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This Brief was commissioned by Queensland Health, in its role as the Secretariat of the Health Policy Advisory Committee on Technology (HealthPACT). The production of this Brief was overseen by HealthPACT. HealthPACT comprises representatives from health departments in all States and Territories, the Australian and New Zealand governments and MSAC. It is a sub-committee of the Australian Health Ministers’ Advisory Council (AHMAC), reporting to AHMAC’s Hospitals Principal Committee (HPC). AHMAC supports HealthPACT through funding.

This brief was prepared by Deanne Forel from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).
Summary of findings

The ER-REBOA™ Catheter received 510k approval from the United States Food and Drug Administration because of its similarity to other legally marketed devices. There are, however, no human studies published on this device. Therefore, the evidence included in this Technology Brief assessed the use of similar technologies to carry out resuscitative endovascular balloon occlusion of the aorta (REBOA).

REBOA may be used in a number of emergency or critical care settings; however, for the purposes of this Technology Brief evidence was limited to the use of REBOA to treat non-compressible haemorrhage as a result of traumatic injury. Trauma appears to be the primary indication for REBOA based on what is represented by the literature.

Four studies were eligible for inclusion in this Brief: one systematic review, two non-randomised comparative studies and one case series study.

The findings of the included studies varied. The systematic review concluded that although REBOA was effective in elevating systolic blood pressure in patients with haemorrhagic shock, there was a lack of clear evidence supporting an improvement in mortality rate. One of the included comparative studies found that REBOA may lead to a higher death rate in surgically-treated severe trauma patients by significantly delaying time to primary surgery. The other comparative study concluded REBOA was a viable alternative to open aortic occlusion, with similar outcomes observed. The case series study provided evidence on a seven French balloon catheter that is similar to ER-REBOA. Based on the results of this study, the smaller catheter appeared to be capable of achieving aortic occlusion equivalent to that of larger catheters without any access-related complications.

All of the included studies recognised the importance of continued, high-quality research into the efficacy of REBOA, as the current evidence base was limited to poor quality studies. Of particular interest is the investigation into the use of smaller diameter catheters, such as the ER-REBOA Catheter. Therefore, although the ER-REBOA Catheter is “substantially equivalent” to other devices used to carry out REBOA, it is not possible to make recommendations about the ER-REBOA Catheter until further studies are published.

HealthPACT Advice

Resuscitative endovascular balloon occlusion of the aorta (REBOA) offers a small number of trauma patients improved survival with less physiological disturbance than current treatment options such as cross clamping the aorta. Although poor outcomes were noted, treatment with the REBOA may be considered a treatment of last resort for patients with few options.

HealthPACT does not support public investment in this technology in clinical practice at this time, except under the auspices of an evaluation trial conducted in a clinical setting, with
clinical utility demonstrated in emergency situations. These trials should be conducted under close supervision in conjunction with other relevant groups which may include emergency physicians, retrieval specialists and surgeons. Therefore, HealthPACT recommends that the evidence for REBOA be reviewed in 24 months.
Technology, Company and Licensing

Register ID            WP248 (nomination from South Australia)
Technology name       ER-REBOA™ Catheter for resuscitative endovascular balloon occlusion of the aorta (REBOA)
Patient indication    Patients with acute massive haemorrhage from trauma to a non-compressible part of the body

Description of the technology

Resuscitative endovascular balloon occlusion of the aorta (REBOA) controls non-compressible haemorrhage by using an inflatable balloon to temporarily block or occlude the aorta and redirect blood flow from the extremities to maintain brain and coronary circulation. REBOA is used as a bridge to definitive haemorrhage control with either surgery or other vessel blocking techniques.¹

In this intervention the aorta is typically categorised into three occlusive zones (Figure 1). Zone I extends from the origin of the left subclavian artery to the coeliac artery (approximately 20 cm long in a young adult male); zone II extends from the coeliac artery to the most posterior renal artery (approximately 3 cm); and, zone III extends from the most posterior renal artery to the aortic bifurcation (approximately 10 cm).² The occlusion zone is dependent on the location of haemorrhage.

Figure 1  Aortic zones relating to REBOA³
The REBOA intervention has five steps:

1) Open the artery and insert the delivery sheath: the common femoral artery is accessed through a small hole in the skin (percutaneously) or directly via open exposure and an introducer sheath (usually 10-14 French [Fr]) is inserted;

2) Select and insert the balloon: a compliant balloon is selected depending on the targeted occlusion zone and fluoroscopically guided into position;

3) Inflate the balloon: the balloon is inflated with a sterile saline and contrast solution and sutured in place; the balloon’s position is monitored to ensure it stays in place;

4) Deflate the balloon: the balloon is deflated slowly to avoid the significant decrease in blood pressure (hypotension) that often occurs;

5) Remove the balloon and delivery sheath: the catheter is removed and the wound closed; restoration of blood flow through the aorta can be determined by palpation or Doppler ultrasound.

