis valve. The device has an effective length of 72 cm and is compatible with 7 Fr or larger introducer sheaths. The introducer sheath can vary in size from 7 Fr to 14 Fr, depending on the particular device used (Table 1). The device is a single use sterile device. The distal tip (P-tip®) eases advancement of the catheter in a blood vessel. The compliant occlusion balloon is capable of occluding vessels up to 32 mm in diameter. Radiopaque platinum iridium marker bands are located at the functional ends of the balloon to facilitate accurate balloon placement. A co-axial catheter shaft provides appropriate stiffness and a dedicated lumen for pressure monitoring distal to the balloon. Pad printed marks on the outer catheter shaft indicate distance to the center of the balloon to facilitate proper placement. The proximal end of the catheter has a hub and extension lines. The stopcocks provide control to each of the catheter's two lumens. The peel-away sheath can be separated from the catheter shaft after insertion if needed. (Figure 2)

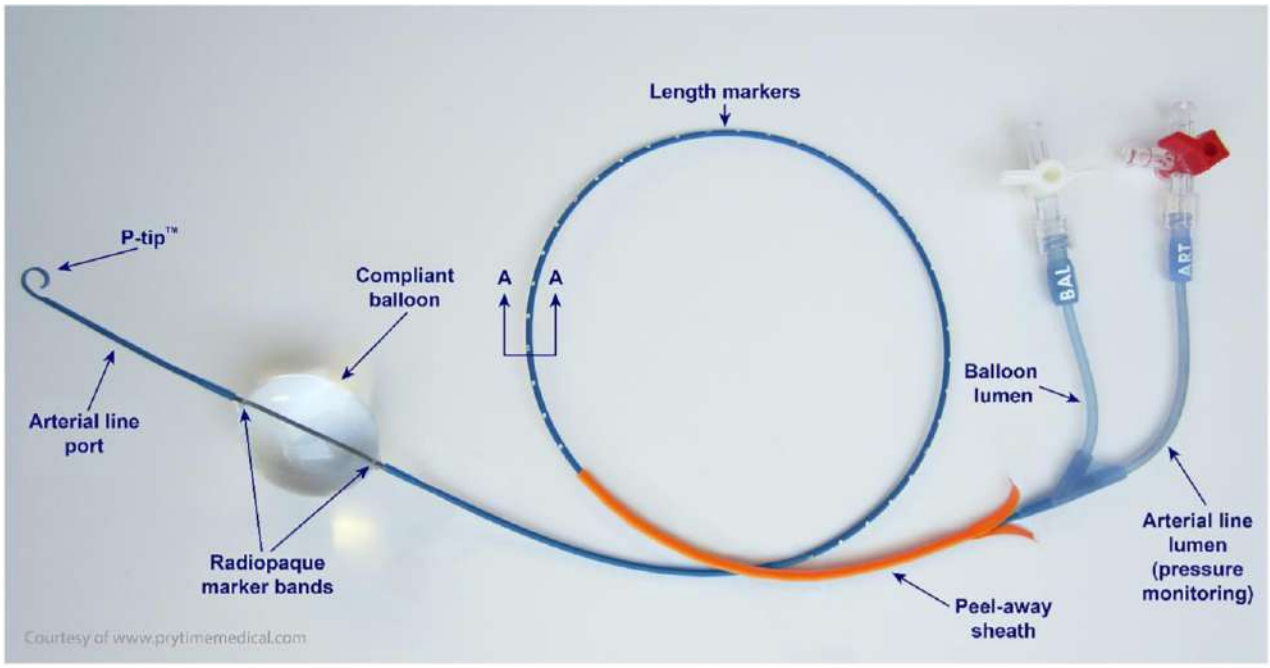

Figure 2: The REBOA Catheter Device

Table 1: Commercial Models and Characteristics of REBOA Catheters[16]

REBOA Device	Sheath (Fr)	Catheter Length (cm)	Balloon Maximum Diameter (mm^2)
1.CODA (Cook Medical)	12-14	100/140	46
2.Reliant (Medtronic Vascular)	12	100	46
3.Equalizer (Boston)	14-16	65/100	40
4.ER-Reboa (Prytime Medical)	7	72	32
5.Resque Balloon (Tokai Medical)	7	80	40
6.IABO Block Balloon (Senko Medica Instrument)	10	145	30

Principle of Operation [11, 12, 17]

The arterial insertion of the REBOA catheter is done either by percutaneous access or surgical cutdown, or exchange over a guidewire from an existing arterial line. The balloon may be inflated in one of three zones (Figure 3) (Zone I – thoracic aorta, from the left subclavian artery to the celiac artery; Zone II – between the celiac and renal arteries; Zone III – infra-renal placement) depending on the location of non-compressible haemorrhage. Two aortic zones; Zone I and Zone III are most commonly targeted for occlusion. Placement in Zone I may be used for massive abdominal haemorrhage or pelvic haemorrhage. The second appropriate zone of placement is within Zone III, which is distal to the renal arteries but proximal to the aortic bifurcation. Zone III placement is appropriate when there is massive pelvic haemorrhage or junctional haemorrhage (bleeding from the inguinal region not amenable to direct pressure) but perfusion to the abdominal contents is to be preserved. (Table 2)

In ensuring proper placement and early identification of potential misplacement, imaging guidance including chest radiographs, ultrasound or fluoroscopy may be used. Blind placement may be done using anatomical landmark. These landmarks include measurement of the distance from the femoral arteries to the suprasternal notch and the measurement of the femoral arteries to the xiphoid process. The REBOA device itself should be shorter than the distance from the femoral arteries to the suprasternal notch, but longer than the distance between the femoral arteries and the xiphoid process. Inflation of the balloon can be accomplished without fluoroscopy or radiograph if needed. This is performed by a combination of tactile feel (meeting resistance) and monitoring the arterial line (A-line) for a change in waveform.

Table 2: Clinical indications for REBOA according to aortic zone[11]

Aortic Zone	Clinical Indication
Zone I (balloon catheter may be inflated at the distal thoracic aorta)	Intra-abdominal haemorrhage
	Retroperitoneal haemorrhage
	Patient with traumatic chest
Zone III (Balloon catheter may be inflated at the distal abdominal aorta)	Pelvic haemorrhage
	Junctional haemorrhage
	Lower extremity haemorrhage

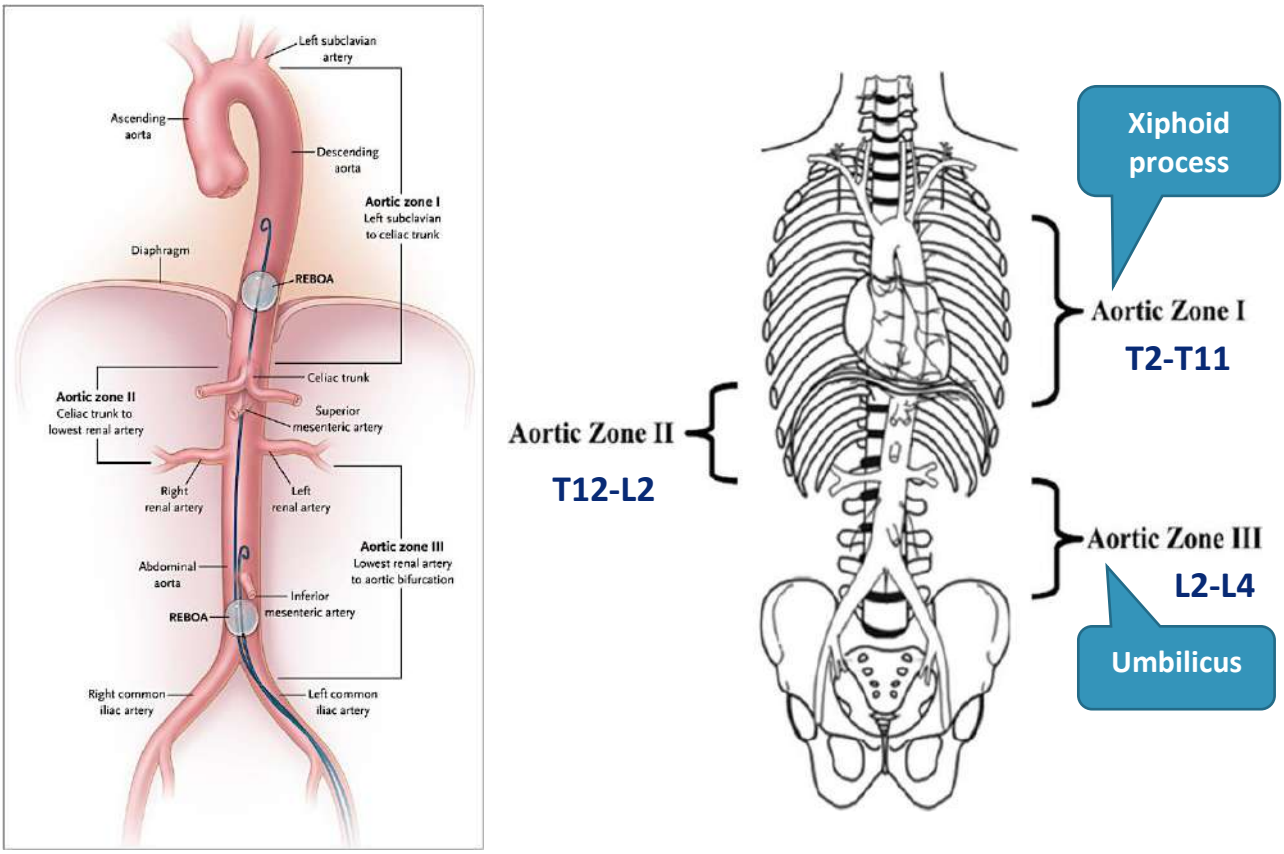

Figure 3: Classification of aortic zone and anatomical landmarks for balloon deployment and placement. Zone 1 surface landmark is the xiphoid process. Zone 3 surface landmark is the umbilicus.

