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Resuscitative endovascular balloon occlusion of the aorta as a potential pre-hospital procedure for the control of non-compressible haemorrhage: A literature review

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Literature review

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Abstract

Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has evolved as a potentially life-saving therapy for the control of non-compressible haemorrhage. With the development of a fluoroscopy free method, the feasibility of introducing REBOA to the pre-hospital setting may lessen the impact of trauma related morbidity and mortality and enhance the level of care provided by emergency services.

Methods

A comprehensive search of the electronic databases was conducted using MEDLINE with Full Text (via EBSCOHost), PubMed and Science Direct. The search included the following keywords: 'resuscitative endovascular balloon occlusion of the aorta', 'REBOA', 'thoracotomy', 'aortic clamping', 'trauma', 'hypovolaemia' and 'pre-hospital'. Cross-referencing using the reference lists of the found articles was used to identify further relevant articles. Studies involving paediatric patients or rats were excluded. Only those articles published after the year 2000 were included.

Results

From the examined literature, it can be determined that there is a definitive absence of pre-hospital attention given towards REBOA, despite its proven benefits in central aortic pressures, mean systolic pressures and overall brain oxygenation. When compared against thoracotomy, as an alternative technique of aortic occlusion, REBOA provided an enhanced metabolic profile and required less resuscitation thereby inducing a greater survivability rate.

Conclusion

The REBOA procedure has reported benefit over aortic cross clamping as a method of proactive aortic control of exsanguinating haemorrhage in porcine and human studies, yet its effectiveness as a pre-hospital technique for reducing mortality and morbidity in trauma patients is yet to be demonstrated within clinical studies.

Keywords:

haemorrhage, REBOA, trauma

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Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) was first performed as a method for haemorrhage control circa 1950 during the Korean War (1). Recently, the use of REBOA as a life-saving therapy for severe uncontrolled haemorrhage has been revisited for application to the pre-hospital care setting as a result of the development of newer fluoroscopy free techniques, which could be used for definitive control of non-compressible haemorrhage such as traumatic pelvic injury (2). Globally, trauma remains the leading cause of mortality and morbidity for all age groups, with uncontrolled haemorrhage being the most common form of preventable death in the trauma setting (3).

For paramedics, identification of any major haemorrhage is an essential component of an initial assessment. However, internal haemorrhage remains difficult to identify due to the lack of available imaging equipment on ambulances and the often delayed signs associated with hypovolaemia, such as decreasing trends in vital signs and poor perfusion. The purpose of this review was to identify if REBOA is a feasible pre-hospital technique for managing uncontrolled lower abdominal haemorrhage. Comparisons were also drawn with pre-hospital thoracotomy and subsequent aortic clamping, as it is the current protocol of the London Helicopter Emergency Medical Service (HEMS).

Method

A comprehensive search of the electronic databases was conducted using MEDLINE with Full Text (via EBSCOHost),

PubMed and Science Direct. The search included the following keywords: 'resuscitative endovascular balloon occlusion of the aorta', 'REBOA', 'thoracotomy', 'aortic clamping', 'trauma', 'hypovolemia' and 'pre-hospital'. Cross-referencing using the reference lists of the found articles was used to identify further relevant articles. Studies involving paediatric patients or rats were excluded. Only those articles published after the year 2000 were included.

Results

A total of 477 articles were identified during the initial search. After de-duplication and exclusion of articles not available as full-text, 18 articles were found to be relevant. Of these, 11 were clinical studies, the rest being clinical reviews providing a comprehensive and informative framework of REBOA's concept and its procedure, likewise current and alternative methods of practice. Only four of the cited articles had a pre-hospital focus. The search results are reported in Figure 1.

Much of the available evidence reporting REBOA effectiveness was drawn from animal studies. These studies are described in Table 1, reflecting the early nature of clinical research into this procedure, and the need to highlight this practice for future potential within pre-hospital clinical practice (2,4-10).

Those studies involving humans are described in Table 2 (11-13). The first was a prospective surgical study, the second a retrospective case series review, and the third was a simulation study.

