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The utility and promise of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the pediatric population: An evidence-based review☆,☆☆

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ABSTRACT

Hemorrhage is the main cause of preventable death in both military and civilian trauma, and many of these patients die from non-compressible torso injuries. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive method used for hemodynamic control of the hemorrhaging patient and has been compared to resuscitative thoracotomy (RT) with cross clamping of the aorta. REBOA has received a great deal of attention in recent years for its applicability and promise in adult trauma and non-trauma settings, but its utility in children is mostly unknown.

The purpose of this review article is to summarize and consolidate what is currently known about the use of REBOA in children. Some of the challenges in implementing REBOA in children include small vascular anatomy and lack of outcomes data. Although the evidence is limited, there are established instances in the literature of children and adolescents who have undergone endovascular occlusion of the aorta for hemorrhage control with positive outcomes and survival rates equivalent to their adult counterparts. There is a need for further formal evaluation of REBOA in pediatric patients with prospective studies to look at the safety, feasibility and efficacy of the technique.

Study Type: Narrative Literature Review
Level of Evidence: IV

Contents

1. Background

The first reported use of resuscitative endovascular balloon occlusion of the aorta (REBOA) was in 1954 in two lethally wounded Korean War casualties with uncontrolled intra-abdominal hemorrhage [1]. The device used was a single lumen, 10 French (Fr), non-radio-opaque, Dotter-Lukas 1 balloon catheter. Although both patients died, the

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catheter was effective in restoring blood pressure temporarily in one case. It was not until 1986 that a preliminary report was published concerning the use of aortic balloon occlusion in cases of human trauma suggesting clinical potential for REBOA [2]. Since then, the utility of REBOA has expanded, and the technique has been used to elevate central blood pressure in cases of hemorrhagic shock in a variety of clinical settings [3–7].

Hemorrhage is the main cause of preventable death in both military and civilian trauma, and many of these patients die from non-compressible torso injuries [8]. REBOA is a less invasive method of hemodynamic control in hemorrhagic settings relative to resuscitative thoracotomy (RT) with cross clamping of the aorta. Survival benefits between the two methods are controversial, as both may lead to unintended adverse effects [9–11]. Both methods pose a risk of hypoxia to distal tissue. Subsequently, hypoxia triggers an elevation of cytokines and increases lactate levels through anaerobic respiration contributing to the lethal triad of hypothermia, acidosis, and coagulopathy which may result in multiple organ failure and death. Other complications of REBOA include vascular injury (dissection, perforation, and rupture), incorrect placement of the access site, balloon migration/rupture, and thrombotic and air embolization. All of these complications can adversely affect survival.

A REBOA catheter can be placed at the bedside using the Seldinger technique which involves puncturing the femoral artery with a hollow needle, threading a guidewire through the needle, and then replacing the needle with an introducer sheath [12]. This technique may be performed using anatomical landmarks and manual palpation of the common femoral artery or under ultrasound guidance. Cannulation can also be accomplished by surgical cut-down, if necessary [10]. Confirmation of the guidewire location may be obtained using ultrasound, plain x-ray, or fluoroscopy.

The introducer sheath can vary in size from 7 Fr to 14 Fr, depending on the particular device used. The REBOA device is comprised of a flexible catheter with a compliant balloon at the tip (Fig. 1). The catheter is advanced through the sheath into the aorta. The balloon is inflated in one of three zones (Zone I – thoracic aorta, from the left subclavian artery to the celiac artery; Zone II – between the celiac and renal arteries; Zone III – infra-renal placement) depending on the location of non-compressible hemorrhage (Fig. 2).

REBOA has received a great deal of attention in recent years for its applicability and promise in adult trauma settings, but its utility in children is mostly unknown. Proper REBOA catheter selection and deployment is largely based on morphometric equations using three-dimensional studies of major vasculature. In one study, torso length and age were the strongest predictors of distance from femoral artery access site to the major artery origins in Zones I through III [13]. Because the majority of subjects studied were adults, the results are unlikely to be translatable for use in children and adolescents [11]. Despite the lack of standardized algorithms and considerations for REBOA in children, its promise relative to other methods of hemodynamic control warrant further investigation in younger trauma patients.