<u>Insertion Setting</u>

REBOA is mostly inserted in emergency departments, in some cases in the operating room or, where available, in a hybrid room.[8] There is also REBOA experience in pre-hospital settings, for example in London's Air Ambulance, although limited to blind placement in zone III only.[18]

4.0 METHODS

4.1 SEARCHING

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials – October 2020, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to October 2020, EBM Reviews - Health Technology Assessment – 4th Quarter 2016, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 31 October 2020.

Appendix 1 showed the detailed search strategies.

4.2 SELECTION

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patients in traumatic arrest and haemorrhagic shock states
Interventions	REBOA
Comparators	No comparator or standard treatment (blood transfusion, resuscitative thoracotomy with aortic cross clamping)
Outcomes	i. Efficacy: - Effect on systolic blood pressure (SBP), reduction in mortality/survival benefit ii. Safety: - Adverse events, complications associated with REBOA iii. Economic implication (cost, cost-effectiveness) iv. Organisational issues
Study design	Health Technology Assessment (HTA), Systematic Review, Randomised Controlled Trial (RCT), non-randomised trial, cohort, case-control, cross-sectional and economic evaluation studies.
	English full text articles

Exclusion criteria

Study design	Studies conducted in animals, case series or case report
	Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and The Cochrane Collaboration's tool. All full text articles were graded according to US/Canadian Preventive Services Task Force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5.0 RESULTS

A total of 4518 titles were identified through the Ovid interface and PubMed, and 15 were identified from references of retrieved articles. After removal of duplicate articles, 2973 titles were screened. A total of 309 abstracts were found to be potentially relevant and were screened using the inclusion and exclusion criteria. Of these, 45 relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria, only 13 full text articles were eligible to be included for qualitative synthesis. The 13 selected full text articles comprised of six systematic reviews (SR), five cohort study, one pre and post intervention study and one economic evaluation study. The selection of studies is as shown on Figure 4.

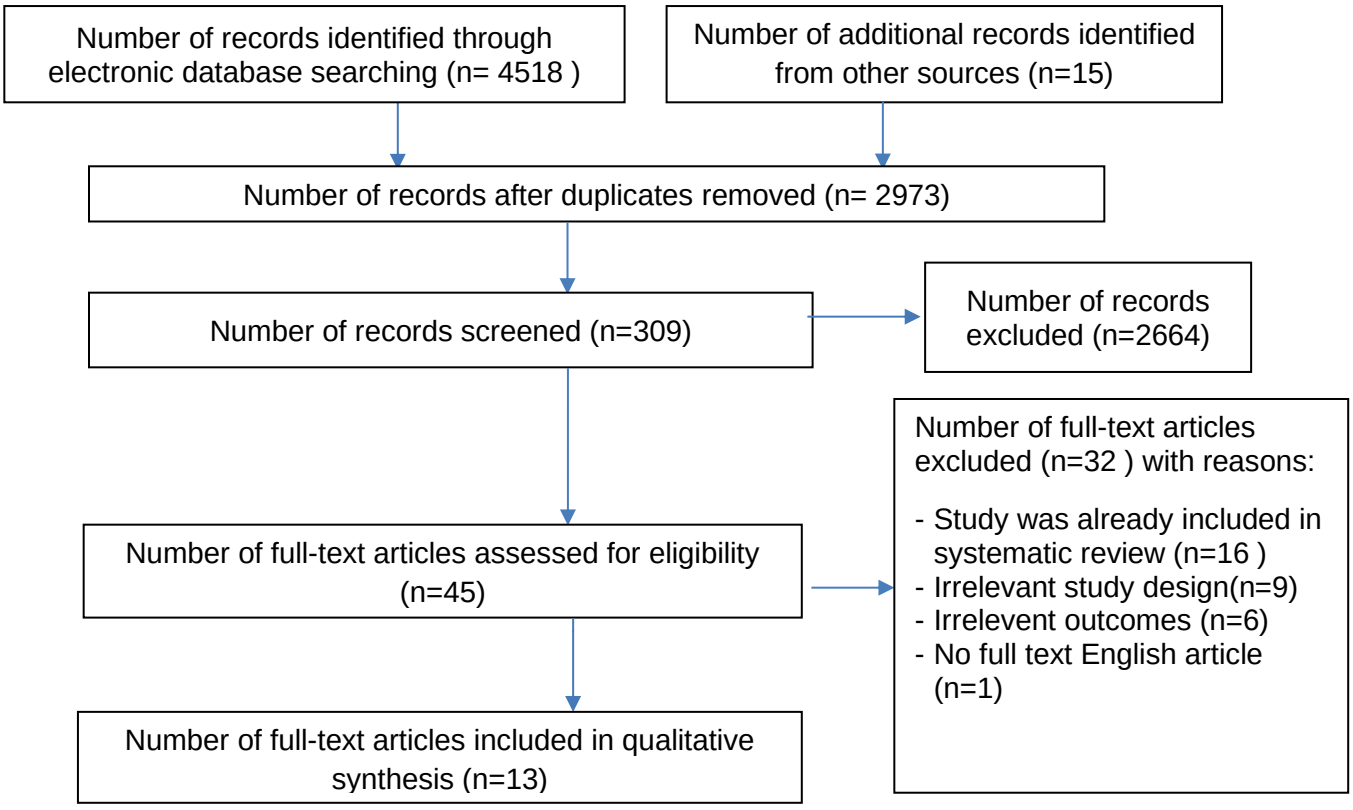

Figure 4: Flow chart of study selection

Assessment of risk of bias in included studies

Risk of bias was assessed using Risk of Bias in Systematic reviews (ROBIS) for SR and Critical Appraisal Skills Programme (CASP) checklist for cohort study. These assessments involved answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias as either:

Table 3: Summary of risk of bias assessment for systematic review using ROBIS

Review	Phase 2				Phase 3
	1. STUDY ELIGIBILITY CRITERIA	2. IDENTIFICATION AND SELECTION OF STUDIES	3. DATA COLLECTION AND STUDY APPRAISAL	4. SYNTHESIS AND FINDINGS	RISK OF BIAS IN THE REVIEW
Borger van der Burg BLS et al.[14]	+	+	+	+	+
Manzano Nunez R et al.[19]	+	+	+	+	+
Manzano-Nunez R et al.[20]	+	+	+	+	+
Ordonez CA et al.[21]	+	+	+	+	+
Gamberini E et al.[8]	+	+	+	+	+
Engberg M et al.[22]	+	+	+	+	+

Table 4: Summary of risk of bias assessment for cohort study using CASP Checklist

Review	Criteria assessed				
	SELECTION OF COHORT	EXPOSURE ACCURATELY MEASURED	OUTCOME ACCURATELY MEASURED	CONFOUNDING FACTORS	FOLLOW-UP OF SUBJECTS
Yamamoto R et al. (2019)[23]	+	+	+	+	+
Yamamoto R et al. (2020)[24]	+	+	+	+	+
Brenner M et al.[25]	+	+	+	+	+
Pieper A et al.[26]	+	+	+	-	+

Whittington JR et al.[27]	+	+	+	-	+

5.1 EFFICACY/ EFFECTIVENESS

There were seven included studies on the effectiveness of REBOA in different population of patients with life-threatening haemorrhage. The effectiveness of REBOA was reported in the context of its effect on systolic blood pressure (SBP) (two studies) [14, 26], survival benefit/reduced mortality (four studies) [19, 23, 24, 25] and haemorrhage control (one study) [21].

