EVIDENCE REPORT

Resuscitative endovascular balloon occlusion of the aorta in NSW trauma

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Contents

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Resuscitative endovascular balloon occlusion of the aorta in NSW trauma

Executive summary

Severe injury remains one of the most important preventable causes of death and long-term disability in the community. Haemorrhage is responsible for over 40% of trauma deaths within the first 24 hours. Non-compressible torso haemorrhage is particularly challenging to manage and often fatal.

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a procedure that involves placement of an endovascular balloon in the aorta to temporarily control non-compressible torso haemorrhage. It offers a potential solution to bridge a patient with critical torso haemorrhage to definitive haemorrhage control.

Despite increased use of REBOA over the last decade and recent endovascular technology advancements, there is insufficient high-level evidence on its effectiveness for improving mortality in trauma.

This document aims to provide:

1. A rapid evidence review on REBOA use in Trauma.
2. A NSW gap analysis assessing potential REBOA cohort.
3. Insights and next steps on the potential use of REBOA in NSW.

The following key findings in the **evidence review** are outlined in this report:

- Although evidence suggests REBOA has positive effects on systolic blood pressure (SBP) and possibly on other clinical endpoints, there is currently insufficient high-level evidence to show benefit on survivability. Uncertainty around which patient cohort is likely to benefit from REBOA remains unanswered. The Trauma Innovation Committee (TIC) recommends further research to ascertain the true survivability benefit in trauma patients.
- There is currently no high grade evidence defining the specific indications to attain a standardised approach for REBOA in trauma. TIC recommends further research to identify the optimal patient group and where and when REBOA is best implemented.
- There is currently insufficient evidence to understand the full extent of complications associated with REBOA. REBOA is potentially a high-risk procedure requiring a balanced approach when implementing; weighing up potential complications versus the benefits on a case-by-case basis.
- An in-hospital REBOA program requires a rigorous framework addressing; governance, guidelines and policies, training and skill maintenance programs, allocation and coordination of roles and responsibilities.
- A REBOA program in NSW is likely to be the remit of a major trauma centre (MTC) under research conditions. A regional trauma centre (RTC) could be considered but would face several challenges and may currently be difficult to justify.

- A prehospital cohort who could benefit from REBOA in NSW is undefined. TIC recommends a prehospital NSW gap analysis be conducted with a focus on metropolitan regions. The gap analysis would firstly examine if a patient subgroup exists; and secondly explore the potential viability for a prehospital REBOA program.
- A prehospital REBOA program requires an 'all of system approach' including receiving trauma centres with an established REBOA program. Balloon inflation to definitive treatment time within the acceptable time windows may prove challenging in the prehospital context.
- The activation and implementation of REBOA requires leadership from very senior clinicians (ideally the clinician responsible for providing definitive haemostasis). REBOA can be inserted in the emergency department (ED), interventional radiology (IR) and operating theatres (OT). It should be inserted by senior clinicians who have had the necessary training, including emergency physicians, interventional radiologists, anaesthetists, vascular surgeons, trauma surgeons or intensive care unit (ICU) consultants.

The following key findings of the NSW **gap analysis** include:

- A total of 220 in-patients over a five year period were possibly eligible for REBOA.
- Potential gaps in arresting torso haemorrhage are suggested in the evidence; mortality rate of 26% (n=58) with the majority (63%) of these patients dying in the ED or OT. This likely translates to 63% of deaths occurring before or during attempts to gain haemorrhage control. REBOA may be indicated in these cases.
- The mortality rate is relatively small (n=58) and distributed amongst multiple trauma centres for patients who could be considered for REBOA. TIC believes this small number and distribution may be challenging to justify a sustainable program.

The following insights and next steps for NSW trauma clinicians to consider are outlined in this report:

- TIC does not support a broad roll out of REBOA programs across NSW trauma centres.
- TIC cautiously supports the establishment of a limited in-hospital REBOA program; likely to be the remit of a level 1 trauma centre, strategically located which could accommodate future prehospital REBOA referrals if required.
- Any future REBOA program is to be conducted under prospective research conditions.

Introduction

In Australia, injury is a leading cause of death, illness, and disability.[1] Haemorrhage is responsible for over 35% of prehospital deaths, and over 40% of deaths within the first 24 hours.[2] Non-compressible torso haemorrhage is both occult and not amenable to control by direct pressure. As a result, it is particularly lethal.[3]

REBOA is a procedure that involves placement of an endovascular balloon in the aorta to obtain proximal control of haemorrhage. It is considered an adjunct for non-compressible torso haemorrhage.

REBOA was originally described in the 1950s.[4] Due to the high complication rate, REBOA was not widely described in the literature until the late 2000s.[5] Trauma specialists worldwide have revisited REBOA with the advancements in endovascular technology.[6] Despite insufficient evidence to show a survival benefit,[7] worldwide REBOA use has been increasing over the last 10 years.[8,9]

With the renewed interest in REBOA, this document aims to provide the current evidence and insights and next steps to NSW trauma clinicians in relation to potential REBOA use for trauma.

Document structure

There are three main components in this review:

1. Examination of the current worldwide evidence on REBOA, addressing a series of questions. These questions were developed and agreed on by the TIC and the NSW Institute of Trauma and Injury Management (ITIM).
2. A gap analysis identifying a potential cohort within the NSW trauma system who could benefit from REBOA.
3. Insights and next steps for NSW trauma clinicians to consider on the potential use of REBOA in the NSW trauma system based on analysis of points 1 and 2 noted above.

Who is this document for?

This document is designed for NSW senior clinicians and leaders who manage frontline major trauma and are considering REBOA as part of their major haemorrhage control strategy within their units.

How was this document designed?

