REVIEW ARTICLE

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REBOA – new era of bleeding control, literature review

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT: It is extremely difficult to provide non-compressible torso hemorrhage control particularly in trauma setting. A vast majority of cases present inability of successful exsanguination arrest, leading to cardiovascular collapse, myocardial and cerebral hypoperfusion and death eventually. The only possible treatment for these patients is prompt bleeding control, either open or endovascular. Aortic occlusion seems to be the most rapid and convenient way to restrain blood loss and possibly increase survival. However, it is not proven yet. Traditional aortic occlusion for trauma consisted of supradiaphragmatic thoracic aorta cross-clamping through resuscitative thoracotomy (RT). This complicated and devastating procedure triggered the necessity to work on a simpler, less invasive resuscitation bridge which can be implemented in emergency departments or even in prehospital setting. Resuscitative balloon occlusion of the aorta (REBOA) provides a novel method of hemorrhagic shock stabilization in bleeding below the diaphragm. The mechanism lies in improving myocardial and cerebral perfusion and ceasing major bleeding itself. This method together with invasive endovascular and surgical procedures creates a new approach of choice for trauma patients. It is called Endovascular Hybrid Trauma and Resuscitation Management (EVTM) and introduces this concept to modern clinical practice. Through a detailed review, this article aims to introduce REBOA procedure to a broader recipient and present REBOA details, benefits and limitations.

KEYWORDS: aortic occlusion, hemorrhage, IABO, REBOA, resuscitation

ABBREVIATIONS

AO – aortic occlusion
ER – emergency room
EVTM – Endovascular Resuscitation and Trauma Management
FAST – Focused Assessment with Sonography in Trauma
NCTH – non-compressible thorax hemorrhage
OR – operating room
rAAA – ruptured abdominal aortic aneurysm
REBOA – resuscitative balloon occlusion of the aorta
SBP – systolic blood pressure
RT – rescue thoracotomy
USG – ultrasound examination
cREBOA – complete resuscitative balloon occlusion of the aorta
pREBOA – partial resuscitative balloon occlusion of the aorta
iREBOA – intermittent resuscitative balloon occlusion of the aorta

INTRODUCTION

Traumatic injuries contribute to almost 9% of early mortality around the world. Among these, approximately 40% are caused by exsanguination which could be prevented [1, 2]. Management of uncontrolled hemorrhagic shock remains challenging and clinicians worldwide strive to avoid its effects such as cardiovascular collapse causing myocardial and cerebral hypoperfusion.

Traumatic bleeding is divided into non-compressible and compressible. The latter carries less risk of mortality as it can be easily controlled [3]. Hemorrhages originating in the torso cannot be directly compressed thus appear to be more challenging. This type of bleeding is known as non-compressible truncal hemorrhage (NCTH) and contributes to major mortality particularly in traumas. Non-traumatic fields with possible NCTH impact are vascular surgery, gastroenterology and obstetrics. To define NCTH criteria adapted by Kisat et al. are used. These consist of an SBP<90 mmHg and specific source of bleeding (pulmonary injury, solid organ injury grade 4, named axial torso vessel injury, pelvic fracture) [4]. NCTH examples are hemorrhages arising from gastrointestinal tract, ruptured abdominal aortic aneurysms, postpartum hemorrhages or any type of traumatic bleeding from the thorax, abdomen or pelvis. NCTH management is only invasive and requires either an open surgical approach such as laparotomy, thoracotomy with cross-clamping or endovascular interventions. The method of choice depends on bleeding location and facility possibilities. The natural history of any uncontrolled hemorrhage leads to cardiovascular collapse causing cerebral and myocardial hypoperfusion, eventually resulting in death [5, 6].

Advanced bleeding resuscitation usually requires complex approach with high availability of resources such as: specialized centers, operating rooms, blood products and equipment. Aortic occlusion (AO) seems to be the most rapid and convenient way to decrease blood loss and possibly increase survival. Early aortic occlusion preserves cerebral and myocardial perfusion, which is crucial for further survival. Traditional aortic occlusion for trauma consisted of supradiaphragmatic thoracic aorta cross-clamping using clam shell resuscitative thoracotomy (RT). This technique remained technically complicated, controversial and had devastating effects on a morbid patient and triggered the necessity to work on a simpler, less invasive resuscitation bridge to improve outcomes, which can be implemented in emergency departments or even in prehospital setting [7, 8]. REBOA gained promising popularity as a minimally invasive alternative to RT for NCTH management below the diaphragm. The initial reports on REBOA use originate from the Korean War and the procedure has been described in a couple of publications [9, 10, 11, 12]. Aortic occlusion utilization in rAAA was originally presented by Heimbecker et al. [13]. Ongoing military conflicts in Iraq and Afghanistan led to increased further research in endovascular approaches to hemorrhage control causing REBOA technique getting widespread.