Figure 1. Literature search results

Table 1. REBOA studies employing animal (swine) subjects

Authors	Study design	Sample size	Results
White JM, Cannon JW, Stannard A, Markov NP, Spencer JR, Rasmussen TE.	3 groups of 6 swine were placed in class IV shock. One group experienced no aortic occlusion, the remaining two groups either underwent thoracotomy with cross clamping, or endovascular balloon occlusion	18	Endovascular Balloon Occlusion resulted in increased central aortic pressure, increased carotid blood flow, and increased brain oxygenation. During resuscitation resulted in decreased acidosis, a decrease in required fluid, and also a decrease in required adrenaline.
Scott DJ, Eliason JL, Villamaria C, Morrison JJ, Houston R, Spencer JR, et al.	2 groups of 8 subjects underwent 60 minutes of REBOA using either a commercially available balloon system with fluoroscopy (CBS), or a self-centring, one component fluoroscopy free prototype (PBS).	16	Accurate positioning and inflation occurred in 100% of the CBS, and 88% in the PBS group. Post REBOA insertion, mean arterial pressure, mortality and lactate levels were comparable for both CBS and PBS groups.
Markov NP, Percival TJ, Morrison JJ, Ross JD, Scott DJ, Spencer JR, et al.	Samples of 6 subjects were placed into 4 groups. 30 minutes of shock alone, 30 minutes of shock with REBOA, 90 minutes of shock alone, or 90 minutes of shock with REBOA	24	Both REBOA groups had greater mean central aortic pressures compared with control groups, however accumulated significantly greater serum lactate level. These levels returned to control levels after 150 minutes for the 30-REBOA group, and 320 minutes for the 90-REBOA group. There were greater levels of liver necrosis and renal dysfunction in the 90-REBOA group compared with the 90-Shock group, as well as the 90-REBOA group requiring more fluid resuscitation.
Andersen NG, Rehn M, Oropeza-Moe M, Oveland NP.	A doctor-paramedic crew performed the REBOA procedure in a realistic pre-hospital environment, with inflation times, systolic and diastolic blood pressures recorded.	3	The mean time from arrival to inflation was 4 minutes and 19 seconds, and from skin contact to inflation was 3 minutes and 12 seconds. There was also a significant increase in both systolic and diastolic blood pressures after inflation.
White JM, Cannon JW, Stannard A, Burkhardt GE, Spencer JR, Williams K, Oh JS, Rasmussen T et al.	Subjects were randomised into 3 groups, with class IV shock induced in all groups. Each group underwent a different method of haemorrhage control; thoracic aortic clamping, trans abdominal supraceliac aortic clamping and direct vascular control. Perfusion, end-organ function and post-mortem tissue analysis were performed.	18	There was no identified difference in mortality across the three groups. All techniques demonstrated an increase in central aortic pressure and carotid and cerebral blood flow, however direct vascular control resulted in less physical derangement and required less fluid and less vasopressor when compared to the other two groups.
Morrison JJ, Percival TJ, Markov NP, Villamaria C, Scott DJ, Saches KA, Spencer JR, Rasmussen TE.	Injury, haemorrhage and intervention served as three phases of study across three groups; no intervention, combat gauze and REBOA. The method was repeated with a dilutional coagulopathy. Physiology, haemorrhage and mortality were measured.	35	Mortality rates for REBOA (0) and combat gauze (5) were reported, compared to 100% in the nil intervention group. The rate of bleeding was lower in the REBOA group, with higher MAP also reported.
Morrison JJ, Ross JD, Markov NP, Scott DJ, Spencer JR, Rasmussen TE.	Subjects endured a controlled haemorrhage of 35% of total blood volume and subsequent thoracic aortic balloon occlusion of 30, 60 and 90 minutes of REBOA.	20	All groups responded positively to aortic occlusion with increases in systolic blood pressure above the baseline values. Significantly elevated levels of IL-6 were measured in the 60 and 90 minute REBOA groups with increased occlusion time resulting in greater IL-6 release.
Höer TM, Skoog P, Nilsson KF, Oikonomakis I, Larzon T, Norgren L, Jansson K.	Nine swine were subjected to ABO and seven swine were subjected to superior mesenteric artery occlusion for one hour, followed by three hours of reperfusion. Data were collected to determine effect on visceral metabolism.	16	Supraceliac aortic balloon occlusion resulted in increased metabolic disturbances over mesenteric artery occlusion.