Question design

The TIC met both in and out of session to discuss and designed several areas applicable to REBOA and its use in trauma especially in the NSW context. These areas are:

- evidence of REBOA improving trauma outcome
- type of trauma patients REBOA could be used on
- who can and who should use REBOA
- using REBOA.

These questions became the basis of the literature search and body of this review.

Search methodology

Literature was attained in May 2020 by searching the PubMed database, using the following search terms; 'REBOA' and 'Resuscitative Endovascular Balloon Occlusion of the Aorta'. The combined search terms yielded 460 articles. Limiting them to the last 10 years resulted in 395 articles. Further filtering to include trauma was performed.
10 systematic reviews and 10 other evidence-based reviews were used in the formation of this review.

Other articles are included by the TIC authors that were not part of the initial search, these are in the reference section.

NSW gap analysis

Gap analysis methodology involved the extraction of NSW trauma data via the NSW Trauma Registry by applying specific clinical metrics (i.e. systolic blood pressure less than 90mmHg on admission) and Abbreviated Injury Scale (AIS) codes according to injury types where REBOA could be applied. The criteria and AIS codes used a similar design format to the Scottish and English/Wales studies.[10] The criteria and format can be found in **Appendix 1**.

Insights and next steps for NSW trauma clinicians to consider

The TIC considered the evidence from the rapid evidence review and NSW gap analysis in their monthly committee meetings and out of session discussions to articulate insights and next steps for NSW clinicians regarding potential use of REBOA in the NSW trauma system.

Evidence review

Evidence of REBOA improving trauma outcome

Effects on systolic blood pressure (SBP) and other clinical endpoints

The following articles reported on the effect of REBOA on systolic blood pressure (SBP) and other clinical endpoints.

Effect of REBOA on systolic blood pressure and other clinical endpoints	Evidence source
In a systematic review and meta-analysis examining multiple patient groups (i.e. truncal and junctional trauma, ruptured abdominal aortic aneurysm (rAAA), post-partum haemorrhage (PPH)) REBOA showed significant increase in SBP with a mean increase of 78.9mmHg in trauma patients, rAAA 56.1mmHg and 52.4mmHg for other patient groups.	Van der Burg[11]
A systematic review reporting on data on hemodynamic profile and mortality in human subjects with multiple conditions (i.e. PPH, trauma, abdominal aortic aneurysm (AAA)) examined; SBP before and after REBOA, with a mean increase of SBP 53mmHg post REBOA.	Morrison[12]
Systematic review reporting on trauma patients receiving REBOA reports on 12 articles examining SBP before and after REBOA. All demonstrated statistically significant increases.	Petrone[9]
In the porcine model, Chaudery reports on the comparative impact between REBOA to resuscitative thoracotomy and aortic clamping. Physiologic impact of haemorrhage with REBOA was less than with thoracotomy (pH 7.35 for REBOA vs. 7.24 for thoracotomy; lactate of 4.27 for REBOA vs. 6.55 for thoracotomy), with less fluid (667mL for REBOA vs. 2,166mL for thoracotomy) and norepinephrine support (0 µg for REBOA vs. 52.1µg for thoracotomy).	Chaudery[13]
Summary of evidence All articles that reported on the effect of REBOA on SBP and other clinical endpoints stated that REBOA significantly increased systolic BP (human) and improves clinical endpoints as demonstrated in the animal model.	

Mortality

The following articles reported the effect of REBOA on mortality.

REBOA on mortality	Evidence source
In a systematic review and meta-analysis reporting on clinical use of REBOA in patients with hemodynamic instability noted; REBOA carries a risk difference of 0.27 (0.14–0.49) in mortality (favouring REBOA) compared with the mortality of patients treated with other means.	Van der Burg[11]
Meta-analysis comparing REBOA to open cross clamping by resuscitative thoracotomy in non-compressible torso haemorrhage patients report no survival odds improvement for REBOA compared with thoracotomy. Although sensitivity analyses showed consistent results on the positive effect of REBOA on mortality compared to resuscitative thoracotomy.	Manzano Nunez[14]
A systematic review reporting on patient mortality data reveals no change in mortality between REBOA and controls. They add, "*the evidence base is weak with no clear reduction in haemorrhage-related mortality demonstrated*".	Morrison[12]
A systematic review analysing REBOA in trauma reports; direct REBOA-related complications seem to have a minor role on mortality.	
Gamberini also noted a study comparing REBOA to resuscitative thoracotomy deaths reporting, "deaths of patients with REBOA appear to be delayed and typically occur when the patient is already out of the emergency department and due to complications other than bleeding".	Gamberini[15]
Analysis of observational prospective data comparing the mortality between adult patients who received REBOA with those who did not from Japan concluding, "*REBOA treatment is associated with higher mortality compared with similarly ill trauma patients who did not receive a REBOA*". They added, "*this higher mortality rate may signal 'last ditch' efforts for severity not otherwise identified in the trauma data*".	Norii[16]
Case-control retrospective analysis examining the outcomes in trauma patients after REBOA placement reported; REBOA in severely injured trauma patients was associated with a higher mortality rate compared with a similar cohort of patients with no placement of REBOA. They concluded, "*there is a need for a concerted effort to clearly define when and in which patient population REBOA has benefit*".	Bellal et al[17]
Systematic review reporting on trauma patients receiving REBOA - 12 articles reviewed examining complications from REBOA insertion - reported no procedure-specific mortality.	Petrone[9]
An opinion piece discussing the role of REBOA in the control of exsanguinating torso haemorrhage concluded; patient outcomes including mortality may be influenced by several factors including patient selection, operator skill and trauma decision-making experience.	Biffl[18]

Summary of evidence

The literature is mixed regarding the effects of REBOA on mortality. Currently, there is insufficient high-level evidence on REBOA's effectiveness for improving mortality outcomes in trauma. This is consistent with Bulger's[19] position and a report from; the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP); "*There is no high-grade evidence demonstrating that REBOA improves outcomes or survival compared with standard treatment of severe traumatic haemorrhage*". Uncertainty around which patient cohort is likely to most benefit (i.e. survival benefit) from REBOA remains a fundamental question; identifying the optimal patient group, where and when REBOA is implemented are some crucial questions, when answered, may provide greater clarity. TIC recommends further prospective studies are necessary to understand the role of REBOA in torso haemorrhage in trauma and which patient group is likely to benefit from REBOA intervention.