This review provides recent evidence on REBOA utilization, the principles of REBOA technique, indications, clinical experience, training and implementation concerns.

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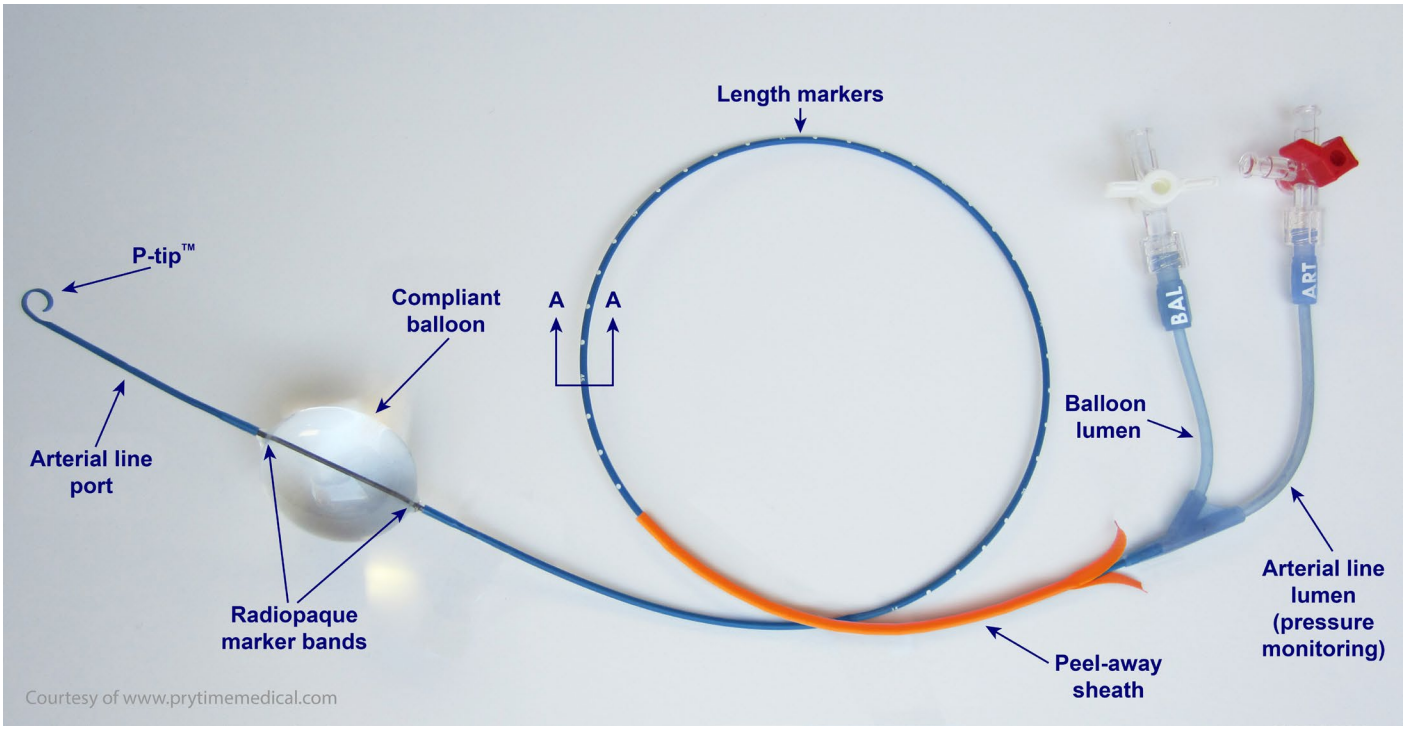

Ryc. 1. Prytime Medical ER-REBOA device.

REBOA UTILIZATION

Indications

The REBOA principle itself is to endovascularly place a flexible catheter with a balloon at its tip and inflate it in a desired position, proximal to the hemorrhage location. This aims to increase afterload and maintain cardiac and cerebral perfusion and subsequently decrease distal blood flow and avoid fatal NCTH bleeding effects [14]. It cannot be forgotten that REBOA is just a temporary adjunct to definitive hemostasis interventions. This is a way to gain time and sustain patient's vitality for further damage control surgery [15].