2. Current applications of REBOA in adults

REBOA has been used in several clinical settings to temporize hemorrhage in adult patients. A meta-analysis by *Morrison et al.* found five major areas that REBOA has been applied and studied [10]:

1. Traumatic abdomino-pelvic hemorrhage
2. Hemorrhage arising from a ruptured abdominal aortic aneurysm (rAAA)
3. Pelvic hemorrhage during (or expected during) pelvic or sacral tumor surgery
4. Postpartum hemorrhage
5. Upper gastrointestinal hemorrhage

In all studies, REBOA was used for hemorrhage control and as a resuscitation adjunct to prevent cardiovascular collapse [14–20]. The majority [n = 31, (76%)] of studies involved the use of REBOA in patients already in established shock. The remaining studies [n = 10, (25%)] reported prophylactic balloon placement in hemodynamically stable patients deemed at risk of significant hemorrhage. In these instances, most patients were undergoing resection of pelvic and sacral tumors.

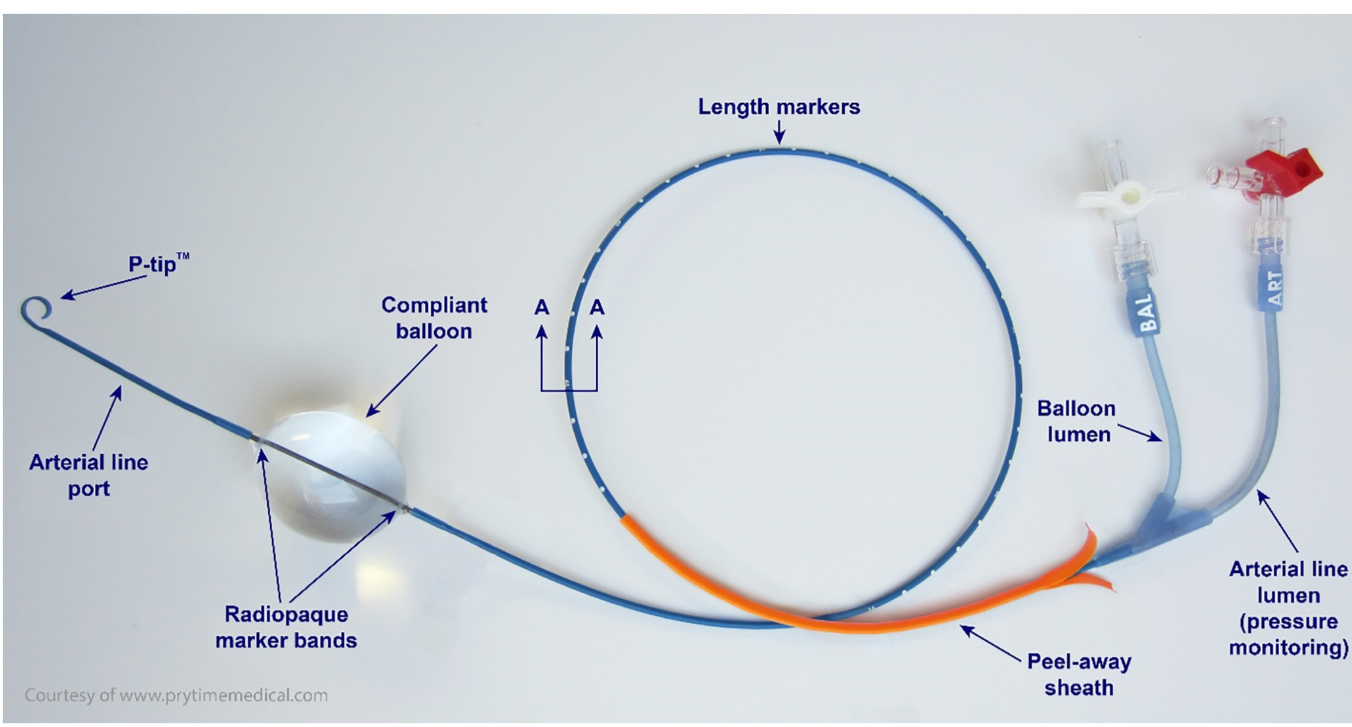

Fig. 1. The ER-REBOA™ Catheter Device. Photo: Courtesy of Prytime Medical Devices, Inc. The REBOA Company™.