Complications of REBOA

Complications of REBOA	Evidence source
Reported in a case-control retrospective analysis of 420 patients (the REBOA group, 140 patients non REBOA group 280); patients in the REBOA group had higher rates of acute kidney injury (15 [10.7%] vs 9 [3.2%]; P=.02) and lower leg amputations (5 [3.6%] vs 2 [0.7%]; P=.04).	Bellal et al[17]
Gamberini systematic review on REBOA in trauma reported on REBOA complications by type of complication (all <1%) however, there was no overall analysis. Most complications are limited to local vascular injuries. Large REBOA introducers (i.e. size 10-12Fr) contributed to ischemic complications that led to lower limb amputations in patients with a smaller build. A 7Fr catheter is now available with reports of reduction in complications coupled with 100% technical success.	Gamberini[15]
Manzano-Nunez's meta-analysis examining the complications from groin access in REBOA. (Includes 13 studies with 424 patients); complications related to groin access was 4-5%.	Manzano-Nunez[14]
Systematic review of REBOA in trauma. 17 articles, total patient numbers 1,340. Reporting two collective case series resulting in 2.4% presented with clinical complications (n=32). Analysis of complications: • 1.8% femoral artery thrombosis (n=9) • 0.8% limb ischemia (n=4) • 0.8% vascular injury (n=4) • 1.2% distal emboli (n=6). Concluding comment from author, "*Although the rate of complications is low, the probability of limb amputation should not be taken lightly*".	Petrone[9]
Biffl et al opinion piece discussing the role of REBOA in the control of exsanguinating torso haemorrhage concluded, "*REBOA is associated with significant risks due to complications of vascular access and ischemia-reperfusion*".	Biffl et al[17]
A review of literature and consensus piece that reports on complications related to REBOA noted that reports are limited to small retrospective case series, propensity analyses, and animal studies only.	Davidson et al[20]
Morrison's systematic review reporting on data on hemodynamic profile and mortality in human subjects with multiple conditions (i.e. PPH, AAA, trauma) reports of episodes of device-related morbidity, including an aortic injury, femoral arterial complications, and balloon-related embolic events stating, "*The overall* rate of morbidity within the reporting literature is 3.7% (14 complications in a population of 381)*".	Morrison[12]

* Note, this systematic review examined "all patient type" including PPH, AAA, and surgical resection of pelvic tumours.

Summary of evidence

REBOA is potentially a high-risk procedure that carries a range of possible iatrogenic injuries (including life and limb events). Although the REBOA complication rate appears relatively low as reported in the literature, there is limited evidence to sufficiently understand the full extent of complications. Further evidence is required to understand the true complication rate of REBOA. Clinicians need to consider the potential risks (i.e. loss of limb) against potential benefits (i.e. saved life) on a case-by-case basis if implementing REBOA.

Indications for REBOA use

The TIC examined the literature for criteria and potential triggers for REBOA implementation including clinical indications and clinical metrics.

Clinical conditions for REBOA

Clinical indications	Evidence source
Traumatic life-threatening haemorrhage below the diaphragm in patients in haemorrhagic shock who are unresponsive or transiently responsive to resuscitation.	Van der Burg[11]
Cardiac arrest from injury due to presumed life-threatening haemorrhage below the diaphragm.	Van der Burg[11]
The balloon catheter may be inflated at the distal thoracic aorta (zone 1) for control of severe intra-abdominal or retroperitoneal haemorrhage, or those with traumatic arrest.	Van der Burg[11] Brenner et al[21]
The balloon catheter may be inflated at the distal abdominal aorta (zone 3) for patients with severe pelvic, junctional, or proximal lower extremity haemorrhage.	Van der Burg[11]
There is no high-grade evidence defining the specific indications for the use of REBOA for trauma.	Cannon[22] Marciniuk[23]

Clinical indications – trigger points

Clinical metrics	Values	Evidence source
Systolic blood pressure	<90 mmHg	Gamberini[15] Morrison[12] Brenner et al[21]
Heart rate	>120bpm	Gamberini[15]
Critical clinical deterioration	Pre-arrest state	Gamberini[15]
Cardiac arrest	CPR <15 minutes in the setting of penetrating trauma	Gamberini[15] Morrison[12]
Response to volume resuscitation	Partial or no response	Gamberini[15] Morrison[12] Brenner et al[21]
Focused assessment with sonography in trauma (FAST)	Positive* FAST	Gamberini[15] Brenner et al[21]

* Can have false negative rate.

Summary of evidence

There is no high-grade evidence defining the specific indications for the use of REBOA for trauma.

Contraindications for REBOA use

Contraindications for REBOA	
• Pulseless electrical activity (PEA) arrest >10minutes* • Thoracic vascular injury resulting in haemorrhage** • Proximal aortic dissection • Cardiac tamponade • Presence of a severe pre-existing illness or comorbidity.	Norii[16]
* Some literature states >15 minutes.	Cannon[22]
** Marciniuk strongly recommends a chest X-Ray to rule out thoracic bleeding as the source of bleeding.	Marciniuk[23]

Requirements for a REBOA program

The literature suggests some essential requirements within a mature trauma system if a REBOA program is to be considered.

