Case Report

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Endovascular Resuscitation with Aortic Balloon Occlusion in Non-Trauma Cases: First use of ER-REBOA in Europe

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is currently evolving and being used worldwide for trauma management. Smaller sheath devices for REBOA and new advances in endovascular resuscitation methods suggest the potential for the procedure to be utilized in hemodynamically unstable non-traumatic patients.
Methods: We describe five adult patients that underwent hemodynamic control using the 7 Fr sheath ER-REBOA™ catheters for non-traumatic hemorrhagic instability at Örebro University Hospital between February 2017 and June 2017.
Results: The ER-REBOA™ catheter was inserted and used successfully for temporary blood pressure stabilization as part of an endovascular resuscitation process.
Conclusion: The ER-REBOA™ catheter for endovascular resuscitation may be an additional method for temporary hemodynamic stabilization in the treatment of non-traumatic patients. Furthermore, the ER-REBOA™ catheter may be a potential addition to advanced cardiac life support in the management of non-traumatic cardiac arrest.

Keywords: *REBOA; Hemorrhage; Hemorrhagic Shock; Endovascular Resuscitation*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is currently evolving and being described worldwide as a potential primary alternative to resuscitative thoracotomy (RT) in the treatment of uncontrolled hemorrhagic shock [1–4]. This minimally invasive technique helps to provide temporary hemodynamic stability, in particular for patients presenting with non-compressible torso hemorrhage (NCTH). By controlling distal bleeding and sustaining carotid and coronary perfusion, definitive open surgical and/or endovascular intervention, such as endografts or embolization, may be performed [5,6]. Advances in endovascular techniques as well as in REBOA technology and smaller balloon systems has allowed the procedure to be utilized more frequently, in different settings and by various medical professionals [7–12].

REBOA has not only been useful for temporary control of traumatic NCTH but also non-traumatic cases such as postpartum hemorrhage (PPH), one of the leading causes of maternal mortality and morbidity, and non-traumatic cardiac arrest (NTCA) [13–15]. The treatment of hemodynamically unstable non-traumatic

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Figure 1 CT showing blood extravasation from the hepatic artery pseudoaneurysms in Patient 1.

patients might also be facilitated by using a multidisciplinary endovascular and hybrid trauma management (EVTM) concept combining open surgery and endovascular procedures. This is part of the emerging concept of endovascular resuscitation [16,17].

Different techniques for the use of REBOA have been suggested. Partial REBOA (pREBOA) has shown promising results, decreasing the risk of organ failure but at the same time giving the possibility of prolonging occlusion time. Another technique described in former case series is intermittent REBOA (iREBOA) [8,9,18–21].

The Prytime ER-REBOA™ catheter (Boerne, TX, USA) has been optimized for use in the emergency setting, while also simplifying the procedure [22,23]. Using a smaller 7 Fr sheath and having an atraumatic tip is said to decrease the risk of arterial damage as well as total femoral artery occlusion. In addition, there are external length markers to assist the positioning of the device, and without the need for a guidewire or fluoroscopic placement verification, allowing quicker hemodynamic control. The possibility of systolic blood pressure (SBP) monitoring proximal to the balloon combined with sheath SBP measurements facilitates verification of pREBOA and iREBOA. Finally, after removing the device, surgical repair is not mandatory as a closure device can be used.

The aim of this study is to report to the best of our knowledge the first cases of the ER-REBOA™ being used to treat non-traumatic hemodynamically unstable patients in Europe.

PATIENTS AND METHODS

This is a description of a clinical case series of ER-REBOA™ performed on five adult patients (four males, one female) at Örebro University Hospital between February 2017 and June 2017. Regional Ethics Committee approval (No 2014/210) was obtained for the REBOA procedure patients. Data was prospectively and retrospectively analyzed by reviewing patients' medical journals. All patients were treated with REBOA procedures performed by the on-call vascular surgeon using a Prytime ER-REBOA™ catheter with a 7 Fr sheath. In all cases but one (Patient 4), the 7 Fr sheath was placed blindly. All vascular accesses were completed in single attempts. Two locations of REBOA were used, either supra-celiac (zone I) or infra-renal (zone III) [1]. In all cases except two (Patient 3 and 4), after removal of the catheter and sheath the vascular access was closed with 6 Fr AngioSeal™ (St. Jude Medical, Little Canada, MN, USA), a method only recommended for experienced users. Distal ischemia was later excluded by palpation of pulsations in the popliteal-, posterior tibial- and dorsalis pedis arteries.