Insertion time (in an experienced trauma centre) is approximately 6 minutes. Aortic zone I occlusion can occur for a maximum of 20 to 30 minutes, with longer periods of occlusion adversely affecting survival. Aortic zone III occlusion may be maintained for much longer, up to 4 to 5 hours (Personal communication, Royal Adelaide Hospital).

Until recently, REBOA was carried out using a selection of endovascular tools (including guidewires, sheaths and balloons) that have been approved for other medical uses, with no one device specifically designed for this intervention. In 2015, the ER-REBOA Catheter (Prytime Medical Devices, Inc., Texas, United States of America) was developed to provide a rapidly deployable, guidewire-free, low-profile aortic occlusion system specifically for use in REBOA.

The ER-REBOA Catheter consists of a compliant occlusion balloon with a rounded tip (P-tip™), a dual-lumen catheter shaft and a hub with extension lines that enable access to each lumen (Figure 2).

The balloon lumen is used to inflate and deflate the balloon, and the arterial line lumen measures blood pressure. The catheter’s all-in-one design can be used without a guidewire. The 72 cm device length can be used in 7 Fr introducer sheaths or larger, and its balloon can occlude vessels up to 32 mm in diameter. Other features include, radiopaque marker bands on the functional ends of the balloon to allow accurate placement and position monitoring.

Unlike other catheters used in REBOA, the ER-REBOA Catheter can be used with smaller diameter (7 Fr) arterial sheaths. This feature has the potential to overcome some of the

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3 The French size is three times the diameter in millimetres.
complications thought to be associated with the traditional larger diameter arterial sheaths (including lower limb ischaemia [insufficient blood supply] and amputation).  

REBOA has been used to control haemorrhage in various settings including gastrointestinal bleeding, postpartum haemorrhage, aortic aneurysm surgery and trauma. The focus of this Technology Brief is the use of REBOA in a trauma setting, which is reflective of the primary indication for REBOA represented in the published literature.

**Company or developer**

ER-REBOA Catheter, Prytime Medical Devices, Inc., Texas, United States of America.

**Reason for assessment**

The concept of temporarily occluding the aorta to redirect blood flow to the brain and heart of trauma patients is not new. The use of REBOA dates back to Korean War casualties. Since the 1990s there has been a re-emergence in its use in military and civilian patients; this is likely owing to advancements in endovascular technology.

A small group of trauma patients may benefit from REBOA in Australia and New Zealand. However, if its efficacy can be determined, particularly in light of new specialised devices (such as the ER-REBOA Catheter), REBOA may offer this small patient group improved survival with less physiological disturbance than current treatment options.
**Stage of development in Australia**

- [x] Yet to emerge*
- [ ] Experimental
- [ ] Investigational
- [ ] Nearly established
- [ ] Established
- [ ] Established *but* changed indication or modification of technique
- [ ] Should be taken out of use

*The ER-REBOA Catheter has not yet been used in Australia. The REBOA intervention, however, has been used in an investigational capacity by Australian centres in Western Australia, Victoria and New South Wales (Personal communication, Royal Adelaide Hospital).

**Licensing, reimbursement and other approval**

The ER-REBOA Catheter does not have Australian Therapeutic Goods Administration (TGA) approval. Correspondence with Prytime Medical Devices, Inc. indicated their intention to obtain TGA approval but with no defined timeline to do so (Personal communication, Prytime Medical Devices, Inc.).

The ER-REBOA Catheter received United States Food and Drug Administration (FDA) 510(k) clearance in October 2015 (K151821). The Catheter was issued a "substantial equivalence determination", which deems it as identical in terms of intended use and basic technological characteristics to legally marketed (predicate) devices. Predicate devices include the Cook Coda® Balloon Catheter, the Coda LP Balloon Catheter and the Cook Pressure Monitoring Catheter (all manufactured by Cook Medical Inc., Indiana, United States of America). The ER-REBOA Catheter received CE Mark approval in November 2016.