Improvement in systolic blood pressure

A systematic review and meta-analysis by Borger van der Burg BLS (2018) (89 studies;1436 patients) reported on the the mortality and morbidity associated with REBOA in patients with haemodynamic instability due to major exsanguination from both traumatic and non-traumatic sources.[14 level I] There was a significant increase of systolic BP with REBOA by a mean of 78.9 mmHg in trauma cases, 56.1 mmHg in ruptured abdominal aortic aneurysm and 52.4 mmHg in other types of patients (post-partum, gastrointestinal bleeding) in established haemorrhagic shock. Meta-analysis revealed a significant difference in mortality ($p < 0.001$) of REBOA compared with the mortality of patients treated with other means [risk difference (RD) of 0.27 ; 95% Confidence Interval (CI) 0.14, 0.49 favouring REBOA].[14 level I]

Pieper A et al. (2018) in their cohort study evaluated REBOA utilisation in severe pelvic blunt trauma and life-threatening haemorrhage at French level 1 trauma centre.[26 level II-2] REBOA inflation was associated with significant haemodynamic improvement (median increase in arterial SBP equal to 55 mm Hg).[26 level II-2]

Survival benefit

Manzano Nunez R et al. conducted a systematic review and meta-analysis (2017) (3 studies; 1276 participants) to determine the effect of REBOA, compared to resuscitative thoracotomy (RT), on mortality among non-compressible torso haemorrhage trauma patients.[19 level I] The mortality was high in all groups (RT, REBOA) with rates ranging from 47% to 90%. However, the analysis showed that the risk of mortality was significantly lower among torso trauma patients who underwent REBOA, compared to those who underwent RT (RR 0.81; 95% CI 0.68, 0.97; $I^2 = 0.0\%$).[19 level I]

Two cohort studies by Yamamoto R et al., using propensity-score matched groups from the Japan Trauma Data Bank provide the largest experience to date on the use of REBOA as an adjunct for haemorrhage control in NCTH.[23, 24 level II-2] Both studies observed the survival benefit with the use of REBOA in comparison to similarly matched trauma patients who did not undergo REBOA. One study conducted in 2019, reported survival to discharge

was significantly higher among patients treated with REBOA than among those treated without REBOA [53 (45.3%) versus 38 (32.5%); odd ratio (OR) 1.72; 95% CI 1.01, 2.93; p = 0.04].[23] level II-2 Survival at 28 days was significantly higher in patients in the REBOA group compared to those in the non-REBOA group [55 (47.0%) versus 38 (32.5%); OR 1.84; 95% CI 1.08, 3.13; p= 0.04]. Hospital-free days to day 90 did not significantly differ between the REBOA and non-REBOA groups (15±26 days versus 11±25 days; p=0.15). REBOA was significantly associated with reduced mortality in patients who survived the first day of injury [hazard ratio (HR) after day 2 = 0.58; 95% CI 0.34, 0.98; p=0.04). Subgroup analysis showed REBOA was particularly significantly associated with improved survival to discharge in patients with isolated abdominal injury or pelvis/lower extremity injury [14 (73.7%) in REBOA group versus 3 (27.3%) in non-REBOA group; OR 7.47; 95% CI 1.40, 39.84; p = 0.02].[23] level II-2

In the following cohort study, Yamamoto R et al. (2020) further investigated the survival benefit of REBOA in severely injured trauma patients who experience delays in surgical intervention, compared to those who do not.[24] level II-2 The REBOA use in patients who experienced transfer times to the operation room between one and three hours after arrival exhibited improved survival, but this benefit did not extend to patients transferred to the operation room within one hour. Survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA in the delayed (operation room transfer between one to two hours) and significantly-delayed (operation room transfer between two to three hours) subgroups [66 (66.6%) versus 30 (33.0%); p < 0.001 and 34 (59.6%) versus 15 (27.3%); p = 0.001, respectively]. There were no significant differences in survival to discharge among the early subgroups (operation room transfer time less than one hour) [26 (39.4%) versus 26 (33.8%); p = 0.49]. Similar findings also were observed with the survival at 28 days [132 (59.2%) versus 79 (35.4%); OR 2.64; 95% CI 1.80, 3.88; p < 0.001] and hospital free days to 90 days (24 ± 30 days versus. 15 ± 35 days; p < 0.001). REBOA use was significantly associated with reduced mortality in the delayed and significantly-delayed subgroups (HR 0.43; 95% CI 0.28, 0.65 and HR 0.42; 95% CI 0.25, 0.71, respectively). The HR was not significant in the early subgroup (HR 0.92; 95% CI 0.60, 1.40) (Figure 8). [24] level II-2

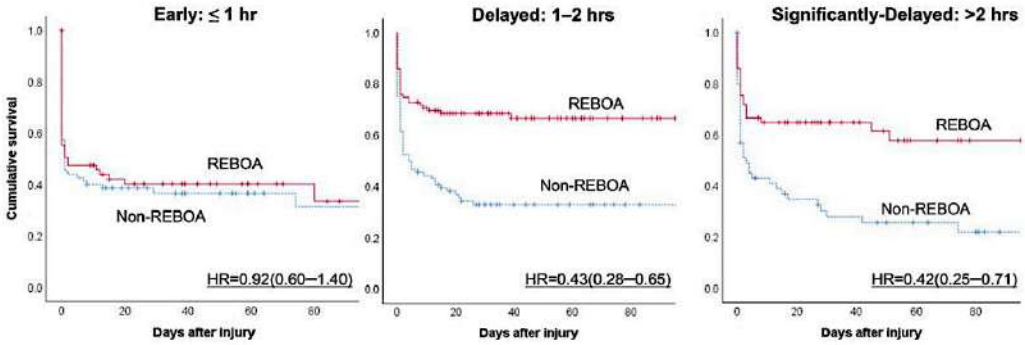

Figure 5: Kaplan-Meier plots of survival curves for patients treated with REBOA and without

REBOA in the early, delayed and significantly delayed subgroups.

Another cohort study conducted by Brenner M et al. (2018), using data from The American Association for the Surgery of Trauma (AAST) Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery (AORTA) multi-institutional database, sought to compare the survival benefit of REBOA and RT in group of trauma patients who required cardiopulmonary resuscitation (CPR) and who did not.[25] level II-2 Patients required CPR before hospital admission and after hospital admission but before aortic occlusion, neither survival beyond the ED nor survival to discharge was significantly different between those underwent RT and REBOA. Patients who did not require any CPR before had a survival beyond the ED of 70% (RT 48%, REBOA 93%; $p < 0.001$) and survival to discharge of 13% (RT 3.4%, REBOA 22.2%, $p = 0.048$). If aortic occlusion patients did not require CPR but presented with hypotension [systolic blood pressure <90 mmHg; 9% (65% RT; 35% REBOA), they achieved survival beyond the ED in 65% ($p = 0.009$) and survival to discharge of 15% (RT 0%, REBOA 44%; $p = 0.008$]. Overall survival beyond the ED was 50% (RT 44%, REBOA 63%; $p = 0.004$) and survival to discharge was 5% (RT 2.5%, REBOA 9.6%; $p = 0.023$).[25] level II-2

<u>Prevention of major haemorrhage in obstetric patients</u>

A systematic review and meta-analysis was conducted by Ordoñez CA et al. (2018) (4 studies; 441 patients) for studies involving pregnant women with a diagnosis of abnormal placentation who underwent an elective caesarean delivery with prophylactic REBOA placement.[21] level I The use of REBOA as prophylaxis for the prevention of major haemorrhage was associated with a lower amount of intraoperative haemorrhage (in milliliters) [weighted mean difference (WMD) -1,384.66; 95% CI -2,141.74, - 627.58] and lower requirements of blood products transfusions (in units) (WMD -2.42; 95% CI -3.90, -0.94). [21] level I

5.2 SAFETY

The use of REBOA has been approved by FDA for the following indications:[15]

i. Traumatic life-threatening haemorrhage below the diaphragm in patients who are unresponsive or transiently responsive to resuscitation
ii. Patients arriving in arrest from injury due to presumed life-threatening haemorrhage below the diaphragm

A meta-analysis conducted by Manzano-Nunez R et al. (2018) reported the pooled incidence of complications related to femoral access was 5% (95% CI 3%-9%).[20] level I A

higher pooled incidence of femoral access complications was observed when anaesthesiologist or radiologist performed REBOA and when it was inserted by surgical cutdown technique (Table 3). The most common complications were thrombotic and/or embolic complications, with or without signs of distal ischaemia, followed by arterial injuries. Other complications were femoral pseudoaneurysms and femoral artery dissection. The analysis also found that three cases of lower limb amputation (0.7%) were directly related to vascular puncture for REBOA insertion.[20] level 1

Table 5: Pooled incidence of femoral access complications according to provider and insertion technique

	Pooled incidence (%) (95% CI)
Pooled incidence by Provider (11 studies)	
Trauma Surgeon (5 studies)	5 (1-9)
Emergency Physician (5 studies)	0 (0-4)
Anaesthesiology/Radiologist (1 study)	16 (5-33)
Pooled incidence by Insertion Technique (12 studies)	
Percutaneous or Surgical Cutdown (5 studies)	5 (2-9)
Only percutaneous (6 studies)	2 (0-8)
Only surgical cutdown (1 study)	11 (2-29)

Gamberini E et al (2017), in their systematic review, described the complications as either related to the insertion, to the REBOA mechanism (pressure increases up-stream from the occlusion) or to the failure of the technique itself.[8] level I The main risk factors were high body mass index, thrombocytopaenia, emergency procedures, big size of the introducer, and use of anti-platelet drugs. Complications seemed to reduce significantly with 7-Fr catheter. Table 6 displays a detailed description of related complications and their rate of occurrence.[8] level I