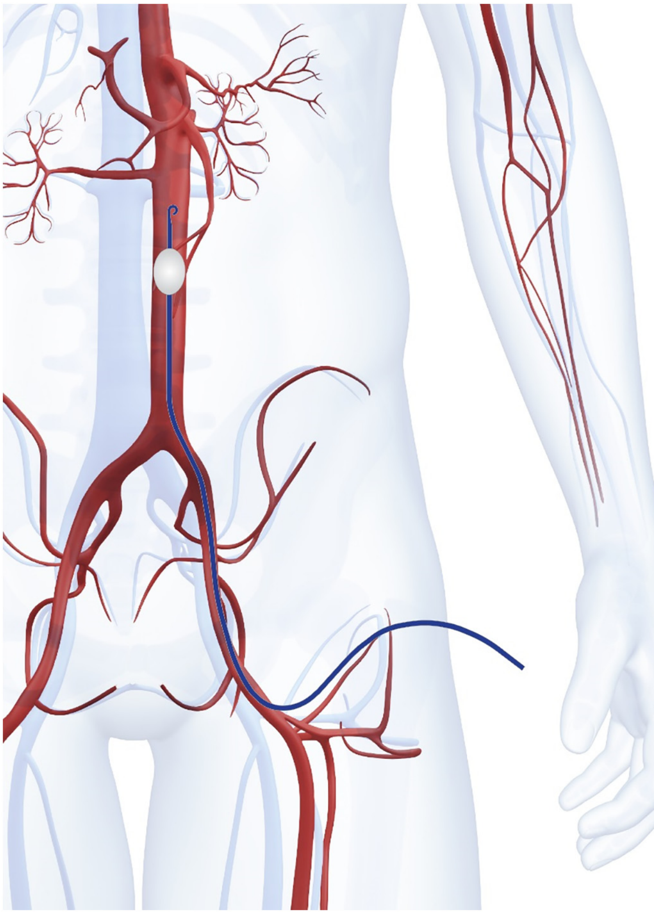

Fig. 2. Diagram of REBOA placement and deployment. Photo: Courtesy of Prytime Medical Devices, Inc. The REBOA Company™.

The American College of Surgeons (ACS) Committee on Trauma, in collaboration with the American College of Emergency Physicians, has released indications for the use of REBOA in trauma patients, as seen in Table 1 [21]. Bleeding must be below the diaphragm in order to use the REBOA. In a study by *Joseph et al.*, trauma patients that had undergone RT and subsequently died were assessed for potential benefit of REBOA. Those considered to have potentially benefited had no evidence of thoracic or iliac vascular injuries on autopsy [22]. Of all patients who underwent RT, 45% may have benefited from REBOA (39% with penetrating injury and 51% with blunt injury). Sub analysis showed that 28% of those that could have potentially benefited had thoracic injury without major vascular injury. The author concluded that adult patients with blunt trauma without thoracic injury were most likely to benefit from REBOA [22–28].

Table 1
Applications of REBOA.