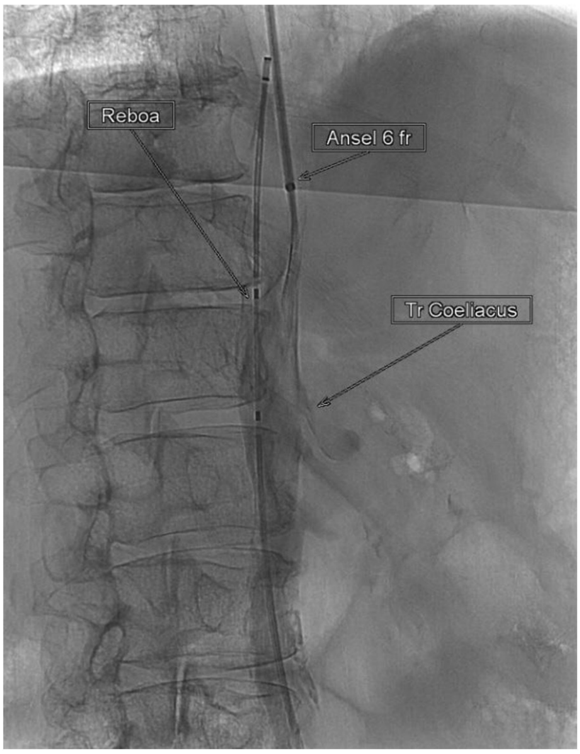

Figure 2 Deflated balloon in zone I during angiography for cannulation of the celiac trunk for bleeding control, by brachial access with a 6 Fr catheter in Patient 1.

RESULTS

Patient 1 (Figures 1–3)

A 76-year-old male with a pancreatic tumor underwent a Whipple procedure with subsequent complications requiring a total pancreatectomy. The patient was discharged but presented to the emergency department a week later in a deteriorated condition with pus exuding

Figure 3 Deflated balloon in the aorta with a balloon in the celiac artery for bleeding control and contrast extravasation seen from the pseaudoaneurysmspseudoaneurysms in Patient 1.

from the surgical wounds and anemia, where hemoglobin had decreased to 58 g/L from 102 g/L on discharge. On day 3 after readmission, the patient reported abdominal pain and was passing bright red blood per rectum. His SBP was 80 mmHg and heart rate (HR) was 90 beats per minute (bpm). A computed tomographic angiography (CTA) showed a ruptured pseudoaneurysm of the hepatic artery with contrast extravasation. The patient was taken to the intensive care unit (ICU) where his SBP further decreased (70 mmHg) despite rapid infusion of fluids and blood transfusion products; a total of nine units of packed red blood cells (PRBC) and four units of fresh frozen plasma (FFP) were given. A 7 Fr sheath was placed blindly in the left femoral artery and zone I REBOA was performed with an immediate increase in the patient's SBP. The patient was then transferred with REBOA to the hybrid operating theater where coil embolization of the hepatic artery was performed. During the procedure, the balloon ruptured but was immediately replaced. Further selective catheterization of the celiac artery enabled insertion of a smaller, selective balloon that replaced the REBOA during embolization. After endovascular intervention, the patient remained hemodynamically stable but needed temporary hemodialysis due to renal failure. At 30 days post intervention the patient was recovering well and no longer in need of dialysis.

Patient 2

A 62-year-old male was admitted due to abdominal pain and underwent surgical repair of a perforated peptic ulcer, with complications causing reoperation to be performed following multiple wound dehiscence. Four days post discharge the patient presented to the emergency department hemodynamically unstable (SBP 75 mmHg, HR 110 bmp) with decreased consciousness, hematemesis, and melena. His hemoglobin had decreased to 64 g/L from 130 g/L on discharge. The patient was transferred to the operating theater where a 4 Fr sheath was placed blindly in the right femoral artery. Simultaneously, a gastroscopy was performed revealing a massive blood clot filling the ventricle. The general surgeon performed a gastrostomy to remove the clot and repair the initial perforated peptic ulcer. During the procedure, the patient's SBP decreased (70 mmHg) and the 4 Fr sheath was replaced with a 7 Fr. Zone I REBOA with total occlusion for 2 minutes was performed with an immediate increase in SBP (95 mmHg). Thereafter, pREBOA was performed for 11 minutes before gradual deflation and removal once SBP had stabilized (125 mm Hg). The remainder of the patient's in-hospital care was uneventful and at 30 days post intervention he was recovering well.