Table 6: Rate of REBOA complications according to type

Type of complication	**Rate (%)**
Complications related to insertion of REBOA catheter	
Infections	0.30
Pseudo-aneurysm in the access site/arterial injury caused by puncture	0.22
Retroperitoneal haematoma	0.07
Complications related to the failure of the REBOA technique	
Introducer insertion failure	0.66
Balloon migration	0.15

Rupture of the REBOA balloon	0.07
Complications related to the REBOA mechanism	
Kidney failure	0.89
Distal ischaemia/thromboembolic events	0.66
Intracranial massive haemorrhage	0.07

Whittington JR et al. (2020) evaluated the risk of vascular complications in prophylactic compared to emergent REBOA in the management of placenta accreta spectrum.[27] level II-2 Three out of five patients with REBOA placed emergently had vascular complication related to the placement (one right iliac artery thrombus, one right iliac artery dissection and thrombus, and one right common femoral posterior wall laceration with right iliofemoral thrombosis). All three patients required intervention including thrombectomy with repair by vascular surgery and recovered without residual complication. There were no vascular complications in the prophylactic placement group. The authors suggested prophylactic placement of REBOA may avoid the risk of vessel trauma associated with the nature of emergent placement and mitigate the potential risks related to hypotension and stasis.[27] level II-2

5.3 COST-EFFECTIVENESS

Cost-effectiveness

A one-year cost–utility analysis was conducted by Renna MS et al. (2019), on REBOA as an intervention for patients with major traumatic non-compressible abdominal haemorrhage, compared to resuscitative thoracotomy with aortic cross-clamping (RTACC) within the U.K.'s National Health Service. The ICER of REBOA when compared to RTACC was £44,617.44 per quality-adjusted life year. The ICER, by exceeding the National Institute for Health and Clinical Effectiveness's willingness-to-pay threshold of £30,000/quality-adjusted life year, suggested that this intervention was not cost-effective in comparison to RTACC. However, REBOA yielded a 157% improvement in utility with a comparatively small cost increase of 31.5%.[28]

5.4 ORGANISATIONAL

Management practices of REBOA

Variation of practice between low middle income countries (LMICs) and high-income countries (HICs)

Manzano-Nunez R et al. (2020) conducted a multinational cross-sectional study to compare the management approaches and clinical outcomes of trauma patients treated with REBOA according to the countries' income based on the World Bank Country and Lending Groups [high-income countries (HICs) versus low-to-middle income countries (LMICs)].[29] Fourteen countries participated: nine high-income countries (the USA, Israel, Sweden, Finland, Japan, Italy, South Korea, Germany, and the Netherlands), four upper-middle-income countries (Russia, Thailand, Colombia, and Turkey), and one low-income country (North Korea). The study revealed that there was lack of standardization in the practice of REBOA worldwide. In HICs, REBOA inserted more often in the emergency room (n=520/710, 73.2%). Contrarily, a higher proportion of patients from LMICs underwent REBOA insertion in the operating room (n=44/73, 60.2%) ($p < 0.001$). While femoral artery cannulation by a blind percutaneous approach was the preferred access technique in HICs (n=370/721, 51.3%), surgical cutdown was more common in LIMCs (n=43/73, 58.9%). Access guided by ultrasound was performed in 30.6% and 21.9% of patients from HICs and LMICs, respectively. Overall, the majority of the REBOAs were deployed by a trauma surgeon (547/727, 75.2%). However, the participation of radiologists and anaesthesiologists in the insertion and deployment was more frequent in HICs. There was also considerable variation in the clinical outcomes associated with REBOA between HICs and LMICs. Patients from LMICs had a significantly higher occurrence of multi-organ dysfunctions (LMICs = 45/68, 66.1% vs. HICs = 85/ 661, 12.8%; $p < 0,001$), and respiratory failure (LMICs = 22/70, 31.2% vs. HICs = 73/657, 11.1%; $p < 0,001$). There were no differences in the occurrence of acute kidney injury, sepsis, and groin access complications. Similarly, there were no differences in ventilator days and mortality between groups.[29]

Training and credentialing

For the practice of REBOA in the USA, a national guideline produced by the American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of Emergency Medical Services Physicians and the National Association of Emergency Medical Technicians on the clinical use of REBOA in civilian trauma systems in the USA, stated that all healthcare providers responsible for performing REBOA are required to go through a nationally recognized course for certification or a course put on by already trained subject matter expert's at each site. Physicians who will be responsible for placing REBOA should receive comprehensive didactic and hands-on skills training in all aspects of the procedure. Didactic training includes the following topics: patient selection; anatomy and physiology of REBOA; complications of REBOA and management of these complications; management of the catheter; management of the patient from the point of aortic occlusion to balloon deflation and the immediate postoperative phase; limb assessment; sheath management and

establishing an appropriate system of care to support REBOA use and its complications. Each institution and department are responsible for analysing qualifications (credentialing) for providers to perform REBOA.[30]

A systematic review by Engberg M et al. (2020) (16 studies; 546 participants) evaluated the effect of simulation-based training and assessment of competence in REBOA and femoral arterial access (FAA).[22] level I The review revealed different type of training model used which include Mentice VIST virtual reality endovascular simulator (eight studies), live porcine model (three studies), perfused human cadavers (two studies) and silicone/plastic physical models (six studies). These training models often accompanied by educational interventions, among others;

- Basic Endovascular Skills for Trauma (BEST) 1-day course of didactic sessions and simulator training
- Endovascular Resuscitation, Bleeding and Trauma Management (EVTM) workshop: A didactic session, including animation video, and individually given instructions at the porcine model
- Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) 2-day course of didactic sessions and simulator training

The examination of the effect of six consecutive procedures performed on a simulator, showed a significant decrease in procedural time. There was also evidence to support improvement in knowledge test scores after training intervention. One multicentre study on FAA found that residents who received an instructed simulation session prior to rotation in an invasive cardiology unit decreased the number of procedures needed to reach proficiency from 20 to 10 ($p<0.01$) compared to a previous cohort of residents. A decrease in complication incidence from 4.5% to 2.1% was also noted ($p<0.01$). Another study in the review reported on REBOA performance in the clinic after simulation-based training. The clinical REBOA procedural time for 28 physicians did not differ from procedural time on a virtual reality simulator (mean 310 seconds versus 277 seconds, $p>0.05$).The review had shown that simulation-based training of REBOA improves skill of the providers. [22] level I

A pre and post intervention study by Hatchimonji JS et al. (2020) sought to evaluate REBOA- specific knowledge following formal training course and long-term durability of such training.[31] level II-3 Sixteen participants (ten trauma surgical faculty members, three fellows) were exposed to four hours REBOA Education for Shock Trauma Acute ResusciTation (RE-START) course. The course included Interactive didactics with hands-on practical training using a 7Fr introducer kit and both a vascular access trainer and a REBOA-specific training mannequin. The knowledge scores improved significantly from precourse (72%±10% correct) to postcourse (88%±8%, $p < 0.001$). At six months, scores remained no different from postcourse ($p = 0.126$); at one year, scores decreased back to baseline ($p = 0.024$ from postcourse; 0.285 from precourse). Subjective comfort with

femoral arterial line placement and REBOA improved with training (p=0.044 and 0.003, respectively). Femoral arterial line comfort remained unchanged from postcourse at six months (p = 0.898) and one year (p=0.158). However, subjective comfort with REBOA decreased relative to postcourse levels at six months (p=0.009), driven primarily by participants with no clinical REBOA cases in the interim.

6.0 LIMITATION

This technology review has several limitations. The selection of studies was done by one reviewer. Only English full text articles were included in this review. The majority of the evidence of systematic reviews consist of case reports and case series with only limited cohort studies which carry significant risk of bias. All of the included studies also have a small sample size which limit the generalisability of the findings.

7.0 CONCLUSION

Based on retrievable evidence, REBOA had shown to improve SBP by an estimation of 50mmHg in major haemorrhage from both traumatic and non-traumatic sources. Survival benefit beyond 28 days was evident among non-compressible torso haemorrhage patients who experience delays in surgical intervention more than one hour and compared to those who underwent RT. REBOA was significantly associated with improved survival to discharge in patients with isolated abdominal injury or pelvis/lower extremity injury. REBOA did not confer any long-term survival advantage when used in traumatic cardiac arrest compared with standard of care. Based limited evidence, the utilisation of prophylactic REBOA among obstetric patients with morbidly adherent placenta had shown to lower the amount of intraoperative haemorrhage and lower the requirement of blood products transfusion.