Indications:
Traumatic life-threatening hemorrhage below the diaphragm in patients who are unresponsive or transiently responsive to resuscitation
Patients arriving in arrest from injury due to presumed life-threatening hemorrhage below the diaphragm
Technique:
The balloon catheter may be inflated at the distal thoracic aorta (Zone 1) for:
- Intra-abdominal hemorrhage
- Retroperitoneal hemorrhage
- Patients with traumatic arrest
The balloon catheter may be inflated at the distal abdominal aorta (Zone 3) for:
- Pelvic hemorrhage
- Junctional hemorrhage
- Lower extremity hemorrhage

REBOA-resuscitative endovascular balloon occlusion of the aorta. Adapted from Brenner et al.[14]

While several studies have shown positive outcomes concerning the use of REBOA in adult trauma patients, not all have had such results [29, 30]. A recent case-control study looking at the 2015-2016 ACS trauma quality improvement data set showed higher rates of mortality, acute kidney injury, and lower extremity amputation among patients who underwent REBOA in the emergency department compared to a matched cohort of patients who did not have REBOA [31]. There was no difference in blood products used or lengths of stay. The study was matched by propensity score for demographics and injury characteristics, and patients who were dead-on-arrival or transfers were excluded. These results suggest that there continues to be a need for research to clearly define when and in whom REBOA has greatest benefit and utility.

There are several other areas of REBOA use in trauma that are under investigation. One such area is hemorrhage control after axillo-subclavian injury. It has been reported that endovascular occlusion is equally, if not more effective, than sternotomy or thoracotomy with subclavian exposure, in reducing long-term mortality [32, 33]. As endovascular techniques continue to expand and show promise for hemorrhage control in a variety of clinical settings in adult patients, and the enthusiasm surrounding occlusive techniques portends great potential utility in pediatric patients.

3. REBOA in children: What is known?

In pediatric trauma, hemorrhage is rare and need for emergent hemorrhagic control is even rarer. RT is performed at an estimated rate of 2.3 cases per 12 million [34]. To our knowledge, there is only one study that has evaluated the mortality and characteristics of children with severe traumatic injury who received REBOA [35]. In this study, *Norii et al.* retrospectively reviewed patients less than or equal to 18 years of age using the Japan Trauma Data Bank from 2004-2015. After excluding those with unknown survival status, they noted a total of 54 patients in this age group who received REBOA. They found that these young patients garnered high anatomic injury severity scores (median 41.2, interquartile range 29-54) with a survival rate of approximately 43%, similar to those found in adult patients who receive REBOA [35, 36]. However, it should be noted that most [n = 39, (72%)] children in this retrospective study were between 16 and 18 years of age, and only one child less than 10 years of age received REBOA. Ultimately *Norii et al.* concluded that both young children and adolescents who underwent REBOA were seriously injured with high anatomical injury severity scores and had equivalent survival rates compared to reported survival rates from studies in adults. These results and conclusions are supported by an unpublished study performed in the United States that indicates REBOA is safe for use in adolescents despite their smaller caliber vasculature [37].

The remaining literature on endovascular balloon occlusion of the aorta for hemodynamic control in children is limited to case reports. One such report is of a 9-year-old girl who experienced massive hematemesis with cardiovascular collapse one day following esophageal foreign body removal that led to formation of an aorto-enteric fistula [38]. Due to rapid exsanguination, the decision was made to insert a 14 mm x 4 cm angioplasty balloon using a 7 Fr sheath via the common femoral artery to provide aortic occlusion of the fistula. The sheath and balloon were selected according to the diameter of the aorta approximated by a previous magnetic resonance imaging (MRI) scan. Hemodynamic control was achieved, and the patient did well post-operatively. The authors advised against blind placement of an aortic occluding balloon in pediatric patients but suggested that the technique itself has promise and can make a significant difference in patient outcome [38].

Another case report of a pediatric blunt abdominal aortic injury in Japan described REBOA use in a 12-year-old boy who was crushed between two personal recreational watercrafts on a lake [39]. Emergency medical services transported him to the hospital, where contrast-enhanced CT revealed an abdominal aortic injury. An occlusive balloon catheter was deployed in the infrarenal aorta and the retroperitoneal cavity was opened. The aortic laceration was surgically repaired, and the patient recovered well post-operatively. This case report further suggests that REBOA is effective in temporizing hemorrhage from the abdominal aorta in children prior to surgical repair [39].