Table 2. REBOA studies using human participants or simulation

Authors	Study design	Sample size	Results
Martinelli T, Thony F, Declety P, Sengel C, Broux C, Tonetti J, et al.	13 patients underwent intra-aortic balloon occlusion without fluoroscopy during initial resuscitation to control pelvic bleeding with consequential haemorrhagic shock.	13	All Balloons were placed successfully in the infrarenal aorta, with a significant increase in systolic blood pressure observed. The survival rate was 46% and was inversely related to the length of inflation and the mean Injury Severity Score.
Brenner ML, Moore LJ, Dubose J, Tyson GH, McNutt MK, Albarado RP, et al.	Descriptive case studies of REBOA used in situation of end-stage haemorrhagic shock. REBOA was performed for 4 blunt injury mechanisms and 2 penetrating mechanisms	6	REBOA resulted in a mean increase in blood pressure of 55mmHg, with a mean aortic occlusion time of 18 minutes. There were no REBOA related complications and no haemorrhage related mortality.
Brenner ML, Hoehn M, Pasley J, Dubose J, Stein, D, Scalea, T.	Simulation study. Faculty member of the Division of Trauma and Critical Care with restricted endovascular training performed the REBOA procedure 6 times via virtual reality simulation. Performance metrics of the procedure were observed.	13	Noteworthy improvements in knowledge of REBOA and procedural task times were measured with the skill learned and performed quickly and safely. There was a noted correlation between procedural time and trial number with the mean procedural time for task 1 being 277 seconds and 129 seconds in task 6.

Discussion

The REBOA procedure

REBOA is best described as a resuscitation technique of positioning and inflating a balloon within the aorta, proximal to a site of non-compressible haemorrhage in an attempt to support central pressure, minimise bleeding and restore haemostasis (8). This minimally invasive procedure is achieved through five specific procedural steps as follows: (1,13)

Phase 1: Arterial access

Arterial access is obtained through the femoral artery. In the pre-hospital setting, this could be achieved by open exposure of the femoral and external iliac artery. An 18 gauge hollow needle is then advanced into the artery followed by the insertion of a guide wire. An introducer (>11 French Gauge) is then inserted over the guide wire to provide a functional port, enabling phases 2 through to 5.

Phase 2: Balloon selection and positioning

Due to the delicate nature of the procedure, balloons must be soft and compliant and of large diameter to permit successful occlusion of the aorta. Inflation of the balloon in aortic zone III provides occlusion for injuries specific to pelvis or femoral haemorrhage.

Phase 3: Balloon inflation

The balloon is inflated with a saline solution according to manufacturer specifications. It is important that inflation is performed slowly to avoid circulatory collapse. Post effective inflation, securing the balloon's position is paramount in order to

maintain occlusion and mean arterial pressures.

Phase 4: Balloon deflation

Deflation is achieved in definitive care with the availability of an anaesthesia team and emergency surgeons due to the inherent risk of metabolic byproducts and acidosis

Phase 5: Sheath removal

Upon definitive haemorrhage control, the deflated balloon and wire may be removed via surgical cut-down of the insertion site (femoral artery). The sheath is then flushed with heparinised saline.

Clinical studies of REBOA effectiveness

The efficacy of REBOA has been evaluated in a series of studies, however of the 10 clinical studies only three animal studies provide comparison between REBOA and alternative methods. These alternative techniques include resuscitative thoracotomy with aortic clamping and manual pressure with a haemostatic agent (6,8,9). Furthermore, the comparative animal studies were conducted on a porcine model of haemorrhagic shock and are consequently not without their limitations. These studies demonstrated a positive haemodynamic effect with clinically significant increases in both systolic (SBP) and diastolic blood pressures (DBP). As the minimally invasive procedure of REBOA is performed without the need for an operating theatre and as a fluoroscopic-free technique, it has potential to be implemented into the pre-hospital setting (6). However, 10 of the clinical studies did not have a pre-hospital focus, suggesting that further research to quantify the usefulness of REBOA in the emergency setting is required.