There was a good level of retrievable evidence that showed the risk of complications with the use of REBOA was 5%. The most common complications included arterial disruption, dissection, pseudoaneurysms, haematoma, thromboembolic problems, and extremity ischaemia. These complications had resulted in limb loss and/or the need for patch angioplasty, complex arterial reconstructions or bypass. The emergent placement carried higher risk of complications compared to prophylactic placement. Other main risk factors were high body mass index, thrombocytopaenia, emergency procedures, big size of the introducer, and use of anti-platelet drugs. Complications seemed to reduce significantly with 7-Fr catheter

Based on a cost utility analysis from the perspective of NHS UK, the use of REBOA was not cost-effective (ICER £44,617.44 per QALY) exceeding WTP threshold of £30,000.

A formal REBOA curriculum improves knowledge and comfort with critical aspects of this procedure. Simulation-based training of REBOA had shown to be effective in improving the knowledge and competency of REBOA placement. This knowledge persisted at six months, though subjective comfort deteriorated among those without REBOA placement in the interim. The REBOA refresher training should be considered at six-month intervals in the absence of clinical REBOA cases.

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APPENDIX 1: HIERARCHY OF EVIDENCE FOR EFFECTIVENESS STUDIES

DESIGNATION OF LEVEL OF EVIDENCE

I Evidence obtained from at least one properly designed randomised controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

APPENDIX 2: SEARCH STRATEGY

Database(s): **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to October 01, 2020

Search Strategy:

#	Searches	Results
1	HEMORRHAGE/	73349
2	bleeding.tw	206323
3	he?morrhage$1.tw	155312
4	GASTROINTESTINAL HEMORRHAGE/	41912
5	(gastrointestinal adj1 he?morrhage$1).tw	4847
6	POSTPARTUM HEMORRHAGE/	7146
7	(postpartum adj1 he?morrhage$1).tw	4020
8	EXSANGUINATION/	355
9	(exsanguinating adj1 he?morrhage$1).tw	194
10	exsanguination.tw.	1992
11	SHOCK, HEMORRHAGIC/	11520
12	(he?morrhagic adj1 shock).tw	9025
13	(aortic adj1 rupture$1).tw	2624
14	ENDOVASCULAR PROCEDURES/	19262
15	((procedure$1 or technique$1) adj1 endovascular).tw	6133
16	REBOA.tw	361
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13	401040
18	14 or 15 or 16	23764
19	17 and 18	3453

APPENDIX 3: EVIDENCE TABLE

Evidence Table : Effectiveness
Question : How effective is the use of REBOA in adult trauma patients?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Borger van der Burg BLS, van Dongen T, Morrison JJ et al. A systematic review and meta-analysis of the use of resuscitative endovascular balloon occlusion of the aorta in the management of major exsanguination. Eur J Trauma Emerg Surg. 2018;44(4):535-550.	Systematic review & meta-analysis **Objective** To examine the use of REBOA and the mortality and morbidity associated with REBOA in patients with hemodynamic instability due to major exsanguination from both traumatic and non-traumatic sources A meta-analysis to calculate the effect on systolic blood pressure and mortality was performed for trauma cohort	I	89 studies with 1436 patients 28 case reports 25 case series 36 cohort studies <u>Type of cases</u> -Trauma (18 studies) -rAAA (50 studies) -Others (PPH, UGIB) (21 studies) <u>Access site</u> Femoral 96.8% <u>Access technique</u> -Percutaneous 75% 23 studies reported on pre-REBOA and post-REBOA SBP values	REBOA	Other interventions (not specified)	-	**Effect on systolic BP (SBP)** - significant increase of SBP by a mean of 78.9 mmHg in trauma, 56.1 mmHg in rAAA and 52.4 mmHg other types of patients in established haemorrhagic shock - pooled analysis of trauma cohort demonstrated an increase in mean systolic pressure by almost 50 mmHg following REBOA use. **Reduction in mortality** - significant difference in mortality ($p < 0.001$) of REBOA compared with the mortality of patients treated with other means. - a risk difference of 0.27 (0.14–0.49) favouring REBOA	

Evidence Table : Effectiveness
Question : How effective is the use of REBOA in non-compressible torso hemorrhage patients ?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Manzano Nunez R, Naranjo MP, Foianini E et al. A meta-analysis of resuscitative endovascular balloon occlusion of the aorta (REBOA) or open aortic cross-clamping by resuscitative thoracotomy in non-compressible torso haemorrhage patients. World J Emerg Surg. 2017;12:30.	Systematic & meta-analysis **Objective** To determine the effect of REBOA, compared to resuscitative thoracotomy, on mortality and among non-compressible torso haemorrhage trauma patients	I	3 cohort studies were included with 1276 participants Age range 15-80 years old <u>Trauma mechanism</u> -Blunt trauma 53.9-93% -Penetrating trauma 7-47.1%	REBOA	Traditional open aortic occlusion by resuscitative thoracotomy	-	**In-hospital mortality** -Mortality was significantly higher in patients that underwent RT (mortality, n (%): REBOA = 60.4% vs. RT = 78.1%, $p < 0.01$]. - The risk of mortality was significantly lower in patients who underwent REBOA, compared to those who underwent RT (RR 0.818; 95% CI 0.683–0.979; $I^2 = 0.0\%$). **Conclusion** A positive effect of REBOA on mortality among non-compressible torso haemorrhage patients	

Evidence Table : Effectiveness and Safety
Question : How effective is the prophylactic REBOA placement in pregnant women who underwent an elective caesarean delivery with possible intraoperative haemorrhage?
How safe is the prophylactic REBOA placement in pregnant women who underwent an elective caesarean delivery with possible intraoperative haemorrhage?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Ordonez CA, Manzano-Nunez R, Parra MW et al. Prophylactic use of resuscitative endovascular balloon occlusion of the aorta in women with abnormal placentation: A systematic review, meta-analysis, and case series. J Trauma Acute Care Surg. 2018;84(5):809-818.	Systematic review & meta-analysis **Objective** To investigate the safety and effectiveness of the use of REBOA during elective caesarean delivery in pregnant women with morbidly adherent placenta (MAP) <u>Inclusion criteria</u> -Studies involving pregnant women with a diagnosis of abnormal placentation who underwent an elective caesarean delivery with prophylactic REBOA placement - Studies were eligible if they assessed intra-operative outcomes: intra-operative haemorrhage, transfusions and REBOA deployment-related complications <u>Exclusion criteria</u> Studies in which REBOA was deployed emergently were excluded <u>Primary Outcomes</u> Intra-operative haemorrhage, blood transfusions and REBOA deployment-related complications were the outcomes of interest. <u>Secondary outcome</u>: Neonatal outcome A **meta-analysis** was performed to assess the overall amount of transfusions and intra-operative haemorrhage of REBOA compared to non-REBOA cases.	I	4 studies included with 441 patients <u>Range of mean age between studies (±SD)</u> 27.5 years (±1.7) – 31.2 years(±5.3) <u>Access technique</u> All studies reported percutaneous REBOA insertion using a Seldinger technique Fluoroscopy confirmed the correct Zone-III deployment of REBOA in all studies. <u>Range of mean occlusion time between studies</u> 23.6min - 32min	Prophylactic use of endovascular aortic occlusion by REBOA	No comparator or usual care	-	**Intraoperative haemorrhage** - Lower amount of intra-operative haemorrhage (in milliliters) [weighted mean difference (WMD): -1384.66; 95% CI -2141.74, -627.58] **Amount of transfusions** - Lower requirements of blood products transfusions (in units) (WMD: -2.42; 95% CI -3.90, -0.94) **Complications** related to REBOA insertion occurred in 0.6% of patients **Secondary outcome** _neonatal data No significant differences in the proportion of patients admitted to the neonatal intensive care unit [REBOA, n (%)= 5 (17.2%) vs. Non-REBOA= 7 (17.5%); p=1] (1 study) Length of neonatal hospitalization did not differ significantly between the REBOA and non-REBOA group [REBOA, mean (SD)= 8.5 days (3.6) vs. Non-REBOA= 6.9 days (1.5); p=0.07] (1 study)	