Framework principles in setting up a REBOA program	Evidence source
REBOA is considered a tool that should only be employed as part of a larger system of damage control resuscitation, it is not a definitive treatment.	Ball[6]
The trauma centre with established services to manage definitive trauma treatments (i.e. 24/7 IR, vascular surgery, ICU) is the likely place for a REBOA program.	Biffl et al[18]
A REBOA program requires a multidisciplinary approach, with necessary health infrastructure such as surgical, radiology theatre and theatre staff, cut-down trays available 24/7.	Ball[6] Zakaluzny[24]
Time from REBOA insertion and balloon inflation to definitive haemorrhage control is extremely time limited. Patients must have access to definitive surgical control of haemorrhage within 15-30mins (zone 1) or 30-60mins (zone 3). Total aortic occlusion times greater than described is associated with increased ischemic complications and risk of mortality.	Bulger[19]
Training requirements	
Physicians who perform REBOA should be credentialed and have completed a recognised course.	Engberg et al[25]
Manzano-Nunez recommended all physicians should complete an endovascular course and undergo mentoring by a REBOA experienced physician to practice.	Manzano-Nunez[14]

Summary of evidence

An in-hospital REBOA program requires a rigorous framework and a trauma centre which addresses the following:

- high volume surgical and radiological services with the ability to provide 24/7 rapid (30-60mins) definitive haemostasis
- definitive haemostasis for zone 1 and 3 placement
- other aspects of related downstream clinical care (i.e. ICU)
- a REBOA policy, guidelines and governance in place
- multidisciplinary allocation of roles and responsibilities
- initial and ongoing training for its staff.

A REBOA program in NSW is likely to be the remit of a MTC that contain the abovementioned points. However, some strategically placed RTCs could be considered if they can provide all components necessary for a REBOA program. TIC acknowledges significant challenges in establishing and maintaining a RTC REBOA program due to factors such as low patient numbers requiring REBOA and training requirements to maintain skills.

Note on prehospital REBOA

- If a prehospital REBOA program is to be considered, it would require an 'all of system approach'. This would include a seamless process between the prehospital team or organisation and the designated receiving trauma centre(s) with an established 24/7 REBOA program.
- Balloon inflation to definitive treatment time within the above-mentioned time window may prove challenging in the prehospital context.

Technical aspects of REBOA

Who decides to insert REBOA?	Evidence source
Within a healthcare facility, the treating surgeon responsible for definitive haemostasis should decide when and in which zone the balloon gets inflated.	Bulger[19]

Who can insert the sheath and REBOA?	Evidence source
Senior emergency physicians, interventional radiologists, anaesthetists, vascular surgeons or ICU consultants can all be considered to prepare and insert the REBOA sheath, provided they have had the necessary training.	Bulger[19] Zakaluzny[24]
REBOA should only be placed by a surgeon or interventionist who is responsible for definitive haemorrhage control. REBOA insertion can also be considered by someone who is trained and qualified in consultation with the person who does perform definitive haemorrhage control.	Bulger[19]
Manzano-Nunez analysed 12 studies, revealing insertion was performed by trauma surgeons and Fellows of the Australasian College of Emergency Medicine (FACEMS).	Manzano-Nunez[14]
REBOA should be performed by an acute care surgeon or an interventionist (vascular surgeon or interventional radiologist) trained in REBOA.	Long[26]
Emergency medicine (EM) physicians with added certification in critical care (EMCC) training in REBOA may train and perform REBOA, if the surgeon(s) is/are immediately available to definitely control the focused source of bleeding.	Long[26]

Insertion setting?	Evidence source
Where insertion occurs is not vital (i.e. ED vs OT vs IR) provided the hospital has an agreement and guidelines in place. Most studies state insertion occurs in ED or OT.	Holcomb[27]

Summary - who can or should use REBOA?
Evidence in the literature suggest that the decision to activate REBOA needs to come from very senior clinicians (ideally the clinician responsible for providing definitive haemostasis). REBOA can be inserted in the ED, IR and OT by senior clinicians who have had the necessary training. This includes: emergency physicians, interventional radiologists, anaesthetists, vascular surgeons, trauma surgeons or ICU consultants. Training in REBOA, policy, guidelines and governance are a vital part in establishing and maintaining a hospital based REBOA program.

Using REBOA

When to implement REBOA – early versus late

The literature does not specifically define timeframes for when REBOA should be deployed. However, a number of studies[22,26] recommend early placement of REBOA in patients who potentially could benefit. A proactive, rather than reactive approach is likely to be better for these patients (i.e. placement of a catheter in preparation for use in the cases with severe injuries not in arrest or profound shock). This cohort of patients has critical bleeding with a window to prevent deaths mostly occurring very early[27] (i.e. within 60 minutes of injury). This suggests that the greatest benefits from REBOA could be in the prehospital cohort.

The evidence could be translated to the following practical approach. A patient with injuries and clinical metrics potentially meeting REBOA criteria could have a femoral sheath inserted with the following potential actions depending on the clinical condition of the patient as per table below.

Staged approach with REBOA insertion

Clinical condition	Potential action	Evidence source
Severe shock	Insert REBOA and inflate balloon.	Vernamonti[28]
Transient responder	Insert REBOA, no inflation.	
Not in shock	No REBOA catheter but sheath is inserted and ready to go*.	
	*Arterial access allows other potential uses i.e. interventional radiology and arterial monitoring.	