An important consideration of the usefulness of REBOA for pre-hospital emergency care is the impact of uncontrolled

haemorrhage on mortality and morbidity in the trauma setting, and the different stages of shock as seen in Table 3 (14).

Table 3. Classes of shock and description

Classes of shock	% of total blood volume lost	Symptoms
Class I	<15%	No shock, mostly asymptomatic
Class II	15%-30%	Anxiety, ↓↓blood pressure(>90 SBP), ↑↑heart rate (100-120bpm)
Class III	30%-40%	Confusion, significantly ↓↓blood pressure (<90 SBP), ↑↑heart rate (120-140bpm)
Class IV (Pre-death)	>40%	As above, plus: lethargy, hypotension, dramatic ↑↑heart rate (>140bpm), absent urine output

REBOA aims to target Class IV shock resulting from non-compressible haemorrhage exemplified by the pattern of injury found in pelvic fractures, and is directed towards enhancing perfusion and oxygen delivery to vital organs (15). Despite uncontrolled haemorrhage following major injury remaining the most common preventable cause of traumatic death, there is less detailed information available on the vulnerability to ischemic injury to other organs (3,15). This may be as a result of the focus on time intervals between initial haemorrhage and the onset of severe myocardial ischemia and cerebral circulation. There is inconclusive data regarding the period before irreversible injury to skeletal and smooth muscle cells, as this can range between 30 and 90 minutes (16).

Considering REBOA is inserted into the femoral artery and advanced into the aorta to control distal haemorrhage, attention must be given to the indicated lactate burden associated with the resuscitative technique. Studies reported that the alternative methods of aortic occlusion (open thoracotomy and aortic clamping), despite sharing a similar haemodynamic effect as REBOA, have a significantly different metabolic profile (6). Pigs treated with REBOA were found to be less acidotic (pH 7.35 vs 7.24; $P < .05$) and to record lower levels of serum lactate concentration (4.27 vs 6.55; $P < .05$), inflammatory infiltrates and a decrease in numeric rates of necrosis requiring less resuscitation, including fluid (667mL vs 2,166 mL; $P < .05$) and adrenaline (0 mcg vs. 52.1 mcg; $P < .05$) than those treated with thoracotomy and clamping (5,9).

In a study conducted in 2010, 13 selected patients suffering from pelvic fractures and associated uncontrolled haemorrhage received intra-aortic balloon occlusion in the surgical setting (13). The global mortality rate from such trauma was 54%, with all deaths occurring in the first 24 hours. However these deaths may be attributed to mean Injury Severity Scores (ISS) of 58, and with a subsequently predicted mortality rate of 100%. The notion that these patients could already be considered clinically deceased must be measured when evaluating the effectiveness of REBOA in this setting.

Identified benefits of REBOA

For REBOA to be considered a feasible technique for the pre-hospital setting, the benefits of the procedure require clarification.

The mean time from arrival at the patient to balloon insertion was four minutes and 19 seconds when tested in a simulated pre-hospital environment (4). In contrast, the mean time taken to insert the balloon from the time of injury to intensive care unit (ICU) admission, where the procedure was performed in a controlled environment, was on average 110 minutes (13). This provides a potential for studying the timeliness of REBOA for the pre-hospital setting, as the reduction in time to insertion may demonstrate improved survival rates among trauma patients (11). Thus the use of this technique has the theoretical advantage of facilitating an extension of the window for salvage and shows significant promise as a bridge to definitive haemostasis (16).

Scott et al reported in their swine study that once occlusion had occurred, mean arterial pressure was maintained at 65 mmHg and systolic blood pressure at 94 mmHg (2). This study also concluded that a positive increase in mean arterial pressure and subsequent rise in cerebral perfusion was associated with an increased survival rate (2). This was further supported by a 100% improvement in cerebral blood flow, post aortic balloon occlusion in a porcine model (9). In addition to REBOA's ability to facilitate positive perfusion pressures in trauma patients, the technique can be used for all patient ages and genders in the setting of trauma related injuries. For example, REBOA was successfully performed on a male, 64 years of age, who had sustained a fractured femur (as a result of a fall) and subsequently presented with hypovolaemic shock (12). A significant rise in SBP was identified (50mmHg vs 135mmHg). In another example, a female, 27 years of age, also underwent a successful REBOA procedure on a grossly deformed pelvic injury resulting from a high-speed car accident (SBP 85 mmHg vs 125 mmHg). Furthermore, REBOA was performed on a

person, 40 years of age, with uncontrolled abdominal bleeding (12). These three cases identify the ability of REBOA to stabilise all patients across discrimination range of traumatic injuries. In turn, this suggests that REBOA has a potential role in managing uncontrolled haemorrhage in the pre-hospital setting (12).