Evidence Table : Effectiveness
Question : How effective is the use of REBOA in severely injured trauma patients who experience delays in surgical?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Yamamoto R, Cestero RF, Muir MT et al. Delays in Surgical Intervention and Temporary Hemostasis Using Resuscitative Endovascular Balloon Occlusion of the aorta (REBOA): Influence of Time to Operating Room on Mortality. Am J Surg. 2020;25:25**.** **Country:** Japan	Retrospective cohort study **Objective** To determine whether REBOA use will improve survival in severely injured trauma patients who experience delays in surgical intervention, compared to those who do not Retrospective analysis of data from the Japan nationwide trauma database; Japan Trauma Data Bank (JTDB) between year 2014-2019. The data bank comprises of over 200 participating hospitals and tertiary care centres. **Inclusion criteria** Trauma patients greater than 15 years of age who arrived with a palpable pulse, were eventually transferred to the OR, and received a transfusion of any blood product type within 24 h after arrival **Exclusion criteria** -Patients with missing or invalid data regarding prehospital information, vital signs on arrival, time of arrival, time of surgery, or in-hospital survival were excluded. -Patients who were transferred to the OR more than 3 h after hospital arrival were also excluded.	II-2	446 patients were selected using propensity score matching divided into REBOA and non-REBOA groups. Further divided into 3 subgroups **1. Early subgroup** (patients with OR transfer times less than 1 h) -143 patients (REBOA 46%) 2. **Delayed subgroup** (OR transfer times between one and 2 h) -191 patients (REBOA 52%) 3. **Significantly-<u>delayed subgroup</u>** (OR transfer times between two and 3 h) -112 patients (REBOA 51%) <u>Mean Age (±SD)</u> REBOA – 56 (±21) Non-REBOA –58 (±22) <u>Mean Revised Trauma Score (RTS)</u> REBOA – 5.75±1.83 Non-REBOA -5.33±1.68 <u>Mean Glasgow Coma Scale (GCS)</u> REBOA -10±5 Non-REBOA - 9±5 <u>Mechanism of injury</u> Blunt 92% Penetrating 6% Unknown mechanism 2% <u>Mean transfer times to the OR after hospital arrival</u> REBOA 1.5 ± 0.8 h	REBOA <u>Current practice</u> In hemodynamically unstable trauma patients without immediate access to surgical intervention, current practice in Japan recommends placement of a REBOA catheter in Zone 1 (between left subclavian artery and celiac artery) through the femoral artery with fluoroscopy and/or ultrasound. The insertion of REBOA was performed by either by trauma surgeons or emergency physicians. 10 Fr REBOA catheters were used until 2013, until 7-Fr options became clinically available	Standard treatment without REBOA	90 days	REBOA use was associated with improved overall survival**.** REBOA use in patients who experienced transfer times to the OR between one and 3 h after arrival exhibited improved survival, but this benefit did not extend to patients transferred to the OR within 1 h **Primary outcome: Survival to discharge** **-**Survival to discharge was significantly higher among patients treated with REBOA compared to those treated without REBOA (126 [56.5%] vs. 71 [31.8%]; **OR = 2.78; 95% CI = 1.89 - 4.09; p < 0.001** **-**Survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA in the delayed and significantly-delayed subgroups (66 [66.6%] vs. 30 [33.0%]; p < 0.001 and 34 [59.6%] vs. 15 [27.3%]; p = 0.001, respectively, whereas there were no significant differences in the early subgroups (26 [39.4%] vs. 26 [33.8%]; p = 0.49) **Secondary outcome: Survival at 28 days and hospital-free days to day 90 (** as defined the number of days alive and out of the hospital between day of hospital arrival and 90 days later) -Survival at 28 days significantly higher in patients in the REBOA group compared to those in the non- REBOA group (132 [59.2%] vs. 79 [35.4%]; OR=2.64; 95% CI=1.80-3.88; p < 0.001 - Hospital-free days to day 90	

			Non-REBOA 1.4 ± 0.8 h				were longer in patients in the REBOA group than in those in the non-REBOA group (24 ± 30 days vs. 15 ± 35 days; p < 0.001) REBOA use was significantly associated with reduced mortality in the delayed and significantly-delayed sub- groups (HR = 0.43; 95% CI 0.28-0.65 and 0.42; 95% CI 0.25-0.71, respectively), the HR was not significant in the early sub- group (HR =0.92; 95% CI 0.60-1.40)	

Question : How effective is the use of REBOA in adult trauma patients?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Yamamoto R, Cestero RF, Suzuki M et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is associated with improved survival in severely injured patients: A propensity score matching analysis. The American Journal of Surgery. 2019;218(6):1162-1168. **Country** Japan	Retrospective cohort study **Objective** To examine the efficacy of REBOA on severely injured patients Data from the Japan Trauma Data Bank (JTDB) retrospectively reviewed and trauma patients who arrived at each participating center between 2004 to 2016 were included in the study. Outcomes in patients treated with REBOA compared with those treated without REBOA, using propensity score matching analysis	II-2	234 patients were included, divided into 2 groups ; **REBOA** (117**)** vs **non-REBOA** (117) Mean age ± SD REBOA group 52±21 Non-REBOA 57±23 Male 64.5% Mechanism of Injury Blunt 95% Penetrate 5% Glasgow Coma Scale (GCS) REBOA group 9.7±4.8 Non-REBOA 8.9±4.7 SBP on arrival REBOA group 96±45 Non-REBOA 91±47 ISS REBOA group 35±13 Non-REBOA 33±11 Revised Trauma Score REBOA group 5.55 ± 2.29 Non-REBOA 5.24 ± 2.23 Trauma and Injury Severity Score (TRISS) calculated probability of survival (Ps) REBOA group 0.56 ± 0.53 Non-REBOA 0.51 ± 0.31	Standard trauma resuscitation and haemostasis procedures + REBOA Current practice of REBOA in Japan REBOA is usually placed at Zone 1 (between left subclavian artery and celiac artery) by emergency physicians or trauma surgeons through the femoral artery with or without fluoroscopy in the setting of uncontrolled haemorrhagic shock. REBOA is recognized as a standard procedure and performed at most of participating hospitals. 10Fr REBOA catheters had been used until 2013 when 7Fr ones became clinically available.	Standard trauma resuscitation and haemostasis procedures **without** REBOA	90 days	**Survival to discharge** (discharge to home or other healthcare facility in the database) -significantly higher among patients treated with REBOA than among those treated without REBOA (53 [45.3%] vs. 38 [32.5%]; OR = 1.72; 95% CI = 1.01-2.93; p = 0.04 **Survival at 28 days and hospital-free days to day 90** (a composite of in-hospital death and hospital length of stay defined as the number of days alive and out of the hospital between the hospital arrival and 90 days later) **-** Survival at 28 days was significantly higher in patients in the REBOA group compared to those in the non-REBOA group (55 [47.0%] vs. 38 [32.5%]; OR = 1.84; 95% CI =1.08-3.13; p= 0.04 - Hospital-free days to day 90 did not significantly differ between the REBOA and non-REBOA groups (15±26 days vs.11±25 days; p=0.15 REBOA was significantly associated with reduced mortality in patients who survived the first day of injury (HR after day 2 = 0.58; 95% CI = 0.34-0.98; p=0.04). REBOA was significantly associated with improved survival to discharge in patients with isolated abdominal injury or pelvis/lower extremity injury (14 [73.7%] in REBOA group vs. 3 [27.3%] in non-REBOA group; OR =7.47; 95% CI = 1.40-39.84; p = 0.02	

Evidence Table : Effectiveness and safety
Question : How effective and safe is the use of REBOA in adult trauma ?
What is the organisational issue related to the use of REBOA?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Brenner M, Inaba K, Aiolfi A et al. Resuscitative Endovascular Balloon Occlusion of the Aorta and Resuscitative Thoracotomy in Select Patients with Hemorrhagic Shock: Early Results from the American Association for the Surgery of Trauma's Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery Registry. J Am Coll Surg. 2018;226(5):730-740. **Country** USA	Prospective cohort study **Objective:** 1.To investigate the use of REBOA and RT as a means of aortic occlusion in adult trauma patients 2. To observe the progression of REBOA use and adoption at enrolled centers. The American Association for the Surgery of Trauma (AAST) Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery (AORTA) multi-institutional database was created in 2013 as a mean for data collection. Patients were enrolled from November 2013 to January 2017 **Inclusion criteria** -Adult trauma and acute care surgery (aged 18 years and older) patients undergoing aortic occlusion (AO) in the acute phases after injury were enrolled - Only patients undergoing AO either REBOA or RT in zone 1 (distal thoracic aorta) in the emergency department (ED) were included. **Exclusion criteria** Patients who received REBOA in the operating room and patients who sustained penetrating thoracic injuries were all excluded	II-2	285 patients were included **Patients were grouped into 3 categories**: 1.CPR before hospital admission - 60.4% 2.CPR after admission but before AO - 20% 3.No CPR required before AO -19.6% 81.8% were males Injury due to penetrating mechanisms 41.4% Mean age ± SD 39.8 ± 17.4 Median Injury Severity Score 34.0 (interquartile range 18) RT was used in 71%, and zone 1 REBOA in 29%.	Zone 1 REBOA	Resuscitative thoracotomy (RT) - occlusion at the level of the descending thoracic aorta	**48 hours**	**Survival benefit REBOA vs RT** Patients required CPR before hospital admission; 129 (75%) of those underwent RT and 43 (25%) had REBOA. Survival beyond the ED and to discharge was not significantly different between groups. CPR after admission but before AO; 44 (77%) had RT and 13 (23%) had REBOA as a resuscitative measure. Neither survival beyond the ED nor survival to discharge was significantly different between groups. Patients who did not require any CPR before had a survival beyond the ED of 70% (RT 48%, REBOA 93%; p < 0.001) and survival to discharge of 13% (RT 3.4%, REBOA 22.2%, p ¼ 0.048). If aortic occlusion patients did not require CPR but presented with hypotension (systolic blood pressure <90 mmHg; 9% [65% RT; 35% REBOA]), they achieved survival beyond the ED in 65% (p = 0.009) and survival to discharge of 15% (RT 0%, REBOA 44%; p = 0.008). Overall survival beyond the ED was 50% (RT 44%, REBOA 63%; p = 0.004) and survival to discharge was 5% (RT 2.5%, REBOA 9.6%; p = 0.023) **Procedure and complications** Most REBOA procedures were performed with the Coda balloon catheter (Cook Medical) (59%), with the ER-REBOA (Prytime Medical Inc) used in 26.5% The right CFA was most frequently accessed (75%) for REBOA Open surgical CFA exposure was required in 53% of patients, and percutaneous methods were used for the remainder, including using external landmarks (28%) and ultrasound-guided (14.5%)	