Recommended approach – insertion site and catheter/introducer size

Insertion site and catheter/introducer size	Evidence source
Much of the literature advocates access to the femoral artery for REBOA insertion (98.8%).	Barnard[10] Norii[16] Bellal et al[17] Biffl[18]
The assisted percutaneous approach including the use of ultrasound-guided approach, is recommended due to lower complication rate compared to open or blind approach.	Barnard[10] Manzano-Nunez[14]
Large REBOA introducers (i.e. size 10-12Fr) contributed to ischemic complications that led to lower limb amputations in patients with a smaller build. A 7Fr catheter is now available with reports of reduction in complications coupled with 100% technical success.	Gamberini[15]
Note: Currently in Australia, the ER-REBOA catheter is the only licenced REBOA device available, which is designed for femoral access only.	
Summary of evidence Current evidence suggests the preferred REBOA insertion occurs under ultrasound guidance via the common femoral artery contralateral to the side of injury (if possible) using a smaller catheter/introducer (i.e. 7Fr) if available.	

Zones - indications for zone placement and inflation times

Zone (anatomical location)	Indication for zone placement	Inflation times
Zone 1		
Extends from the origin of the left subclavian artery to the coeliac artery.[15]	Indicated for intra-abdominal haemorrhage due to blunt trauma or penetrating torso injuries.[(29)] Used for control of severe intra-abdominal or retroperitoneal haemorrhage.[24]	Zone 1 REBOA placement should not be used if patients cannot proceed to definitive haemorrhage control procedure within 15 minutes. Total aortic occlusion times greater than 30 minutes are associated with increased ischemic complications and risk of mortality.[14] Chudery[13] reports in their comparative impact between REBOA to resuscitative thoracotomy and aortic clamping in the animal model; 40 minutes of ischemia time (i.e. REBOA balloon inflation) was identified as the safe threshold.
Zone 2		
Extends from the coeliac artery to the most caudal renal artery.[15]	Zone 2 is rarely chosen and considered as a no occlusion zone as it involves direct obstruction of visceral arteries.[15 10]	N/A
Zone 3		
Extends distally from the most caudal renal artery to the aortic bifurcation.[15]	Suspected pelvic fracture and isolated pelvic haemorrhage and uncontrolled haemorrhage from a junctional vascular injury.[24]	Zone 3 REBOA may be tolerated for longer periods of time than Zone 1.[24] Maximum acceptable occlusion time for Zone 3 is unknown, however targets of less than 30 minutes and no greater than 60 minute occlusion time is highly desirable.[24]

General principles on inflation times

Gamberini states that an ideal time of occlusion has not been established, although it is clear that it must be as short as possible.[15]

A maximum of 20 minutes inflation time has been suggested as the gold standard.[15]

Some evidence suggests that occlusion time was shorter in survivors than in patients who died.[29]

Summary of evidence

Zone 1 and 3 are potentially suitable for REBOA placement, respective to the above indications. Zone 2 placement is not recommended. Inflation times are of critical importance with swift transfer to definitive treatment:
Zone 1 <30 minutes and Zone 3 <60 minutes. Times greater than these risk higher mortality and morbidity.

Full vs partial inflation vs intermittent

The concept of extending the potential window of REBOA inflation time by inflating the REBOA balloon intermittently (iREBOA) or partially (pREBOA) is described conceptually in animal studies[30] with one case report in a human.[31] Manzano-Nunez states, "*there is insufficient data to recommend intermittent inflation*"[14] *and Johnson et al states, "there is no evidence to support these (i/pREBOA) techniques*".[32]

Summary of evidence
Although the concept of extending REBOA placement is appealing by either applying iREBOA or pREBOA, there is insufficient evidence to recommend these techniques. Note: pREBOA and iREBOA would require blood pressure monitoring proximal and distally to the balloon which is technically difficult to achieve with available technology. Currently ER-REBOA (only device TGA approved in Australia) only monitors proximally to the balloon therefore clinicians will have to place an art line in contralateral femoral artery in order to measure BP.

Ongoing management and care

Some literature discusses the importance of ongoing and post insertion care. Manzano-Nunez suggests REBOA guidelines should include routine extremity care and monitoring during sheath removal and post resuscitation care must be in place in a REBOA program.[14]

Financial costs of REBOA

When considering the true costs of REBOA each trauma service needs to consider the following:

- cost of the ER-REBOA device – current cost AU$5,950 (expiry date three years)[33]
- training and maintaining skills costs
- guideline and policy development.

However, the costs of setting up a REBOA program may have potential cost-offsets in the following areas:

- reduced blood product usage
- reduced costs and occupational risks related to resuscitative thoracotomy and aortic clamping
- the potential of life saved and reduced disability especially if or when patient selection is further refined.

NSW trauma gap analysis

A rapid gap analysis was performed by analysing data from the NSW Trauma Registry. A focus on potential patient cohorts eligible for REBOA indications were considered (refer to Appendix 1). Previous and similar gap analysis criteria[10] were considered and adopted for this gap analysis, including AIS codes, clinical metrics, inclusion and exclusion criteria (i.e. death due to isolated head injury AIS >3 were removed).

Limitations

The data used in this gap analysis is in-hospital data only. Prehospital data was not in scope in this review. Further consideration regarding the potential benefits of REBOA in the prehospital domain is worth exploring into the future.

Summary

The following points from the gap analysis can be surmised:

- During 2013-2018, there were 19,514 number of trauma admissions with 220 theoretical REBOA candidates.
- Most patients arrived direct from the prehospital scene (76%) compared to transfer from another acute care facility (24%).
- A decreasing trend in patient admissions over the five-year period was noted. 2015 had 55 patients, 2018 had 31 patients.
- Most patients were male (n159=72%).
- 65% of patients were admitted to a MTC vs 30% at a RTC.
- 41% patients underwent laparotomy.
- The overall mortality rate was 26% (n=58).
- Location (i.e. facility department) of death; 41% of patient die in the ED, 22% in OT, 24% ICU and 1.7% in angio suite.
- John Hunter and Royal North Shore hospitals received the highest number of patients over the time period.
- 63% of deaths occurred in ED and OT collectively.