In addition to prevention of traumatic hemorrhage in children, vascular balloon occlusion has been used in complex congenital heart surgery. It is used in conjunction with Blalock-Taussig (BT) shunts to control major aorto-pulmonary collaterals. *Hjortdal et al.* described two children who underwent balloon occlusion for this purpose [40]. The first child was an 8-year-old female with a hypoplastic left ventricle, subpulmonary ventricular septal defect, severe pulmonary artery and vein stenosis, and bilateral BT shunts. She underwent cardiac catheterization because of increasing cyanosis and breathlessness. Balloon occlusion of both BT shunts was achieved without altering central venous pressure. The patient was placed on cardiopulmonary bypass, and the pulmonary venous stenosis was surgically relieved using a sutureless pericardial patch technique. The balloons were deflated intraoperatively without complication. The second child was a 7-year-old boy with left atrial isomerism, an absent left atrioventricular connection, and bilateral BT shunts who developed right atrioventricular valve regurgitation and needed a valvuloplasty. During the procedure, a balloon occluder was positioned in the left BT shunt during bypass to minimize systemic hypoperfusion and flooding of the surgical field. Hemodynamic stability was maintained throughout the procedure without complications. While these two cases do not involve direct balloon occlusion of the aorta, they help to reinforce the growing body of literature supporting endovascular balloon occlusion for hemodynamic control in children.

4. Anatomical considerations for REBOA in children

One particular challenge in the implementation of REBOA in children is the proper selection of the introducer sheath and the balloon catheter. The diameter of the common femoral artery increases with age and is also related to body size and sex in adult models (Table 2), but the translation of these findings to pediatric patients is not entirely clear. *Sandgren et al.* found that the femoral diameter in adolescent children was not significantly different between males and females (7.8 ± 1.7 mm vs. 6.2 ± 1.2 mm; $P>0.05$), but in all adult age groups, males demonstrated larger common femoral artery diameters [41]. A 12 Fr sheath has an outer diameter of 4.67 mm and is often too large for very young pediatric patients [35, 41]. The 12 Fr-compatible REBOA catheter was the only commercially available catheter in the US until 2016, when the 7 Fr sheath, whose outer diameter is only 3 mm, was introduced [42].

Similarly, aortic length and balloon deployment zones have been widely studied in adults, but there is limited data in children. *Hegde et al.* published a retrospective study that sought to determine the effective diameter (i.e. the average anteroposterior and lateral diameters) of the aorta in children using axial CT scans with double-oblique reconstructions. Their logarithmic regression models found that the aorta effective diameter differed according to sex and body surface area [43]. For example, in a male child with a body surface area of 1.4 m^2, the expected aorta effective diameter would be approximately 22 ± 2 mm [43]. The ER-REBOA^{TM} Catheter has a maximum balloon inflation diameter of 32 mm, which is more than adequate for nearly all male and female children according to the study results. Because the balloon may be inflated much larger than a child's aortic diameter, it is essential that caution be taken to not overinflate.

In continued effort to examine the diameter of the aorta in pediatric patients, *Carrillo, et al* used the approximate aortic diameters from CT scans of 289 patients to create artificial aortas using a three-dimensional (3D) printer [44]. The aortas were then inserted into a circulatory system model that both simulated abdominal and upper body perfusion. Sonographic flow meters and pressure transducers were placed along the circuit, and measurements were recorded as a REBOA device was inflated in the aortic segment. Zone 1 and 3 aortic diameters were measured and grouped according to pediatric Broselow category. Recommendations were then made for REBOA inflation volumes according to the results (Table 3). The results were also compared to the aortic diameters predicted by *Hegde, et al*, and it was noted that many of the measurements were significantly different from one another per Broselow category.