							The most common radiographic method used to confirm device placement was bedside X-ray (56.6%), followed by ultrasound in 3.6%; however, 31.3% were placed in the emergent setting without imaging assistance. Successful AO was achieved in 94% of REBOA patients. The complication rate of REBOA and RT for those who survived longer than 24 hours were 10% and 1.5%, respectively. Balloon migration occurred in 3.6% due to premature removal of the platform guide wire and failure to secure the balloon catheter. Patients experienced access site infection (1.2%), distal thromboembolism (4.8%), and lower-extremity amputation (1.2%)	

Evidence Table : Effectiveness and Safety
Question : How effective and safe is the use of REBOA in patients with severe pelvic blunt trauma?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Pieper A, Thony F, Brun J et al. Resuscitative endovascular balloon occlusion of the aorta for pelvic blunt trauma and life-threatening hemorrhage: A 20-year experience in a Level I trauma center. J Trauma Acute Care Surg. 2018;84(3):449-453. **Country** France	Retrospective cohort study **Objective** To retrospectively describe a 20-year experience of REBOA utilization in terms of efficacy and safety in consecutive patients with severe pelvic blunt trauma and life-threatening haemorrhage admitted in a French Level I trauma center. **Inclusion** Patients with a suspicion of severe pelvic blunt trauma that required a REBOA procedure due to haemorrhagic shock or a prehospital cardiac arrest	II-2	32 trauma patients underwent a REBOA procedure were included 11 patients presented with refractory (n = 3 patients) or temporary (n = 8 patients) cardiac arrest before admission. Median age (IQR) 46 (37–53) No. patients per period, n (%) Before 2000 3(9%) 2000–2009 17 (53%) 2010 to today 12(38%) Median ISS 44 (35–57) Abbreviated Injury Scale score of 5 (5–5) except for three patients. Median SBP on admission (IQR) 60 mmHg (35–73 mmHg) Mechanism of injury, n (%) Road traffic accident 11(34%) Fall 11(34%) Sport accident 5(16%) Crush injury 4(13%) Other injury 1(0.03%) Definitive hemostasis was obtained by embolization alone (n = 12 patients), surgery alone (n = 4 patients), or both embolization and surgery (n = 13 patients).	REBOA + standard care	Standard care (infusion of crystalloids, continuous infusion of epinephrine and/or nor-epinephrine, pelvic belt placement, and transfusion of red blood cells units)	28 days	The REBOA significantly improved median SBP from 60 (35–73) mm Hg to 115 (91–128) mm Hg ($p < 0.001$). Median REBOA total inflation time was 55 minutes (37–70 minutes). Observed 28-day mortality was 59% (19 of 32 patients). A high rate of vascular complications (19%, n = 5 patients) was reported but no amputation. **Complications** of REBOA procedure were inferior limb ischemia for 5 patients, and iatrogenic aortic dissection for 1 patient. No limb amputation was done. 2 patients required surgical thrombectomy, and one patient a surgical reconstruction of the superficial femoral artery. 2 patients were also treated with aponeurotomy. All patients received anticoagulation. Renal replacement therapy was initiated in 11 patients, and 15 patients had severe rhabdomyolysis**.** **Conclusion** REBOA inflation was associated with significant hemodynamic improvement (median increase in arterial SBP equal to 55 mm Hg) REBOA successfully restored arterial blood pressure in diverse clinical settings without reducing hemorrhage-related mortality. The effect of REBOA on mortality remains unclear.	

Evidence Table : Safety
Question : How safe is the use of REBOA in adult trauma patients?

<table>
<tr><th>Bibliographic citation</th><th>Study Type/ Methods</th><th>LE</th><th>Number of Patients & Patient Characteristics</th><th>Intervention</th><th>Comparison</th><th>Length of Follow Up (If Applicable)</th><th>Outcome Measures/Effect Size</th><th>General Comments</th></tr>
<tr>
<td>Manzano-Nunez R, Orlas CP, Herrera-Escobar JP et al. A meta-analysis of the incidence of complications associated with groin access after the use of resuscitative endovascular balloon occlusion of the aorta in trauma patients. J Trauma Acute Care Surg. 2018 ;85(3):626-634.</td>
<td>Systematic review & meta-analysis

Objective:
To estimate the incidence of complications related to groin access from the use of REBOA in adult trauma patients.

Inclusion criteria
- Patients were adult (> age 16) victims of blunt or penetrating trauma who underwent REBOA
- Studies with the outcome: of the incidence of complications associated with groin access during the use of REBOA.</td>
<td>I</td>
<td>13 studies included with 469 participants

Publication year: 1989-2018

Median sample size (IQR): 27 (21-44)

Trauma patients 94.5%

Characteristics of the REBOA procedure

<u>Type of Endovascular Provider</u>
1. Trauma surgeons (7 studies)
2. ED physician (7 studies)
3. Radiologist (2 studies)
4.Vascular surgeons (1 study)
5. Anaesthesiologists (1 study)

<u>Puncture technique</u>
1. Percutaneous access 73.4%
2. Surgical cutdown 26.5%</td>
<td>REBOA</td>
<td>No comparator</td>
<td></td>
<td>- The incidence of complications was 5% (95% CI 3%-9%).

- A higher pooled incidence of arterial access complications when anesthesiologist or radiologist performed REBOA and when it was inserted by surgical cutdown

<table>
<tr><th>Incidence by Provider (11 studies analyzed)</th><th>Incidence (95% CI)</th><th>Heterogeneity</th></tr>
<tr><td>Trauma Surgeon (5 studies)</td><td>5% (1%-9%)</td><td>I^2=0%</td></tr>
<tr><td>Emergency Physician (5 studies)</td><td>0% (0%-4%)</td><td>I^2=0%</td></tr>
<tr><td>Anesthesiologist/Radiologist (1 study)</td><td>16% (5%-33%)</td><td>NA</td></tr>
<tr><th>Incidence by Insertion Technique (12 studies analyzed)</th><th></th><th></th></tr>
<tr><td>Percutaneous or Surgical Cutdown (5 studies)</td><td>5% (2%-9%)</td><td>I^2=23.09%</td></tr>
<tr><td>Only percutaneous (6 studies)</td><td>2% (0%-8%)</td><td>I^2=30.47%</td></tr>
<tr><td>Only surgical cutdown (1 study)</td><td>11% (2%-29%)</td><td>NA</td></tr>
</table>

Type of complications
- The most common were thrombotic and/or embolic complications, with or without signs of distal ischemia, followed by arterial injuries. Other complications were femoral pseudoaneurysms and femoral artery dissection.
- Three cases of lower limb amputation (0.7%) were directly related to vascular puncture for REBOA insertion.</td>
<td></td>
</tr>
</table>

Evidence Table : Safety
Question : How safe is the use of REBOA in adult trauma patients?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Gamberini E, Coccolini F, Tamagnini B et al. Resuscitative Endovascular Balloon Occlusion of the Aorta in trauma: a systematic review of the literature. World J Emerg Surg. 2017;12:42.	Systematic review **Objective** To analyse procedure related complication **Inclusion criteria** -Adult trauma population who underwent REBOA during emergency department (ED) and operating room (OR) resuscitation phase were considered.	I	61 included studies with 1355 participants 149 patients were treated with REBOA in zone I, 5 in zone II, and 38 in zone III. Others - REBOA zone was not described.	REBOA	No comparator	-	Complications may be related to the insertion, to the REBOA mechanism (pressure increases up- stream from the occlusion), or to the failure of the technique itself. <u>Type and rate of complications</u> -0.66% distal ischemia/thromboembolic events (with eventual need for amputation) -0.07% intracranial massive hemorrhage -0.22% pseudo-aneurysm in the access site /arterial injury caused by puncture -0.89% kidney failure -0.15% balloon migration (e.g., in zone II) -0.30% infections -0.07% retroperitoneal hematoma following the blind insertion; this is more common in obese patients in whom multiple attempts are performed -0.66% introducer insertion failure -0.07% rupture of the balloon	