Discussion

One question requiring an answer; is there a potential gap for which REBOA may benefit the NSW Trauma system and its patients? The data would suggest there are potential gaps in arresting torso haemorrhage with a mortality rate of 26% (n=58) with the majority (63%) of these patients dying in the ED or OT. This likely translates to 63% of deaths occurring before or during attempts to gain haemorrhage control. However, some caveats need to be applied.

- The mortality rate needs to be put into the context of relatively small numbers (i.e. n=58 out of 19,514 trauma patients over a five-year period) distributed over multiple NSW trauma centres.
- REBOA is not recommended to bridge systemic gaps in the provision of definitive care. REBOA should not be used to compensate for systematic inefficacies within a trauma facility (i.e. gaps in service provision such as acceptable door to scalpel times). Each trauma facility needs to address any reasonable abovementioned gaps before considering introducing a REBOA program.

With the majority of 'potential REBOA' cases occurring in MTC at 65%, from the reviewed literature the MTC would appear to be the most appropriate place to locate a REBOA program. Centres that see high volumes of this type of trauma could be considered to introduce a REBOA program.

Comment on the prehospital context

The in-hospital eligible REBOA cohort (n=220) indicates there may be many other prehospital patients who die at the scene or en-route to hospital. Considering the majority of traumatic haemorrhage deaths occur in the prehospital setting,[12] the greatest cohort to potentially benefit from REBOA could be the prehospital patient. TIC strongly recommends a prehospital gap analysis be conducted to further understand the potential for REBOA in the field.

Insights and next steps

TIC has considered the current literature and NSW gap analysis. Based on the limited high-level evidence for REBOA use in trauma and emerging potential benefits, TIC suggests NSW trauma clinicians consider the following points.

- TIC does not support a broad roll out of REBOA programs across NSW trauma centres.
- TIC cautiously supports the establishment of an in-hospital REBOA program with the following caveats:
  - Any future REBOA program is to be conducted under prospective research conditions.
  - A REBOA program is likely suited to the remit of a level 1 trauma centre, strategically located with a relatively high volume of patient types with injuries where REBOA is indicated; and who could accommodate future prehospital REBOA referrals if required.
  - A REBOA program could be considered in a RTC noting that several previously mentioned challenges will need to be overcome.
  - A REBOA program requires a well-established indication-criteria framework based on the current available evidence with regular periodic revisions when further evidence becomes available.
  - A REBOA program requires a rigorous framework addressing governance, guidelines, policies, training and skill maintenance programs with the allocation and coordination of roles and responsibilities across multidisciplinary staff.
  - Regarding REBOA activation, TIC recommends a proactive approach in gaining early vascular access for high-risk cases likely to require REBOA.
  - TIC recommends clinicians use a small gauge (7Fr) REBOA catheter/introducer to minimise risks to distal perfusion and other complications.
  - The decision to activate REBOA (i.e. balloon inflation) needs to come from a senior clinician and ideally the clinician responsible for providing definitive haemostasis.
- TIC does not recommend i/pREBOA until high level evidence supports the benefits of this practice.
- TIC does not recommend that REBOA is used to bridge systemic gaps in the provision of definitive care.
- TIC recommends further research in REBOA for the following areas:
  - understand the true mortality benefit in trauma patients
  - identify the optimal patient group and where and when REBOA is best implemented
  - understand the true complication rate associated with REBOA.
- TIC recommends a gap analysis be strongly considered in the prehospital patient cohort with a focus on metropolitan regions to examine:
  - REBOA appropriate patient subgroup
  - the potential viability for a prehospital REBOA program.

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Appendix 1: NSW gap analysis

Search Criteria

- In hospital data gained from the NSW Trauma registry
- Admission SBP <90mmHg
- Time range: 2013-2018
- Mortality included
- AIS codes inclusions and exclusions listed below.

Table 1: Inclusions

NSW Trauma Registry (Collector) data used in gap analysis.

AIS Code	Definition
516006.3	Abdominal injury – Penetrating with >20% blood loss by blood volume
510606.3	Abdominal injury skin/subcutaneous/muscle >20% blood loss by blood volume
510806.3	Abdominal injury – avulsion >20% blood loss by blood volume
520099.9	Vascular injury in abdomen
520299.4	Aorta, abdominal
520204.4	Aorta, abdominal – laceration; perforation; puncture
520206.4	Aorta, abdominal – minor involvement <20% blood loss
520208.5	Aorta, abdominal – major rupture >20% blood loss by blood volume
520408.5	Aorta, abdominal – celiac artery – major rupture >20% blood loss by blood volume
520608.4	Aorta, abdominal – Iliac artery – major rupture >20% blood loss by blood volume
521108.4	Aorta, abdominal – superior mesenteric artery – major rupture >20% blood loss by blood volume
520806.4	Abdominal – Iliac vein – major rupture >20% blood loss by blood volume
521206.4	Abdominal – vena cava - major rupture >20% blood loss by blood volume
521606.4	Abdominal – other named veins - major rupture >20% blood loss by blood volume
541626.4	Kidney > 1cm lac
541628.5	Kidney – hilum avulsion
541640.4	Kidney – rupture
541826.4	Liver – lac – burst injury – major
541828.5	Liver – parenchymal disruption >75%
541830.6	Liver – avulsion
541840.4	Liver – rupture