Identified controversies of REBOA

Before a technique such as REBOA can be implemented into pre-hospital practice, patient morbidity rates need to be considered against current methods of haemorrhage control. The potential presented risks of the procedure include injury to aortic root or carotid arteries through over inflation of the balloon, or by inadvertent movement of the stiff wire during insertion. There is also the potential of losing the balloon, and thus creating an occlusion in an undesired location within the aorta or other proximal vessels (1).

Additionally, the amount of time that the balloon spends in the aorta can significantly increase serum lactate levels, resulting in a negative metabolic profile. One study found that although 60 minutes of REBOA indicated that there were no negative effects on the swine, 90 minutes of REBOA, although maintaining a level of survivability, was associated with major physiological derangement and non-reversible organ ischemia and damage (2). Although there was no significant damage found after 30 minutes of REBOA, after 90 minutes there was definitive, irreversible renal damage as well as liver necrosis (5). As a result of these findings, considerations should be made regarding transport time. However in Australia most major trauma centres are within a 60 minute flight radius, therefore the need to maintain REBOA for a time-frame longer than this is unlikely, thus reducing the possibility of irreversible organ damage and ischemia (17). These potential risks must form the basis for a comprehensive analysis of the applicability and safety of REBOA for the pre-hospital setting.

Comparison of REBOA and thoracotomy procedures

Thoracotomy with aortic cross clamping involves opening the chest cavity in order to clamp the aorta in attempt to prevent haemorrhagic shock from occurring (18). REBOA has been compared in animal studies to thoracotomy and aortic clamping to identify which method is better suited for acceptance into the pre-hospital setting.

Mortality rates differed greatly between the two variables. A survival rate of 16% was achieved when conducting the thoracotomy and aortic clamping method of haemorrhage control in large animal subjects (9). In comparison, a study of REBOA in a porcine model found that out of 35 swine there was a mortality rate of 0%, thereby suggesting the less invasive nature of the REBOA technique results in a lower mortality rate (6). It was unclear if the higher mortality rates associated with thoracotomies could be attributed to blood-borne diseases prevalent within open surgical procedures creating increased risk of mortality rather than the closed, less invasive process defined by REBOA (19).

Additionally, of the survivors who underwent an emergency department thoracotomy, 74% had long-term social, cognitive, or psychological impairment. Furthermore, 10% died after hospitalisation, and 48% had limited normal functioning, 24% required assistance with normal daily tasks and 13% were wheelchair bound post thoracotomy (19). Finally, drug and alcohol dependence was prominent across all survivors, consequently showing a decrease in social activity and quality of life even if the patient were to survive operation (19). Arguably, whilst the limited evidence available suggests the potential application of REBOA as an alternative method of occlusion for non-compressible haemorrhage in the pre-hospital setting, thoracotomy will remain an important skill component of any therapeutic regimen.

The practicality of performing REBOA in the pre-hospital setting

The five step method of REBOA described earlier has reported mean insertion time from skin contact to inflation of 3 minutes and 12 seconds (SD +/- 42 seconds), resulting in significant mean arterial pressure (MAP) increases, thus maintaining adequate cerebral and myocardial perfusion (4). These times were recorded using porcine models in a realistic pre-hospital environment. However it was only performed three times, suggesting a limited generalisability of the results, thus the feasibility of REBOA in the pre-hospital setting remains unknown.

It has been suggested that the use of fluoroscopic guidance and observation compliments Phase 2 and 3 of the REBOA procedure, thereby currently limiting this technology to the hospital emergency department (1). However, recent developments in the models of haemorrhagic shock have produced a low profile, less complicated and more amenable REBOA system designed to be positioned in the absence of fluoroscopic guidance (2). With such advancements in technology and limited alternate techniques, REBOA could provide a practical solution to circulatory support for these patients in the pre-hospital setting, as it is designed to support critical physiology until definitive haemorrhage control (surgery) is available (1).