Evidence Table : Safety
Question : How safe is the use of REBOA in adult trauma patients?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Whittington JR, Pagan ME, Nevil BD et al. Risk of vascular complications in prophylactic compared to emergent resuscitative endovascular balloon occlusion of the aorta (REBOA) in the management of placenta accreta spectrum. J Matern Fetal Neonatal Med. 2020:1-4. **Country** USA	Retrospective cohort study **Objective** To compare the risk of vascular complications in prophylactic and emergent resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter placement in the management of placenta accreta spectrum Retrospective data analysis of all patients with placenta accrete spectrum (January 2018 to January 2020) at a single tertiary center who underwent prophylactic or emergent REBOA for caesarean hysterectomy. The Acute Care Surgery (ACS) team (trauma/acute care surgeons) performed the placement of the 7 French ER-REBOA^{TM} (Prytime Medical, Boerne, Texas) catheter percutaneously under ultrasound guidance, placed in the operating room	II-2	16 pregnant patients Type of REBOA placement -Prophylactic placement (11 patients) -Emergent placement (5 patients) Mean age : 34±6 years old Mean gravidity: Emergent: 3±4 Prophylactic: 4±4 Mean no of previous LSCS Emergent: 2±0.5 Prophylactic: 3±1 Mean gestational age at delivery (week) Emergent: 32 Prophylactic: 35 Estimated blood loss (in liters) Emergent: 5 Prophylactic: 2	Prophylactic REBOA placement (Prophylactic placement was defined as catheter placement prior to the start of the procedure in a hemodynamically stable patient)	Emergent REBOA placement (Emergent placement was defined as catheter placement in a hemodynamically unstable patient or in the setting of acute haemorrhage intraoperatively)	-	REBOA complications (N) Emergent: 3 Prophylactic: 0 Complications 1.Right iliac artery thrombus – 1 2.Right iliac artery dissection and thrombus -1 3. Right common femoral posterior wall laceration with right iliofemoral thrombosis -1 All three patients required inter-vention including thrombectomy with repair by vascular surgery. All three patients recovered without residual complications. The use of REBOA in these 3 emergent cases was subjectively felt to slow blood loss, allowing for completion of the hysterectomy and hemorrhage control. **Conclusion:** A multidisciplinary approach for the management of placenta accrete spectrum utilizing REBOA is feasible in the setting of both planned and emergent caesarean hysterectomy and can aid in the control of acute hemorrhage. The risk for vascular access site complications related to REBOA catheter placement is higher in the emergent setting compared to prophylactic placement.	

Evidence Table : Cost/Cost-effectiveness
Question : How cost-effective is the use of REBOA in adult trauma patients?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Renna MS, van Zeller C, Abu-Hijleh F et al. A one-year cost-utility analysis of REBOA versus RTACC for non-compressible torso haemorrhage. Trauma. 2019;21(1):45-54 **Country** UK	Economic evaluation **Objective** To perform a one-year cost–utility analysis of REBOA as an intervention for patients with major traumatic non-compressible torso haemorrhage (NCTH) above the aortic bifurcation within the abdomen compared to resuscitative thoracotomy with aortic cross-clamping (RTACC) -A retrospective analysis of the outcomes following REBOA and RTACC was conducted based on the published literature of survival and complication rates after intervention. -Utility was obtained from studies that used the EQ- 5D index and from self-conducted surveys. Costs were calculated using 2016/2017 National Health Service tariff data and supplemented from further literature. -A cost–utility analysis was then conducted. **Model** The **decision tree** for patients undergoing REBOA was designed by primarily using data from 2 studies ; Morrison et al and Rhee et al. **Perspective** Health system (NHS) **WTP of NHS**: £20,000–£30,000 **Discounting** No discounting was performed **Time horizon** I year	-	**Population:** Patients with major traumatic non-compressible abdominal haemorrhage 12 studies for REBOA and 20 studies for RTACC were included. <u>Mean injury severity scores</u> RTACC 34 REBOA 39	REBOA	RTACC (current gold standard)	**-**	-The ICER of REBOA when compared to RTACC was £44,617.44 per quality-adjusted life year. -The ICER, by exceeding the National Institute for Health and Clinical Effectiveness's willingness-to-pay threshold of £30,000/quality-adjusted life year, suggests that this intervention is not cost-effective in comparison to RTACC. -However, REBOA yielded a 157% improvement in utility with a comparatively small cost increase of 31.5%.	

Evidence Table : Organisational (Training)
Question : What is the organizational issue related to the use of REBOA?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Engberg M, Taudorf M, Rasmussen NK et al. Training and assessment of competence in resuscitative endovascular balloon occlusion of the aorta (REBOA) - a systematic review. Injury. 2020;51(2):147-156.	Systematic review **Objective** To report and evaluate research in training and assessment of competence in REBOA and femoral arterial access (FAA) with the aim to investigate the effect of simulation-based training in the procedure **Inclusion criteria** All studies on the effect of simulation-based training of REBOA and FAA on procedural competence which contained a hands-on element in the form of a simulator, animal-, or cadaver model.	I	16 studies were included with 546 participants (12 studies on REBOA and 4 studies on FAA) <u>Sample size</u>: 2-280 participants <u>Type of study design</u> -Pre-test/post-test (7 studies) -RCT (1 study) -Non-randomised study (1 study) -Cross-sectional (7 studies) <u>Type of participants</u> - Surgical and non-surgical physicians on minimum resident level (11 studies) - Medical students (3 studies) - Military non-physician medical personnel (2 studies) <u>Outcome measures</u> - Procedural time (8 studies) - Test of knowledge (6 studies) - Observer rating (6 studies) - Self-evaluated confidence (4 studies)	REBOA training models <u>Training model</u> - Mentice VIST virtual reality endovascular simulator (8 studies) - Live porcine model (3 studies) - Perfused human cadavers (2 studies) - Silicone/plastic physical models (6 studies) <u>Educational interventions</u> 1. 'BEST' 1-day course of didactic sessions and simulator training 2. EVTM' workshop: A didactic session, including animation video, and individually given instructions at the porcine model 3. ESTARS' 2-day course of didactic sessions and simulator training	Each other	-	-3 studies examined the effect of 6 consecutive procedures performed on a simulator, all with a significant decrease in procedural time. -4 studies found evidence to support improvement in knowledge test scores after training intervention. -1 feasibility study demonstrated that an extensive simulation-based training portfolio enabled 2 physicians without previous endovascular experience to perform REBOA on perfused human cadavers in austere environments, but cut-down technique was required in 50% of cases. -1 multicentre study on FAA found that residents who received an instructed simulation session prior to rotation in an invasive cardiology unit decreased the number of procedures needed to reach proficiency from 20 to 10 ($p<0.01$) compared to a previous cohort of residents. A decrease in complication incidence from 4.5% to 2.1% was also noted ($p<0.01$). -1 study reported on REBOA performance in the clinic after simulation-based training. The clinical REBOA procedural time for 28 physicians did not differ from procedural time on a virtual reality simulator (mean 310 s vs. 277 s, $p>0.05$), **Conclusion:** Simulation-based training of REBOA improves skills	

Evidence Table : Organisational (Training)
Question : What is the organizational issue related to the use of REBOA?

Bibliographic citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristics	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
Hatchimonji JS, Sikoutris J, Smith BP et al. The REBOA Dissipation Curve: Training Starts to Wane at 6 Months in the Absence of Clinical REBOA Cases. J Surg Educ. 2020;30:30 **Country** USA	Pre and post-intervention study **Objective** To evaluate REBOA-specific knowledge following formal training course and long-term durability -A comprehensive REBOA course was developed including didactics and hands-on practical simulation training. -Baseline knowledge and comfort were assessed with a precourse objective test and a subjective self-assessment using 5-point Likert scales. -REBOA knowledge and comfort were then re-assessed immediately postcourse and again at 6 months and 1 year. **Study site:** Urban Level I trauma center.	II-3	13 participants <u>Type of participants</u> -10 trauma surgical faculty members -3 fellows.	REBOA Education for Shock Trauma Acute ResusciTation (RE-START) - 4 hours course - Interactive didactics with hands-on practical training using a 7Fr introducer kit and both a vascular access trainer and a REBOA-specific training mannequin. <u>Type of assessment</u> 1. Objective knowledge questions were categorized into the following subsets : Background, Technique, and Case-based. 2. Self-assessment measures included comfort with ultrasound-guided femoral arterial line (a-line) placement and REBOA deployment.	-	6 months and 1 year	-The scores improved significantly from precourse (72%±10% correct) to postcourse (88% ± 8%, $p < 0.001$). At 6 months, scores remained no different from postcourse ($p = 0.126$); at 1 year, scores decreased back to baseline ($p = 0.024$ from postcourse; 0.285 from precourse). -Subjective comfort with femoral arterial line placement and REBOA improved with training ($p=0.044$ and 0.003, respectively). Femoral arterial line comfort remained unchanged from postcourse at 6 months ($p = 0.898$) and 1 year ($p=0.158$). However, subjective comfort with REBOA decreased relative to postcourse levels at 6 months ($p=0.009$), driven primarily by participants with no clinical REBOA cases in the interim. **Conclusion** A formal REBOA curriculum improves knowledge and comfort with critical aspects of this procedure. This knowledge persists at 6 months, though subjective comfort deteriorated among those without REBOA placement in the interim. REBOA refresher training should be considered at 6-month intervals in the absence of clinical REBOA cases.	

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