**Australian Therapeutic Goods Administration approval**

- [x] Yes
- [ ] No
- [ ] Not applicable

**Technology type**

- Device

**Technology use**

- Therapeutic

**Patient Indication and Setting**

**Disease description and associated mortality and morbidity**

Traumatic injury describes physical injuries of sudden onset and severity which require immediate medical attention. Traumatic injuries may lead to haemorrhage and shock (insufficient blood flow to organs) and can arise from a variety of mechanisms, such as vehicle collisions, falls, physical violence and natural disasters.
The natural progression of uncontrolled haemorrhage is cardiovascular collapse, ultimately leading to death.\(^1\) Haemorrhage is the leading cause of preventable death in trauma patients.\(^9\) Non-compressible torso haemorrhage is defined as bleeding caused by damage to blood vessels in the chest, abdomen and pelvis, lung tissue, solid abdominal organs or the bony pelvis that results in hypotension or shock.\(^10\) Torso haemorrhage is particularly challenging to treat given its non-compressible nature and remains a significant cause of mortality.

Traumatic injury is the leading cause of death in people younger than 45 years of age and a leading cause of morbidity, mortality and permanent disability in Australia.\(^11\) Approximately 600,000 Australians live with disability due to a traumatic injury; of these, 10 per cent report profound limitation of core activity (communication, mobility and self-care), 28 per cent report mild limitation to core activity and 45 per cent report schooling or employment restrictions.\(^11\) Overall, traumatic injury accounts for seven per cent of the burden of disease in Australia.\(^11\)

Injury severity is measured using the Abbreviated Injury Scale (AIS) or Injury Severity Score (ISS); a summary of these grading systems is presented in Table 1.

**Table 1** Abbreviated Injury Scale and Injury Severity Score\(^8,12\)

<table>
<thead>
<tr>
<th>Abbreviated Injury Scale (AIS)</th>
<th>Injury Severity Score (ISS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – no injury</td>
<td>Six ISS body regions are awarded an AIS score.</td>
</tr>
<tr>
<td>1 – minor injury</td>
<td>ISS body regions include: 1) head or neck</td>
</tr>
<tr>
<td>2 – moderate injury</td>
<td>2) face</td>
</tr>
<tr>
<td>3 – serious injury</td>
<td>3) chest</td>
</tr>
<tr>
<td>4 – severe injury</td>
<td>4) abdomen</td>
</tr>
<tr>
<td>5 – critical injury</td>
<td>5) extremities</td>
</tr>
<tr>
<td>6 – untreatable injury</td>
<td>6) external</td>
</tr>
<tr>
<td>AIS scores range from 0 to 6.</td>
<td>ISS is determined by adding the squared AIS of the three most injured ISS regions ((ISS = AIS^2 + AIS^2 + AIS^2)).</td>
</tr>
<tr>
<td></td>
<td>ISS scores range from 1 to 75.</td>
</tr>
</tbody>
</table>

AIS: Abbreviated Injury Scale; ISS: Injury Severity Score.

**Number of patients**

Traumatic injury is a significant public health problem in Australia.\(^11\) On average, over 1,000 people are admitted to hospital daily for traumatic injuries and there are approximately 27 deaths per day as a result of traumatic injuries – equating to approximately 10,000 deaths per year.\(^11\)

The cost of traumatic injury to the Australian healthcare system is estimated to exceed $3.4 billion per year, comprising seven per cent of Australia’s annual total healthcare costs. Traumatic injury also costs the Australian economy an estimated $18 billion annually.\(^11\)
impact of trauma on younger people also causes losses in economically productive years of life.

In New Zealand, approximately 1,955 fatal injuries and 8,651 serious non-fatal injuries were reported in 2011.¹³

**Speciality** Emergency care

**Technology setting** General hospital; Specialist hospital (Level I Trauma Centre)

**Impact**

**Alternative and/or complementary technology**

REBOA may be considered an alternative technology to current treatments for traumatic injuries and haemorrhage. If the safety and efficacy of REBOA, in particular the ER-REBOA Catheter, is proven to be comparable or superior to current techniques, it may offer a less invasive substitute for current techniques.

**Current technology**

Resuscitative thoracotomy (RT) with clamping of the descending aorta has been used to control bleeding temporarily and increase blood flow to the heart and brain in patients in extremis (at the point of death).⁵ RT involves gaining rapid (approximately 2 minutes) access to the heart and major thoracic vessels through an incision into the front and side of the chest wall (anterolateral thoracotomy) and is performed in the emergency department.¹⁴ RT is often used as a final attempt to save a patient’s life, consequently the survival rate of patients undergoing RT is low (approximately 30% following blunt trauma, personal communication, Royal Adelaide Hospital).⁵

Other interventions used following traumatic injuries include laparotomy and angiography. Laparotomy, or accessing the abdomen through an incision, allows physicians to visualise and repair damaged organs and blood vessels.¹⁵ Angiography, or the x-ray visualisation of blood vessels, allows sources of haemorrhage to be identified and then repaired with embolisation (blocking of the damaged vessels).¹⁶ Embolisation slows the blood flow and controls the bleeding rather than blocking blood flow completely, which may lead to large areas of ischaemia or tissue death.¹⁶