REBOA has to be adopted to a certain group of patients to preserve its favorable effect. An ATLS accepted indication is a trauma patient in hypovolemic shock (systolic blood pressure SBP <90 mmHg) being a non-responder or partial responder to fluid/blood product resuscitation [16]. It is essential to perform chest X-ray before any REBOA utilization decision. This imaging is important to rule out any thoracic trauma that could be a source of patient's hemodynamic collapse. Any suspicion of thoracic bleeding such as penetrating thoracic injury, broadened mediastinum, hemothorax or any signs of bleeding above potential balloon inflation zone are pointed as contraindications to REBOA. Potential features pointed above indicate RT being performed. The focused assessment with sonography for trauma (FAST) examination is another rapid and easily available possibility for additional bleeding source identification. Patients with hypotension and a positive abdominal FAST can be indicated Zone I occlusion whilst patients with a negative FAST and a pelvic fracture can be candidates for Zone 3 occlusion [17].

Technique

Detailed maneuver description can be found in an original article by Stannard et al. [18]. It consists of five steps: vascular access, balloon placement, balloon inflation, balloon deflation and access sheath withdrawal.

The arterial access establishment is the first step and is crucial for REBOA deployment. It is considered as a limiting part of REBOA; therefore, its mastering has to be emphasized. A standard Seldinger's technique approach is performed. Initial micropuncture with a 5Fr sheath placement should always be considered and common femoral artery is an ideal aim for access sheath placement. It reduces possible access site complication rate in particular when REBOA insertion success is uncertain [19]. Further upsizing to 7Fr–14Fr sheath is never troublesome and gradual increase in sheath diameter appears less traumatic for atherosclerotic vessels. The upsized sheath size depends on a balloon system provided. Utilization of a 7Fr access sheath obviously tends to be a worldwide preferred option if available [20].

Common femoral artery can be cannulated using open cut-down or percutaneous approach. The cut-down ensures perfect artery control although requires surgical skills to perform. The percutaneous access can be obtained by any physician either blindly or with ultrasound guidance. Ultrasound use should always be considered where available as it improves success rate of the procedure especially in patients with non-palpable pulses and in hypovolemic shock where blind puncture is difficult to impossible [21]. If percutaneous approach is impossible due to non-palpable pulse, open surgical cut down has to be performed [22].

There are several possible occlusion balloons. Coda (Cook Medical), Reliant (Medtronic), Bernstein (Boston Scientific) have already been used to restrain bleeding in ruptured abdominal aneurysms (rAAA). However, their limitation of at least 12Fr sheath necessity triggered the development of REBOA dedicated 7Fr balloons: ER-REBOA (Prytime Medical) (Fig. 1.) or Rescue Balloon (Tokay Medical Products). Additional advantages of these low-profile de-

vices is curved atraumatic tip and ability to continuously measure systolic blood pressure above the balloon [21, 23].

If access sheath is placed correctly, REBOA system can be inserted. Balloon landing place is planned before its insertion and is based on three anatomical zones: Zone I (thoracic aorta to celiac trunk), Zone II (celiac trunk to renal arteries), Zone III (infrarenal) (Fig. 2.) [24]. The choice depends on the source of bleeding. Zone I is selected for any hemorrhages originating below the diaphragm and patients in cardiac arrest, Zone III in pelvic injuries with no evidence of intraabdominal bleeding [25]. Zone II is rarely chosen and considered as no occlusion zone as it involves direct obstruction of visceral arteries. Uninflated balloon catheter positioning has to be followed by either X-ray or fluoroscopy [26]. Zone I positioning is confirmed by imaging the balloon above the diaphragm, zone III if the balloon is located at L2–L3 vertebrae. If none of these imaging methods is available for prompt use, ER-REBOA balloon catheter is equipped with calibrated scale external landmarks providing reference on how deep the balloon is inserted. Instructions for use indicate approximately 46 cm for Zone I and 28 cm for Zone III [27].

Inflation of the balloon leads to SBP increase and loss of contralateral femoral pulses. REBOA balloon is usually inflated with a syringe containing a solution of saline and contrast media. A volume of 3mL in Zone III and 8 mL in Zone I is preferably used regarding the Prytime ER-REBOA catheter, which is recommended by Joint Trauma System Clinical Practice Guidelines [23]. Overinflation has to be avoided as it can lead to balloon or vessel wall rupture [23, 28, 29]. The maximum inflation volume is 24 mL [27]. Recent animal model studies try to compile definitive occlusion volume basing on the balloon diameter [29]. Another confirmation of proper balloon deployment should be performed by most likely fluoroscopy or at least X-ray, based on anatomical landmarks or clinical examination of contralateral femoral pulse loss [30]. Every procedure has to be relevant to ER resources.