Intensive care paramedics in the pre-hospital setting could perform the REBOA procedure, when occlusion of the aorta to increase proximal and central perfusion in the setting of uncontrolled non-compressible haemorrhage is required. The five-step procedure, as discussed above, has been successfully taught through developed endovascular training and virtual reality simulation and thus has potential to be adopted and applied as an intensive care skill. Following a didactic and instructional session, 13 trauma surgeons with no previous advanced endovascular training performed the REBOA procedure on a virtual reality simulator (VIST-C) and were examined on their performance, procedural task times and overall achievement. These assessment reported a significant decrease in procedural task time, along with notable improvements in knowledge and understanding of REBOA. The report concluded that the successful completion of the course allowed these participants to independently perform REBOA (11). It is possible that a similar program could be applied to intensive care paramedic training.

Furthermore, the endovascular skills for trauma and resuscitative surgery (ESTARS) 2-day course was developed to meet specific learning objectives with focus on obtaining competency in basic endovascular skill utilised in vascular injury management (20). The course consisted of pre-course instructional materials and knowledge test, didactic lectures, endovascular simulation, exposure to endovascular and REBOA instruments and hands-on practice sessions with live swine models before a final assessment. None of the participants had formal vascular or endovascular surgery training (20). With the use of ESTARS curriculum, more than 90% of participants demonstrated aptitude in the defined skill set, including arterial access, exchange of sheaths, wires, and catheters and the performance of urgent REBOA and has consequently inspired new innovative and concise hands-on education to emerge that is increasingly portable, repeatable, and solely focused on providing participants with the skills to perform REBOA.

These two studies, and the increasing development of other hands on training, demonstrate the potential applicability of the curriculum. It is acknowledged that the participants were trauma surgeons, however further examination through a trial program may demonstrate potential to extend the curriculum to intensive care paramedics.

Limitations of this study

Assessing REBOA as a potential pre-hospital therapy for uncontrolled abdominal or pelvic haemorrhage is challenged by the study focus on large animal models. Of the 11 studies related to REBOA, seven of these were related to humans, illustrating the need for further human research. There is also limited data currently available on the use of REBOA for the pre-hospital setting. Of the studies reviewed, none were conducted in the pre-hospital setting. One study piloted their research in a simulated pre-hospital environment, and whilst this cannot be completely discounted, it is important to consider the unpredictable nature of true roadside pre-hospital care, which cannot always be accurately recreated by simulation (4). Similarly, all other studies where REBOA was conducted occurred in a controlled emergency department, with physicians and equipment not available on emergency ambulances. Further studies and considerations need to be made specifically for pre-hospital environments if REBOA is to become part of an intensive care paramedic scope of practice.

Conclusion

The REBOA procedure has demonstrated a capacity to improve upon aortic cross clamping as a method of proactive aortic control of events involving exsanguinating haemorrhage (11). The minimally invasive procedure of REBOA may provide a superior method of haemorrhage control in the field of pre-hospital medicine than current alternatives such as thoracotomy

and aortic clamping. Patients involved in trauma can often suffer internal haemorrhage which cannot be controlled via compression, thus a form of intravascular control is required to improve mortality and morbidity rates. Fluoroscopy free methods allow fast, accurate insertion to control haemorrhage, which would otherwise remain uncontrolled until arrival at the ED. Rapid aortic stemming via REBOA will be beneficial in patients in class IV shock due to the increase in MAP, resulting in the restoration in cerebral and myocardial perfusion. This prompt haemorrhage control and its benefits have a positive effect on both mortality and morbidity rates, thereby increasing the patients' quality of life post trauma. However due to the limited number of studies on humans, coupled with the lack of available data on pre-hospital REBOA procedures, further clinical studies in a human population are required to establish REBOA as a feasible pre-hospital procedure.

Conflict of interest

The authors declare they have no competing interests. One author, Gavin Smith declares his position as Associate Editor of the *Australasian Journal of Paramedicine*.

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