**Diffusion of technology in Australia**

The ER-REBOA Catheter is yet to be used in Australia. The REBOA intervention is performed in several hospitals across Perth, Melbourne and Sydney to treat traumatic injuries (Personal communication, Royal Adelaide Hospital). Currently, the catheters being used to carry out REBOA in Australia are a similar diameter (10-14 Fr) to those reported in the included literature.
International utilisation*

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td></td>
<td>✅</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td></td>
<td></td>
<td>✅</td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td>✅</td>
<td></td>
</tr>
<tr>
<td>Europe</td>
<td></td>
<td>✅</td>
<td></td>
</tr>
</tbody>
</table>

*: For the intervention of REBOA.

The ER-REBOA Catheter has been sold since January 2016 and is currently available in 25 per cent of trauma centres in the United States of America (Personal communication, Prytime Medical Devices, Inc.).

Cost infrastructure and economic consequences

Clinical correspondence indicates a cost of approximately $700-$1,000 for a single-use REBOA kit (using a 12 Fr catheter) (Personal communication, Royal Adelaide Hospital). The cost of the ER-REBOA Catheter is significantly more, at $2,614b (Personal communication, Prytime Medical Devices, Inc.).

Ethical, cultural, access or religious considerations

No ethical, cultural, or religious considerations were identified that may limit the use of this technology. The performance of REBOA, given its complexity and potential for complications, should be limited to Level I Trauma Centres.

Evidence and Policy

Safety and effectiveness

There were no human studies identified using the ER-REBOA Catheter. Consequently, studies examining REBOA for traumatic injury were eligible for inclusion in this Technology Brief.

Four studies were assessed: one systematic review3 (level III-3 intervention evidence), two non-randomised comparative studies with historical controls (level III-3 intervention evidence)17, 18 and one prospective case series study (level IV intervention evidence)5.

The two comparative studies and case series study were published after the search end date of the systematic reviews (October 2015). The case series study was included because it examined REBOA and used a 7 Fr catheter to carry out REBOA, which is similar to the ER-REBOA Catheter.

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b 1 USD = 0.76 AUD (XE Currency Converter, 23/08/16).
### Table 2  Included study characteristics

<table>
<thead>
<tr>
<th>Study/design</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Patient numbers</th>
<th>Conflicts of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morrison et al 2016¹</td>
<td>English language, original studies in humans.</td>
<td>Publications that reported non-haemorrhage-related pathology, ineligible study types (including letters and reviews).</td>
<td>587</td>
<td>Two authors reported stock options with Prytime Medical Devices, Inc. and other medical companies which do not appear to manufacture any of the balloons used in their included studies.</td>
</tr>
<tr>
<td>Non-randomised comparative study Japan</td>
<td>Trauma patients who had undergone emergency surgery or transcatheter embolisation on the chest, pelvis or abdomen.</td>
<td>Patients aged &lt;16 years, patients with cardiopulmonary arrest on arrival to emergency or patients with unsurvivable injuries (systolic blood pressure of 0 mmHg and AIS score of 6)</td>
<td>625 with REBOA 625 without REBOA</td>
<td>Authors declared no conflicts of interest.</td>
</tr>
<tr>
<td>DuBose et al 2016¹⁰</td>
<td>Adult (≥18 years) patients undergoing aortic occlusion identified from the American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery registry.</td>
<td>NR</td>
<td>46 REBOA 68 open aortic occlusions</td>
<td></td>
</tr>
<tr>
<td>Teeter et al 2016⁶</td>
<td>Patients receiving REBOA through 7Fr sheaths for refractory traumatic haemorrhagic shock across 5 centres.</td>
<td>Non-trauma cases, patients &lt;18 years of age.</td>
<td>33</td>
<td>Two authors were clinical advisory board members for Prytime Medical Devices, Inc. and Tokai Medical Products, respectively.</td>
</tr>
</tbody>
</table>

¹. The systematic review included a total of 41 studies in the following clinical settings: postpartum haemorrhage (5 studies), upper gastrointestinal haemorrhage (3 studies), pelvic haemorrhage from surgery (8 studies), traumatic abdominopelvic haemorrhage (15 studies) and haemorrhage from ruptured abdominal aortic aneurysm (10 studies). For the purposes of this Technology Brief, only results from the 15 studies reporting the use of REBOA for abdominopelvic trauma were included.

AIS: abbreviated injury scale; Fr: French; NR: not reported; REBOA: resuscitative endovascular balloon occlusion of the aorta.