REBOA deployment acts only as a resuscitation bridge and eventually brings the proper surgical or endovascular damage control intervention in order to achieve hemostasis. Once it has been successful and patient is stable, the balloon can be deflated and removed [19].

REBOA deflation may lead to rebound cardiovascular collapse, recurrent bleeding or severe reperfusion syndrome. Thus, strict patient monitoring has to be conducted directly after removal. If the patient's state is satisfactory, definitive REBOA and sheath removal may be performed. Arterial puncture closure depends on the utilized sheath size and access method. Cut downs are closed surgically, percutaneous punctures either with a dedicated closure device or manual compression for 30 minutes. Manual compression is restrained only to low profile access sheath choice [23]. Eventually lower limb perfusion has to be confirmed checking clinical pulses or using Doppler ultrasound examination.

Types or REBOA

The REBOA intervention can be performed using different balloon inflation techniques: complete occlusion (cREBOA), partial occlusion (pREBOA) or intermittent (iREBOA). These techniques have been invented in order to eliminate cREBOA limitations. Prolonged occlusion with REBOA balloon of more than 40 minutes leads to distal profound ischemia resulting in further increased risk of severe

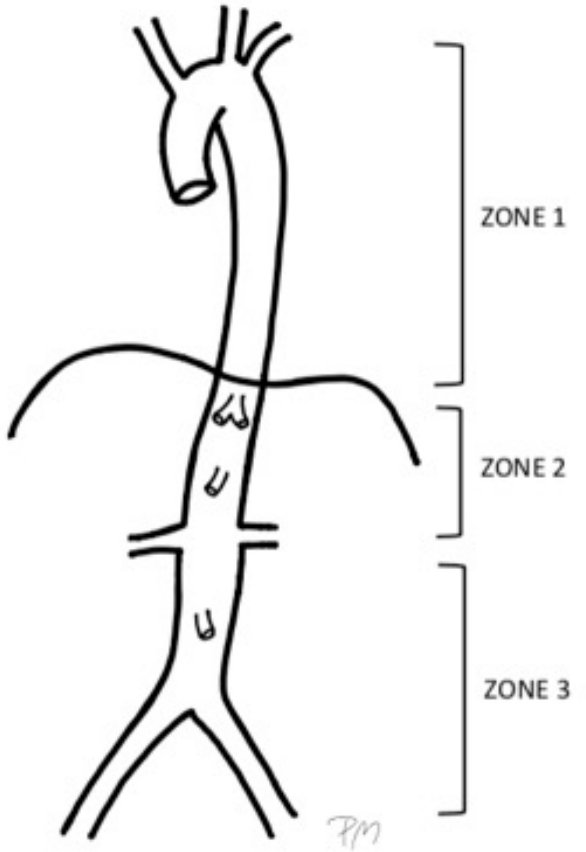

Fig. 2. Aortic zones related to REBOA.

reperfusion syndrome. Besides, instant, unbuffered supraphysiologic increase in blood pressure proximally to the balloon can cause rapid progression of traumatic brain injury and cardiac failure. The available evidence originates from different animal model studies presenting a potentially increased mortality with cREBOA [31].

Some animal studies show pREBOA and iREBOA being superior to cREBOA [31, 32]. However, no specific methodology for pREBOA has been implemented yet. In general, the balloon is inflated partially allowing an endoleak around the balloon to occur. The SBP is maintained above 70 mHg.

Favorable time limit of inflation has not been defined. Different animal studies showed the maximum time of 60–90 min without severe complications. However, it cannot be easily transferred to humans [33, 34]. Translational research suggests that time longer than 60–90 min leads to irreversible damage do visceral organs. Reva et al. suggested a goal of <60 minutes of occlusion in Zone 1 and around 90 minutes in Zone 3, until rapid definitive surgical management. The aim of REBOA is to improve survival, not prolong time to death. All in all, it is highly important to measure the time of balloon inflation and attempt to decrease occlusion time as much as possible. Available registries prove that patients who benefited from REBOA have a shorter occlusion time.

Complications

Complications may be related to the vascular access necessary for REBOA insertion, REBOA mechanism itself or failure of the technique. Described possible complications are as follows: distal ischemia of the limb with eventual amputation, intracranial hem-

orrhage, pseudoaneurysm at the access site, acute kidney failure, balloon migration, infection, aorta or iliac artery rupture or dissection, [35]. More complications have been reported with large 14–12 French systems, but 7 French ones are not complication-free [20, 35]. As major vascular complications are possible to occur, REBOA should be performed by a trained clinician with knowledge or potential ones. Besides, in order to treat possible complications, vascular surgeon should be available on prompt call. All in all, REBOA remains a resuscitation tool and its use should not be abandoned for patients in restraints.