Patient 3

A 73-year-old male with multiple illnesses, including liver cirrhosis with esophageal varices, and receiving anticoagulation treatment for atrial fibrillation, presented to the emergency department hemodynamically unstable (SBP 90 mmHg, HR 100 bpm) with decreased consciousness, high fever, and massive melena. He was admitted to the ICU and a CTA was performed showing massive bleeding from both the ventral and dorsal rectal wall. SBP continued to decrease (60 mmHg) despite receiving blood transfusion products, a total amount of 22 units PRBC, 20 units FFP and seven units of platelets (PLT). He was transferred to the operating theater where a 7 Fr sheath was placed blindly in the left femoral artery. Zone III REBOA was performed with an immediate increase of SBP (100 mmHg). Simultaneously the general surgeon tried to further identify and attempt to treat the source of bleeding. After total occlusion for 60 minutes, the balloon was partially deflated (pREBOA) and positioned just proximal to the aortic bifurcation with the patient remaining hemodynamically stable. While changing the position, the balloon ruptured but was immediately replaced and zone III pREBOA was continued for an additional 30 minutes. The balloon was subsequently deflated with no further bleeding per rectum. The balloon ruptured once again but as the patient remained hemodynamically stable there was no need for further replacement. As the ER-REBOA™ catheter could not easily be withdrawn from the sheath, surgical cut-down and repair of the common femoral artery were performed. The patient remained hemodynamically stable but developed multiple organ failure. A CT was performed showing a large cerebral infarct and the patient died 12 days later.

Figure 4 CT of Patient 4 showing a distended colon and pREBOA.

Patient 4 (Figures 4 and 5)

A 69-year-old male arrived at the emergency department hemodynamically unstable with a distended abdomen and decreased consciousness after experiencing back pain for 2 days. The patient went into cardiac arrest upon arrival and cardiopulmonary resuscitation (CPR) was initiated. A 7 Fr sheath was placed in the right femoral artery using ultrasound guidance and zone I REBOA with total occlusion was performed. A 5 Fr sheath was also placed using ultrasound guidance in the left femoral artery for BP monitoring. After a few minutes, an increase in SBP (80 mmHg) was seen with the return of spontaneous circulation (ROSC). As the patient stabilized, the balloon was partially deflated (pREBOA) with overall occlusion time around 10 minutes before deflation. While performing a CT, which revealed a distended colon, the patient again became hemodynamically unstable and pREBOA was re-inflated, increasing SBP (90 mmHg). The patient was transferred to the ICU and, using both pREBOA and iREBOA together with adrenalin infusion for an additional 60 minutes, the patient was stabilized. He was then taken to the operating theater where a laparotomy confirmed severe colonic ischemia and a total colectomy was performed. The patient died a few hours later before the ER-REBOA™ catheter was removed. Post-mortem

Figure 5 Patient 4 during a pause in CPR for a pulse check in the emergency department. Notice the bilateral ultrasound assisted femoral artery access performed.

examination of the CT showed a small dissection of the right iliac artery (used for REBOA access).

Patient 5

A 31-year-old pregnant female with total placenta previa was planned for a caesarian section and hysterectomy due to placenta accreta, increta, and percreta. Due to the risk of hemorrhagic instability by both procedures, a 7 Fr sheath was placed blindly in the right femoral artery and a deflated balloon was positioned in zone III. A caesarian section was performed successfully by the gynecologist who then continued with a hysterectomy. During the following procedure, iREBOA was used for 5–10 minutes per inflation in conjunction with periods of hemorrhage. The patient remained hemodynamically stable throughout the whole procedure and the remainder of the patient's hospital stay was uneventful and at 30 days post intervention, she was recovering well.

Additional traumatic patient illustrating the use of ER-REBOA™

A 21-year-old female arrived at the emergency department unconscious and hemodynamically unstable with severe penetrating brain injury (PBI) after being hit in the skull with an axe. The patient went into cardiac arrest upon arrival and CPR was initiated with ROSC. While a CT was being completed CPR was again initiated and a 7 Fr sheath was placed blindly in the left femoral artery and zone III REBOA was performed. An immediate increase in SBP with ROSC was seen and total occlusion was continued for 15 minutes. Subsequently, the balloon was deflated but later re-inflated during surgery because of continued hemodynamic instability. Throughout the surgery, iREBOA was continued in conjunction with hemodynamic instability to facilitate central circulation with a total occlusion time of 40 minutes. Thereafter, the ER-REBOA™ was repositioned and inflated in the left common iliac artery for an additional 2 minutes. The patient remained hemodynamically stable (SBP 110 mmHg) but died two days later due to massive brain injury.