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**Morrison et al 2016⁵**

This systematic review included 41 studies from five clinical settings: postpartum bleeding, upper gastrointestinal bleeding, pelvic bleeding during pelvic/sacral tumour surgery, traumatic abdominopelvic bleeding and bleeding from ruptured abdominal aortic aneurysms. For the purposes of this Technology Brief, only the 15 studies using REBOA for traumatic injury were reported (two comparative studies, nine case series and four case reports), which described outcomes for a total of 587 patients.
Morrison et al (2016) employed rigorous methodology outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Group. The review had pre-defined research questions, inclusion and exclusion criteria and data extraction and appraisal tools. Broad search terms and search dates were utilised and multiple literature databases were used. Study selection and full-text assessment was undertaken by two independent reviewers with disagreements being resolved through third party arbitration. The authors used the Cochrane Risk of Bias Tool to determine the scientific quality of the included studies and noted this quality when formulating conclusions.

Information regarding balloon insertion method was available for 13 of the 15 studies which used REBOA to treat trauma. Insertion took place via the femoral artery in 11 studies and the brachial and carotid arteries in one study each. Percutaneous access was used in the majority of studies (six studies), with three studies utilising the cut-down method and four studies using a mix of both percutaneous and cut down techniques. Fluoroscopic guidance was used in five of the included studies to confirm correct balloon placement. Other methods of balloon placement confirmation included “clinical methods” (loss of pulse oximetry in the lower extremities or loss of left brachial pulse; four studies), a combination of clinical methods and “other” methods (two studies), and “other” methods alone (one study).

Safety

Morrison et al (2016) reported safety outcomes in the form of device-related morbidity. Of the 15 studies using REBOA to treat traumatic injuries, three reported device-related morbidity (Table 3). An additional study, reported technical failures in the form of failed percutaneous access (N = 5) and failed cut down (N = 1).

<table>
<thead>
<tr>
<th>Study</th>
<th>Complication</th>
<th>N (cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gupta et al</td>
<td>Femoral artery thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Martinelli et al</td>
<td>Balloon rupture</td>
<td>1</td>
</tr>
<tr>
<td>Saito et al</td>
<td>Renal failure</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Access complication and amputation</td>
<td>3</td>
</tr>
</tbody>
</table>

Effectiveness

Morrison et al (2016) reported the following three effectiveness outcomes: effect on systolic blood pressure (SBP), balloon occlusion time and mortality.

Systolic Blood Pressure:

A meta-analysis was performed using a random-effects model to determine the effect of REBOA on SBP in patients in haemorrhagic shock. Six studies reported pre- and post-REBOA
SBP values for patients in shock. Of these, five took place in a trauma setting and one in a postpartum setting (Although the focus of this review is the performance of REBOA in the trauma setting, these outcomes were included as 5 of 6 studies examined REBOA in the setting of interest). The data exhibited moderate heterogeneity ($I^2 = 36\%$); REBOA was found to increase SBP by a mean of 53 mmHg (95% confidence interval [CI] 44, 61).

Balloon occlusion time:
Ten studies reported REBOA balloon occlusion times for zone I, zone III occlusions or both (see Figure 1). Seven of these took place in a trauma setting, two were postpartum studies and one was an upper gastrointestinal bleeding study (Although the focus of this review is the performance of REBOA in the trauma setting, these outcomes were included as 7 of the 10 studies examined REBOA in the setting of interest). The median zone I occlusion time was 63 minutes (interquartile range [IQR] 33, 88) and median zone III occlusion time was 45 minutes (IQR 30, 105). No study reported significant balloon migration.

Mortality rates were reported for 14 of the 15 included studies (Table 4).

Table 4  Mortality rate in the trauma studies reported by Morrison et al

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>N</th>
<th>Mortality rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hughes et al24</td>
<td>1954</td>
<td>2</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td>Low et al25</td>
<td>1986</td>
<td>15</td>
<td>13/15 (86.7%)</td>
</tr>
<tr>
<td>Wolf et al26</td>
<td>1986</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Gupta et al21</td>
<td>1989</td>
<td>21</td>
<td>14/21 (66.7%)</td>
</tr>
<tr>
<td>Matsuoka et al27</td>
<td>2001</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Martinelli et al22</td>
<td>2010</td>
<td>13</td>
<td>7/13 (53.8%)</td>
</tr>
<tr>
<td>Brenner et al28</td>
<td>2013</td>
<td>6</td>
<td>2/6 (33.3%)</td>
</tr>
<tr>
<td>Wang et al29</td>
<td>2013</td>
<td>5</td>
<td>Unknown</td>
</tr>
<tr>
<td>Green et al30</td>
<td>2014</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Uchida et al31</td>
<td>2014</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Irahara et al32</td>
<td>2015</td>
<td>14</td>
<td>9/14 (64.3%)</td>
</tr>
<tr>
<td>Moore et al9</td>
<td>2015</td>
<td>24</td>
<td>15/24 (62.5%)</td>
</tr>
<tr>
<td>Norii et al33</td>
<td>2015</td>
<td>452</td>
<td>343/453 (75.9%)</td>
</tr>
<tr>
<td>Ogura et al34</td>
<td>2015</td>
<td>7</td>
<td>1/7 (14.3%)</td>
</tr>
<tr>
<td>Saito et al23</td>
<td>2015</td>
<td>24</td>
<td>10/24 (41.7%)</td>
</tr>
</tbody>
</table>
The two comparative studies included by Morrison et al (2016) reported conflicting findings with regards to mortality. The first comparative study which used propensity score matching to generate two treatment groups from registry data found patients who underwent REBOA had a higher mortality rate compared with those whose traumatic injuries were managed by other means (odds ratio of survival 0.30, 95% CI [0.23, 0.40]). The second study compared REBOA with RT and found the REBOA group had fewer early deaths and an overall improved survival rate of 38 per cent compared with 10 per cent in the RT group ($p = 0.003$).