DISCUSSION

Possible REBOA benefit appears to be very promising. The technique has gained popularity worldwide in the last years with an increasing number of applications reported, particularly in traumas. A crucial point in REBOA is that it can never be used as a definitive care tool; it is always a bridge to further surgical or endovascular management. REBOA acts as a part of a broader trauma management system called Endovascular Resuscitation and Trauma Management (EVTM). There is still lack of high-grade evidence on specific indications and proper technique. No clear evidence on mortality decrease has been reported. A couple of recent systematic reviews tried to gather and explain current contrasting evidence [28, 36, 37]. Knowledge about REBOA efficacy is only based on retrospective case-report series, since it is highly difficult to create a structured randomized trial due to insufficient volume and inability to predict cases. The first trial enrolling randomized patients for REBOA utilization has been recently started, and it is called UK-REBOA Trial. Due to insufficient high-grade data, the REBOA concept is still not introduced in many centers. Global registries try to capture all REBOA cases and identify specific data and outcomes and are being used to develop and refine protocols to optimize patient's survival. This includes AORTA registry, ABOTrauma registry and DIRECT-IABO registry.

The most important question is whether REBOA impacts the survival benefit. The prospective observational study AORTA 1 showed the REBOA vs. RT mortality of 72% vs. 84% respectively [38]. However, this study included all patients who received REBOA with significantly varied causes of bleeding and overall status at the time of intervention. The overall survival was 21.1% with no significand difference between REBOA and RT (28.2% vs. 16.1%, P = 0.12). The next big multicenter study AORTA 2 investigated a more selective group of patients. It demonstrated that REBOA can offer a significant survival benefit over RT, particularly in patients not requiring CPR (93% vs. 48%, P <0.001)[39]. Japanese population registries provide the most extensive evidence, e.g. DIRECT-IABO registry. Surprisingly, large high-volume reports by Norii, et al. and Inoue, et al. presented unfavorable effects of REBOA with a higher mortality [40, 41]. On the other hand, different Japanese reports showed priority of REBOA compared to RT [42, 43]. The conclusion is not clear as these studies are not specifically dedicated to compare REBOA and RT efficacy. As shown above, this experience is not supported by any American and European data. Despite good results these publications are clinical series or case reports (grade IV evidence), which is a major limitation. None of the currently available publications can be compared because they lack homogeneity. It is also unclear if REBOA was used as a formal damage-control protocol or as the last resort option for unsalvageable patients. What is more, comparing RT and REBOA may create a major selection bias. RT indications are different as mentioned above, for example patients with a severe thoracic injury are contraindicated REBOA utilization and would benefit from RT use. Comparison of these two techniques has to be revised.

As opposed to aortic occlusion through RT, REBOA seems a less dramatic and less invasive alternative. REBOA seems to be of use especially among selected patients with ongoing non-compressible hemorrhage originating below the diaphragm and hypotension but with no hemodynamic collapse. Its deployment through femoral access may be better tolerated than direct thoracotomy, which requires additional anesthesiological actions. Moreover, balloon placement does not necessarily mean inflation. Deflated REBOA (dREBOA) can be used as a security device if the risk of hemodynamic instability is high.

Despite REBOA being a lifesaving method that should be known to all physicians, it requires dedicated training. It may be challenging for those with limited previous endovascular experience. However, it can be performed by non-surgical specialties if provided with an appropriate course. There are several courses that teach all necessary skills. Examples are Basic Endovascular Skills for Trauma BEST course (USA), Endovascular Skills for Trauma and Resuscitative Surgery ESTARS course (USA), Endovascular Resuscitation and Trauma Management EVTM Workshop (Sweden). These use lectures, simulations or cadaver models to teach particular REBOA skills. Moreover, each year an EVTM Symposium is conducted to summarize the collected data and evidence.

CONCLUSION

Resuscitative balloon occlusion of the aorta presents a promising adjunct to NCTH management dedicated for bleeding originating below the diaphragm. Its utilization provides a bridge hemorrhage control and gains time for further definitive hemorrhage management.

There is an immense necessity to continue research and develop technology that will expand possible REBOA indications. Practitioners have to keep obtaining necessary skills, stay up to date with upcoming evidence and share and implement REBOA worldwide with multidisciplinary teams. The introduction of REBOA into clinical practice should follow the IDEAL recommendations (Idea, Development, Exploration, Assessment, Long-term study). Currently it falls between the E and A phase. Major clinical trials have to be conducted before widespread adoption.

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