Another study by *Carrillo et al*. looks at the feasibility of using the REBOA as a temporizing measure for inferior vena cava injury in children [45]. Similar to the previous study, the pre and posthepatic IVC diameter was measured using the initial CT scan performed. Penrose drains were used to model the resulting vessel diameters of the five largest Broselow categories. Hydrodynamic testing was then performed using the REBOA. The recommended filling volumes to obtain 50% occlusion were smaller range compared to the aortic study and ranged from 5.7-12.4cc for prehepatic occlusion and 7.7-12.4cc for posthepatic occlusion.

Other morphometric models have been used to calculate aortic diameter and distance between the femoral vessels and major aortic side branches in adults [46, 47]. Strong correlations have been found between arterial length and torso height, which can be measured easily in the emergency setting to predict insertion length for REBOA [46, 47]. Unfortunately, these models have been created from adult white males and have not accounted for varying degrees of vessel tortuosity among different age groups [47].

A cadaver-based study looking at surface landmark-guided placement of the REBOA balloon catheter is described by *Linnebur et al.* They found that using the mid-sternum as an external landmark yielded a 100% likelihood of deployment in zone 1 with an acceptable margin of safety [48]. Although the results were excellent, only 10 adult cadavers were used. Like many of the morphometric analyses, extrapolation to pediatric populations is limited.

Considering the variations in vascular anatomy of children, many

Table 2
Common femoral artery diameter in healthy male and female subjects.

Age Group	Sex	Age (years)	*P*-value	Femoral diameter (mm)	*P*-value
Adolescent	Male	12.7 ± 2.9	NS	7.8 ± 1.7	NS
	Female	10.8 ± 2.5		6.2 ± 1.2	
Young Adult	Male	25.4 ± 3.3	NS	9.0 ± 0.8	<0.001
	Female	24.0 ± 3.8		7.5 ± 0.7	
Adult	Male	39.8 ± 5.9	NS	10.0 ± 1.0	<0.001
	Female	42.5 ± 4.9		8.2 ± 0.6	
Older Adult	Male	66.8 ± 7.0	NS	10.4 ± 1.1	<0.001
	Female	67.9 ± 8.5		9.2 ± 0.9	

NS- Not Significant. Reproduced from Sandgren et al.[38]

Table 3
Recommended initial REBOA inflation volumes and zone distances (cm) for the five largest Broselow categories.*

Broselow Category	Average age (years)	Average weight (kg)	Inflation at zone 1: Aorta at the xyphoid process (ml)	Inflation at zone 3: Aorta at the umbilicus (ml)	Zone 1-zone 3 distance (cm)
Black	12.3	49.1	7.5	5.5	21.8
Green	9.4	33.5	6	3.5	14.5
Orange	7.3	26.3	5.5	3	13.0
Blue	5.5	21.2	5	2	12.8
White	3.6	18.3	3	1.5	11.8

*Inflation volume based on occlusion of flow by approx. 75%. REBOA-resuscitative endovascular balloon occlusion of the aorta. Adapted from Carrillo et al.[44]

more studies are required to ascertain ideal REBOA sizing in this population. Even in the largest study by *Norii, et al,* there was a lack of information pertaining to balloon catheter selection [35]. The use of REBOA in children is likely to gain wider acceptance with the advent of smaller REBOA-compatible catheters. A limitation to using small balloons in narrow vessels is that small changes in the diameter of the balloon can result in large changes in flow rate, making control of distal flow by manual adjustment extremely difficult [49, 50]. As studies continue and more REBOA devices are produced, use in children may be a realistic expectation for the future.

5. Alternatives to the commercially available REBOA catheters

While use of alternative devices for occlusion of the aorta in children is experimental, there are a few vascular devices that may have potential. Aortic occlusion balloons function primarily by temporizing the leak with gentle traction to achieve adequate hemostasis, allowing time for controlled surgical repair [51, 52]. A strong attribute of the REBOA catheter is that it is compliant, and when inflated to a diameter larger than the aorta, the balloon molds itself to the vessel, minimizing possible injury [53].