It is important to note that the mortality rate varied greatly across the included studies, and that these differences do not appear to be reduced in more recent studies. There were no device-related deaths reported.

Inoue et al 2016

This study used registry data from the Japan Trauma Databank (JTDB), a national trauma registry established in 2003 to improve and assure the quality of trauma treatment. Focusing on efficacy outcomes only, propensity score matching analysis was used to compare the outcomes in patients who underwent emergency surgery/transcatheter embolisation with or without REBOA. Of the 13,780 patients in the JTDB registry, a total of 1,250 patients were included following propensity matching: 625 who underwent REBOA and 625 who did not.

Safety

No safety outcomes were reported in this study.

Effectiveness

The primary outcome of this study was in-hospital mortality. Secondary outcomes were mortality in the emergency room, door-to-primary-surgery time and door-to-blood-transfusion time.

Mortality and survival:

The emergency room mortality rate was higher in patients who underwent REBOA, compared with RT. Similarly, the in-hospital mortality rate was also higher amongst REBOA patients within the first two days, but this difference was not statistically significant beyond the third day (see Table 5).

Subgroup analyses found significant reductions in the in-hospital mortality rate among REBOA patients who:

- Arrived at hospital with an SBP lower than 80 mmHg (8% versus 24%; $p = 0.003$)
- Underwent surgery within 60 minutes of arrival (3% versus 20%; $p = 0.03$)
- Underwent embolisation (11% versus 28%; $p = 0.007$).
Table 5  Patient mortality and survival statistics reported by Inoue et al\textsuperscript{18}

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Statistic [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital mortality</td>
<td>Absolute difference 16.5% [10.9, 22.0]</td>
</tr>
<tr>
<td>Emergency room mortality</td>
<td>Absolute difference 7.3% [3.5, 11.2]</td>
</tr>
<tr>
<td>2-day survival</td>
<td>Hazard ratio 1.7 [1.43, 2.03]</td>
</tr>
<tr>
<td>30-day survival</td>
<td>Hazard ratio 1.6 [1.36, 1.86]</td>
</tr>
</tbody>
</table>

CI: confidence interval.

Time-to-surgery and time-to-blood-transfusion:
Door-to-primary-surgery and door-to-blood-transfusion times were shorter for patients in the REBOA group. The median reduction in time was 14 minutes for both surgery (95% CI -23, -5) and blood transfusion (95% CI -25, -3).

DuBose et al 2016\textsuperscript{17}
This comparative study prospectively included patients from the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry who underwent aortic occlusion across eight Level I Trauma Centres in the United States of America. Inclusion criteria were adult (≥ 18 years) trauma and acute care patients undergoing aortic occlusion in acute phases after injury.

A total of 114 patients were eligible for inclusion; 46 who underwent REBOA and 68 who underwent open aortic occlusion (OAO) (via anterolateral thoracotomy [N = 43], clamshell thoracotomy [N = 18] or laparotomy [N = 7]). Patients undergoing REBOA were less likely to be men (70% versus 88%; \(p = 0.013\)) or to have sustained a penetrating injury (24% versus 47%; \(p = 0.013\)) and more likely to have required pre-hospital intubation (37% versus 12%; \(p = 0.002\)) compared with those patients undergoing OAO. Other significant differences between the patient groups are summarised in Table 6.