AIS Code	Definition
542026.4	Mesentery massive – avulsion
544226.4	Spleen – major devascularisation >25%
544228.5	Spleen – hilar disruption with total devascularisation
811001.4	Amputation partial/complete at hip
811010.5	Amputation partial/complete at hip bilateral
856162.4	Pelvic ring - # open
856163.4	Pelvic ring - # blood loss <20% by volume
856164.5	Pelvic ring - # blood loss >20% by volume
856171.4	Pelvic ring - # complete disruption of posterior arch and floor
856172.4	Pelvic ring - # complete disruption of posterior arch and floor < 20% blood loss
856173.5	Pelvic ring - # complete disruption of posterior arch and floor >20% blood loss
856174.5	Pelvic ring - # complete disruption of posterior arch and floor - open

Table 2: Exclusions

NSW Trauma Registry AIS codes excluded from this gap analysis:

121003	122803	122005	122605	122607	140212	140214	140216	140218	410606	410806	420299
420206	420208	420210	420212	420216	420218	42049	121003	122803	122005	122605	122607
140212	140214	140216	140218	410606	410806	420299	420206	420208	420210	420212	420216
420218	420499	420404	420406	420408	420800	421099	421004	421006	421008	421009	421499
421404	421406	421408	422004	422006	422008	420602	420604	420606	420608	421202	421204
421206	421207	421602	421604	421606	421802	421804	421808	422202	422204	422206	420404
420406	420408	420800	421099	421004	421006	421008	421009	421499	421404	421406	421408
422004	422006	422008	420602	420604	420606	420608	421202	421204	421206	421207	421602
421604	421606	421802	421804	421808	422202	422204	422206				

The following category without an AIS code was excluded from this gap analysis:

- death due to isolated head injury AIS >3 for head injury.

Table 3: Results

The below table demonstrates the progressive number of trauma cases from the NSW trauma registry when each inclusion criteria is applied.

Description	Number of cases
Total number from 1 July 2013-6 July 2018	19,514
Inclusion criteria: AIS codes as per Table 1	1,394
Inclusion criteria: AGE_YEARS > 13 & AGE_YEARS < 75	1,179
SBP <90 mmHg	220
Patients potentially eligible for REBOA is n=220.	

Table 4: Breakdown of NSW patient cohort group potentially eligible (n=220) for REBOA by year

Financial year	Overall (n=220)
2014	55 (25.0%)
2015	47 (21.4%)
2016	48 (21.8%)
2017	39 (17.7%)
2018	31 (14.1%)

Table 5: Patient cohort potentially eligible for REBOA (n=220) who died or survived and came from scene or transferred from another facility

System	Died (n=58)	Survived (n=162)	Overall (n=220)
Prehospital (direct from scene)	55 (94.8%)	113 (69.8%)	168 (76.4%)
Transfer from another acute care facility	3 (5.2%)	49 (30.2%)	52 (23.6%)

Table 6: Patient cohort potentially eligible for REBOA (n=220) who died or survived and either had laparotomy or not

Laparotomy	Died (n=58)	Survived (n=162)	Overall (n=220)
False	33 (56.9%)	96 (59.3%)	129 (58.6%)
True	25 (43.1%)	66 (40.7%)	91 (41.4%)

Table 7: Patient cohort potentially eligible for REBOA (n=220) who died or survived, male or female and either came from metro or rural area

	Female		Male		Overall	
Area	Died (n=14)	Survived (n=47)	Died (n=44)	Survived (n=115)	Died (n=58)	Survived (n=162)
Metro	8 (57.1%)	39 (83.0%)	34 (77.3%)	63 (54.8%)	42 (72.4%)	102 (63.0%)
Rural	6 (42.9%)	7 (14.9%)	9 (20.5%)	44 (38.3%)	15 (25.9%)	51 (31.5%)
Missing	0 (0%)	1 (2.1%)	1 (2.3%)	8 (7.0%)	1 (1.7%)	9 (5.6%)

Figure 1: Receiving hospitals for cohort potentially eligible for REBOA (n=220) either from metro or rural region