Unfortunately, REBOA is not recommended by the manufacture for aortas less than 15 mm in diameter. The smallest recommended inflation diameter of the REBOA is 9mm using 2cc of fluid [54]. From previous studies, the zone 3 aortic diameter may be as small as 8mm in children falling in the black Broselow category and gets smaller as the categories go down [44]. Small standard angioplasty balloons, even low pressure balloons, carry the risk of aortic injury if there is a mismatch between the size of the aorta and the diameter of the selected balloon. An ideal alternative for the small sized aortas of babies and young infants would be a reliable, atraumatic balloon that goes through a small vascular sheath. There are case reports of the off-label use of balloon catheters to occlude and control vascular injuries in the pediatric and young adult populations prior to REBOA. Examples include the application of a Fogarty balloon catheter to manage an iatrogenic injury of the aorta/innominate artery, as well as a 16GFoley catheter in the management of an aortic tears [51, 52]. An inflatable balloon catheter has also been reportedly used to seal a false ascending aortic aneurysm [55].

The Tyshack Mini® balloon from NuMED, a pediatric valvuloplasty catheter used by cardiologists for sizing atrial septal defects, might be an adequate alternative to REBOA for small diameter aortas given its low profile, tip flexibility, and small required introducer system. The device ranges in diameter from 4-10mm, and in length from 2-4mm. They are designed to go through 3-4 F introducer sheaths. However, unlike the REBOA catheters that are placed directly through the sheath, these require placement over a guidewire with fluoroscopy guidance, which may inhibit expedited placement in an emergency situation.

6. Concluding remarks about REBOA in pediatric trauma

Although the evidence is limited, there are established instances in the literature of successful use of REBOA for temporary control of massive hemorrhage in trauma and non-trauma pediatric patients. Compared to RT with occlusion of the aorta after trauma, REBOA is less invasive and may avoid associated morbidity, allow for more rapid and earlier hemorrhage control, decrease overall blood loss, minimize hypothermia, and improve overall survival. Essentially, it could serve as a bridge to the operating room, as it can be placed in minutes in the emergency room, whereas getting to the operating room and gaining access to the bleeding source in the abdomen could take much longer, especially in pediatric centers where an operating room may not always be available for trauma. It should be noted that these instances are extremely rare in pediatric trauma; however, with the increased incidence of penetrating injuries, these scenarios may become more commonplace in our experience.

Other possible uses of REBOA include prophylactic placement by interventional radiologists prior to operations where massive arterial bleeding is expected such as operation for vascular pelvic or sacral tumors, and emergent placement when massive bleeding inadvertently occurs intraoperatively or in the interventional radiology suite. For the latter instance, the benefit would be temporizing the bleeding until adequate exposure and resources are rapidly deployed to obtain definitive vascular repair.

Some limitations to REBOA use in children include the lack of systematically evaluated high-quality evidence, availability of equipment, lack of experienced clinicians, and possibility of procedural complications, including vascular injury. Therefore, it should be approached with caution. With the advent of the 7 Fr (3 mm diameter) sheath, REBOA has become a more realistic option for larger pediatric patients, but the commercially available catheter is likely too big for younger children. However, alternate balloon catheter options may be considered. Pediatric trauma surgeons should become familiar with the indications and technique for REBOA, and establishing institutional protocols in conjunction with vascular surgery or interventional radiology may be a consideration at free-standing pediatric trauma centers. Inserting the commercially available catheters requires minimal training that most pediatric surgeons skilled in vascular access should be comfortable with if interventional radiologists or vascular surgeons are not rapidly available. Once more commonly utilized, prospective, multi-center reviews will be necessary to fully evaluate the safety and effectiveness of this technique.

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