Table 6  Differences in patients undergoing REBOA versus open aortic occlusion reported by DuBose et al\textsuperscript{17}

<table>
<thead>
<tr>
<th>Outcome</th>
<th>REBOA</th>
<th>Open aortic occlusion</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension (SBP ≤ 90 mmHg) on admission</td>
<td>48%</td>
<td>69%</td>
<td>0.02</td>
</tr>
<tr>
<td>Median SBP on admission</td>
<td>23 mmHg (IQR 105)</td>
<td>0 mmHg (IQR 80)</td>
<td>0.02</td>
</tr>
<tr>
<td>Active CPR during initial aortic occlusion attempt</td>
<td>72%</td>
<td>46%</td>
<td>0.008</td>
</tr>
<tr>
<td>Procedure performed by fellow</td>
<td>4%</td>
<td>31%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure performed by resident</td>
<td>0%</td>
<td>12%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure performed by trauma/acute care surgery attending</td>
<td>87%</td>
<td>57%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure performed by vascular surgery attending</td>
<td>7%</td>
<td>0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Second occlusion attempt required</td>
<td>4%</td>
<td>13%</td>
<td>0.01</td>
</tr>
</tbody>
</table>

CPR: cardiopulmonary resuscitation; IQR: interquartile range; REBOA: resuscitative endovascular balloon occlusion of the aorta; SBP: systolic blood pressure.
Safety

Complications among survivors of aortic occlusion included: acute kidney injury requiring dialysis (2 patients in each treatment group; p = 0.660), acute lung injury or respiratory distress syndrome (no REBOA patients versus 3 OAO patients; p = 0.149), pneumonia (2 REBOA patients versus 5 OAO patients; p = 0.512) and multi-organ dysfunction (2 REBOA patients versus 5 OAO patients; p = 0.512).

Of the patients who underwent REBOA, one developed an arterial pseudo-aneurysm at the incision site and two experienced blood vessel blockages elsewhere in the body. No infection or amputation was reported in this group. Balloon migration was observed in two patients. Of the patients undergoing OAO, one developed a retained haemothorax (a blood clot in the fluid-filled space around the lung) and two developed infections; all three patients required additional surgical intervention.

Effectiveness

Following occlusion, patients in the REBOA treatment group had a significantly higher mean SBP (90 mmHg versus 65 mmHg; p = 0.03) and were less likely to have an uncontrolled source of bleeding above the level of aortic occlusion (10% versus 27%; p < 0.001), compared with OAO patients.

The overall mortality rate was not significantly different between the treatment groups (72% for REBOA and 84% for OAO). Similarly, the rate of survival in the emergency department was not significantly different for those undergoing REBOA (15%) or OAO (6%).

Significantly more post-REBOA deaths occurred in the emergency department or operating theatre compared with post-OAO deaths; however, significantly more OAO patients died in the intensive care unit (Table 7).

Table 7  Location of death following REBOA or open aortic occlusion reported by DuBose et al17

<table>
<thead>
<tr>
<th>Location of death</th>
<th>Mortality rate (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>REBOA</td>
<td>Open aortic occlusion</td>
<td></td>
</tr>
<tr>
<td>Emergency department</td>
<td>54%</td>
<td>46%</td>
</tr>
<tr>
<td>Operating theatre</td>
<td>26%</td>
<td>16%</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>20%</td>
<td>37%</td>
</tr>
</tbody>
</table>

Teeter et al 20165

This retrospective, multi-centre case series examined the safety profile of small diameter catheters (compatible with 7 Fr sheaths) in REBOA. The authors noted that the larger arterial sheaths (10-14 Fr) generally used for REBOA may be associated with severe complications, including lower limb ischaemia and amputation. These complications were attributed to the ‘near-occlusive’ diameter of the sheaths, the time that they remain in the
artery, the location of their insertion and the potential damage caused by their insertion. Teeter et al (2016) hypothesised that the use of smaller diameter sheaths would reduce complications.

A total of 33 non-consecutive patients underwent REBOA with a 7 Fr sheath for refractory traumatic haemorrhagic shock, between January 2014 and June 2015, across five centres in Japan. REBOA was performed by an emergency medicine physician with or without cross-training in interventional radiology or an interventional radiologist. Definitive bleeding control was achieved through surgery or vessel embolisation, as indicated.

The intervention undertaken to carry out REBOA was as follows: a 7 Fr sheath was placed in the common femoral artery via percutaneous puncture (blind or ultrasound-guided) or open exposure. A balloon (Rescue Balloon Occlusion Catheter, Tokai Medical Products Inc., Japan) was inserted over a guidewire and inflated.

The majority of patients were men (N = 23) with a mean age of 50 years. Median ISS was 38, with blunt trauma being the predominant mechanism of injury (94%).

Safety

There were no complications related to sheath insertion or removal, and no blood clots or ischaemic events identified during the follow-up period (up to 30 days). One patient experienced acute reversible kidney injury during the intervention and required renal replacement therapy for 15 days. Twelve patients required mechanical ventilation due to respiratory failure for a mean duration of nine days.