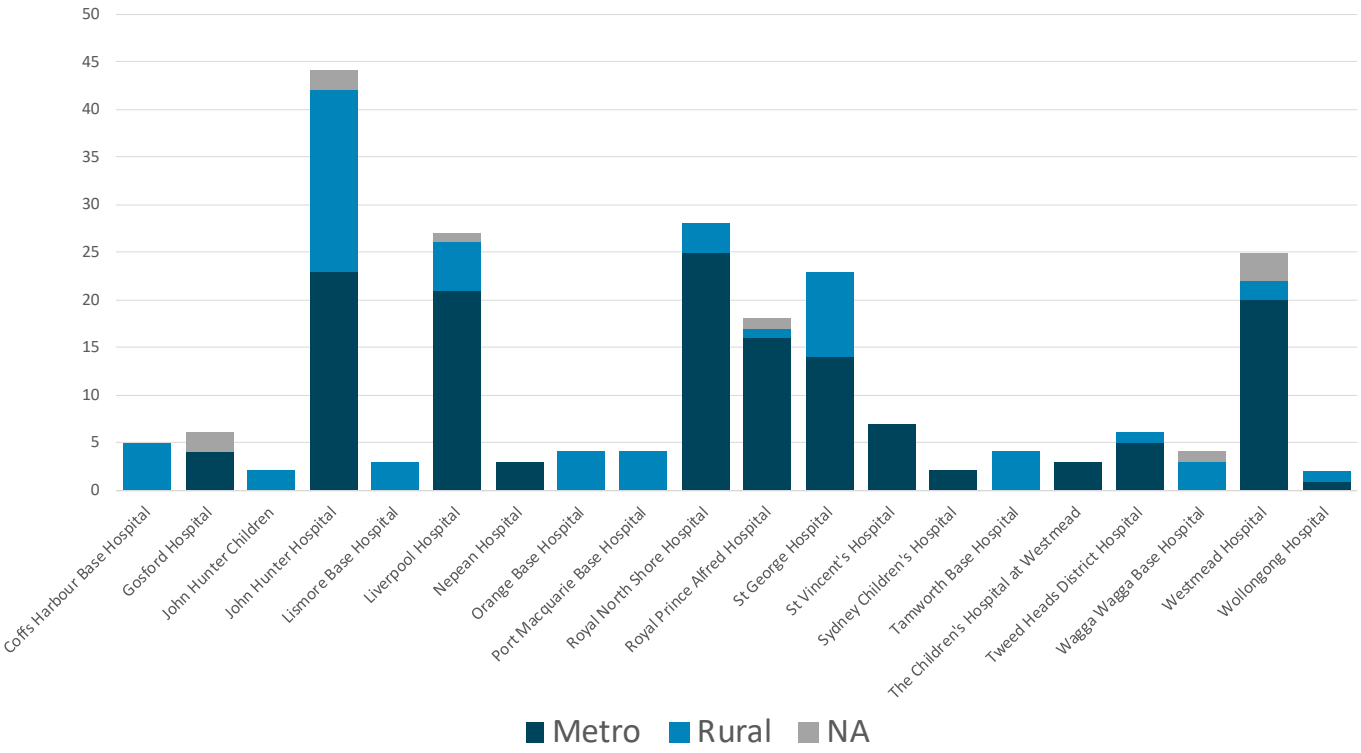

Table 8: Location of death within hospital

Location of death	Number (n=58)	Percentage
Emergency department (ED)	24	41%
Angio/cath lab	1	1.7%
Operating theatre (OT)	13	22%
ICU	14	24%
General ward	1	1.7%
Unknown	3	5%

Glossary

Abbreviated Injury Scale (AIS) is an anatomically based, consensus-derived, global severity scoring system that classifies each injury by body region, according to its relative importance on a six-point ordinal scale. The AIS is the basis for the Injury Severity Score (ISS) calculation of the multiply injured patient.

Definitive care is defined as the hospital providing the highest level of care to meet all the clinical needs of the patient. Many patients receive definitive care at regional trauma centres, but a small number of patients are transferred to a major trauma service (higher level) for specialised care.

ER-REBOA is the trade name of a REBOA device available and TGA approved in Australia.

Location of injury is defined as either metropolitan or rural based on the recorded postcode of injury.

Injury Severity Score (ISS) assesses the combined effects of the multiply injured patient and is based on an anatomical injury severity classification, the AIS. The ISS is an internationally recognised scoring system which correlates with mortality, morbidity and other measures of severity. The ISS is calculated as the sum of the squares of the highest AIS code in each of the three most severely injured ISS body regions.

ISS body regions consist of six anatomical regions as defined in the AIS dictionary:

- head or neck
- face
- chest
- abdominal or pelvic contents
- extremities or pelvic girdle
- external.

Major trauma is defined as all patients of any age, who were admitted to a designated NSW trauma service within seven days of sustaining an injury, and had one of the below:

- an ISS >12 (moderate to critically injured)
- were admitted to an intensive care unit (irrespective of ISS) following injury
- died in hospital (irrespective of ISS) following injury, except those with an isolated fractured neck of femur injury sustained from a fall from a standing height (<1 metre) and those aged 65 years or older who die with minor soft tissue injury only.

Major trauma centres can provide the full spectrum of care for major and moderately injured patients, from initial resuscitation through to rehabilitation and discharge. There are currently seven adult and three paediatric designated major trauma services in NSW.

Mechanism of injury refers to the mechanisms whereby energy is transferred from the environment to the person.

Polytrauma is defined as serious injury (AIS severity >2) in two or more ISS body regions.

REBOA is a procedure that involves placement of an endovascular balloon in the aorta to obtain proximal control of haemorrhage. It is considered an adjunct for non-compressible torso haemorrhage.

Regional trauma centres can provide all aspects of care to patients with minor to moderate trauma, and definitive care to a limited number of major trauma patients in collaboration with the major trauma service. A regional trauma centre provides initial assessment, stabilisation, definitive care and initiates transfer to a major trauma centre when a patient requires services not available at the regional trauma centre. There are currently 10 designated regional trauma centres in NSW.

Transient responders are patients who respond to an initial fluid bolus with improvement in their vital signs but deteriorate when the bolus infusion is slowed or ceased.

Abbreviations

AAA	Abdominal aortic aneurysm
ACEP	American College of Emergency Physicians
ACS COT	American College of Surgeons Committee on Trauma
AIS	Abbreviated Injury Scale
ED	Emergency department
FACEMS	Fellow of the Australasian College of Emergency Medicine
FAST	Focused Assessment with Sonography in Trauma
IR	Interventional radiology
MTC	Major trauma centre
OT	Operating theatre
PEA arrest	Pulseless Electrical Activity arrest
PPH	Post-partum haemorrhage
REBOA	Resuscitative endovascular balloon occlusion of the aorta
RTC	Regional trauma centre
TIC	Trauma Innovation Committee

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Conflict of interest and declarations

TIC members and ITIM staff have declared they have no affiliations, conflicting or financial interests associated with the commercial aspects with the REBOA device.

The Agency for Clinical Innovation (ACI) is the lead agency for innovation in clinical care.

We bring consumers, clinicians and healthcare managers together to support the design, assessment and implementation of clinical innovations across the NSW public health system to change the way that care is delivered.

The ACI's clinical networks, institutes and taskforces are chaired by senior clinicians and consumers who have a keen interest and track record in innovative clinical care.

We also work closely with the Ministry of Health and the four other pillars of NSW Health to pilot, scale and spread solutions to healthcare system-wide challenges. We seek to improve the care and outcomes for patients by re-designing and transforming the NSW public health system.

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