Effectiveness

Mean SBP prior to REBOA was 62 mmHg (standard deviation [SD] 36), which improved significantly following aortic occlusion (106 mmHg [SD 40]; \( p < 0.001 \)). The treatment characteristics and clinical outcomes reported for the 33 patients who received REBOA are summarised in Table 8.

The number of patients surviving to 24 hours was not affected by the setting in which REBOA took place (pre-hospital, emergency department, angiography suite), the arterial access method or site, the imaging method used, the duration of aortic occlusion or operator specialty or experience.

The significant increase in SBP observed following REBOA indicated that smaller catheters are capable of achieving effective aortic occlusion. Device migration occurred in two patients, which is not dissimilar to previous reports using larger diameter catheters.
Table 8  Treatment characteristics and clinical outcomes of REBOA patients reported by Teeter et al²

<table>
<thead>
<tr>
<th>Characteristic and outcome</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from arrival to occlusion</td>
<td>Mean 32 minutes (IQR 18, 77)</td>
</tr>
<tr>
<td>Time from arrival to haemostatic procedure</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>Mean 35 minutes (IQR 15, 52)</td>
</tr>
<tr>
<td>Angio-embolisation</td>
<td>Mean 64 minutes (IQR 43, 96)</td>
</tr>
<tr>
<td>Haemostatic procedure</td>
<td></td>
</tr>
<tr>
<td>Laparotomy</td>
<td>N = 12 (36%)</td>
</tr>
<tr>
<td>Extraperitoneal packing</td>
<td>N = 3 (9%)</td>
</tr>
<tr>
<td>Angio-embolisation</td>
<td>N = 24 (73%)</td>
</tr>
<tr>
<td>24-hour survival</td>
<td>N = 16 (48%)</td>
</tr>
<tr>
<td>30-day survival</td>
<td>N = 14 (42%)</td>
</tr>
<tr>
<td>Balloon migration</td>
<td>N = 2 (6%)</td>
</tr>
</tbody>
</table>

IQR: interquartile range.

Economic evaluation

There was no cost-effectiveness or economic analyses identified in the retrieved literature regarding the use of REBOA or the ER-REBOA Catheter.

Ongoing research

Searches of trial registers found no ongoing trials using the ER-REBOA Catheter.

Other issues

There were no studies that used the ER-REBOA Catheter for REBOA in humans. Although the device is similar to the devices used in the included studies to make assumptions about its efficacy, it is necessary for studies using ER-REBOA to become available before a definitive recommendation can be made about the device itself. The conclusions of this Technology Brief concern the value of REBOA as an intervention only.

A balloon catheter of similar size to the ER-REBOA Catheter that was also designed for REBOA was identified. The Rescue Balloon Occlusion Catheter was released in Japan in 2013. Correspondence with the manufacturer confirmed that it is seeking CE approval, but there are no immediate plans to seek other regulatory approval. The study completed by Teeter et al (2016), included above, provided safety and efficacy data on this catheter, but no cost data were available.

Clinical feedback indicated that REBOA should be performed in major trauma centres (Level I Trauma Centres) by trauma surgeons, not by emergency physicians, owing to the skills required to undertake the intervention and address potential complications.

In a letter to the editor, a Clinical Advisory Board Member for Prytime Medical Devices, Inc. commented that although the ER-REBOA Catheter claims to be “fluoroscopy free” and is designed to be placed without a wire, this is not actually the case. The Catheter’s 510(k)
approval is based on it being substantially equivalent to legally marketed devices that require fluoroscopy.

Authors of two of the included studies declared associations with Prytime Medical Devices, Inc. and Tokai Medical Products.\(^1,5\)

Prytime Medical Devices, Inc. provided ASERNIP-S with two studies that purportedly used the ER-REBOA Catheter to treat human trauma patients.\(^9,22\) Both studies were included in the systematic review by Morrison et al (2016); however, neither study appears to use the ER-REBOA Catheter. One of the studies described the use of a Berenstein latex balloon with a 10 Fr catheter\(^22\) and the other did not provide information about which balloon or catheter was used.\(^9\) Further clarification was requested from Prytime Medical Devices, Inc.; however, no response has yet been received.

**Number of studies included**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies: 4

Total number of Level III-3 studies: 3

Total number of Level IV studies: 1

**Search criteria to be used (MeSH terms)**

(Resuscitative endovascular balloon occlusion of the aorta) OR (Endovascular balloon occlusion AND Aorta)

**Date searched**

05/08/2016

**References**


score analysis'. *The journal of trauma and acute care surgery*, 80 (4), 559-66; discussion 66-7.