DISCUSSION

The use of REBOA in traumatic exsanguinating patients dates back to the Korean War [24]. However, since then, RT with aortic cross-clamping has been the method of choice, despite very poor survival rates [25]. Further development, as a result of military conflicts in Iraq and Afghanistan [26] and advances in vascular surgery in the last few decades [27,28], has permitted renewed interest in the application of REBOA for hemodynamic control. In 2011, Stannard et al. released a detailed report on the clinical use of REBOA and there have since been several studies reporting a possible increased survival rate for REBOA compared to RT in treating traumatic hemorrhagic shock [1,3,29,30]. Further use of REBOA has also been reported in patient series when treating PPH, pelvic surgery, iatrogenic injuries and other hemodynamic instabilities [13,31–33].

We present here to the best of our knowledge the first series of clinical cases using the Prytime ER-REBOA™ device through a 7 Fr sheath for endovascular resuscitation in non-traumatic hemodynamically unstable patients in Europe. All five non-traumatic patients received REBOA either to facilitate the treatment of, or proactively prevent, hemodynamic instability.

Using a multidisciplinary team approach (EVTM), open surgery or endovascular embolization was performed simultaneously with REBOA to gain temporary endovascular hemorrhage control [16]. Rapid first attempt percutaneous arterial access was achieved in all cases, despite hemodynamic instability or ongoing CPR. The use of the ER-REBOA™ catheter immediately improved hemodynamic stability with an increase of SBP and was used for proximal control and as a resuscitative adjunct, to proactively facilitate definitive surgery in these severely hemodynamically unstable non-traumatic patients. In two cases, REBOA during CPR probably aided in ROSC by increasing carotid and coronary perfusion, and allowed the anesthetist to gain increased vein access to stabilize the patient, suggesting an improved outcome [15,34]. The use of REBOA during CPR in these patients (Patient 4 and additional traumatic patient) further demonstrates its potential use as an adjunct in advanced cardiac life support (ACLS) for ROSC in both traumatic cardiac arrest and NTCA. Furthermore, as demonstrated in Patient 5 and previously performed by Cui et al. [35] and our own Institute (personal communication), REBOA was used as a prophylactic adjunct in an elective procedure to diminish the possibility of hemodynamic instability during a procedure with high risk of increased hemorrhage. This further establishes the benefits of using REBOA in both traumatic and non-traumatic patients to prevent hemodynamic instability for both elective and immediate surgical intervention and as part of the EVTM concept [16,17,22,36].

Previous studies have shown that REBOA causes less ischemic insult with increased occlusion time in comparison to RT [21,37]. Despite this, occlusion time should still be kept as short as possible to decrease the risk of organ failure or spinal cord ischemia [38]. In this report, we have demonstrated successful utilization of both pREBOA (Patient 2, 3 and 4) and iREBOA (Patient 4, 5 and the additional traumatic patient) using the ER-REBOA™ catheter. After regaining hemodynamic stability in Patients 2, 3 and 4, pREBOA allowed us to continue to maintain this control while minimizing distal ischemia. The benefit of using iREBOA in Patient 5 was through proactively minimizing times of increased hemorrhage when needed during the procedure, decreasing the potential risk of hemodynamic instability.

REBOA is not without risk of complications [39]. To avoid these, the technique should be performed by an experienced medical professional with appropriate training [3,16,40]. Several possible complications were noted in this study. Balloon rupture was seen in Patients 1 and 3, most probably because of multiple atherosclerotic plaques, fast replacement of the catheter is essential in such events (personal communication). Difficulties with balloon and sheath removal and the need for surgical cut-down and repair in Patient 3 and a small iliac artery dissection noted in Patient 4 were seen as complications possibly caused by the vascular access. We have noted that flushing with saline fluid while removing the balloon and sheath might help to prevent these complications, as well as removing both balloon and sheath simultaneously together with manual compression. Renal failure in Patient 1 and multiple organ failure in Patient 3 could have been a consequence of REBOA usage but might have occurred due to prolonged hemorrhagic shock. SBP monitoring proximal to the balloon was at times problematic due to clot formation (personal communication).

During this study period, the ER-REBOA™ catheter was also used in one patient with a traumatic hemodynamic instability (Additional traumatic patient). This was briefly described as we consider the reason for the patient's hemodynamic instability not to be due to hemorrhage from the PBI, but instead a neurologic response to the traumatic insult. REBOA was useful for ROSC and SBP elevation as part of the EVTM concept.

LIMITATIONS

In this case series, only the direct postoperative period is described and the patients have not been observed for long-term complications post 30-days.

CONCLUSION

The ER-REBOA™ catheter for endovascular resuscitation might be an additional method for temporary hemodynamic stabilization in the treatment of non-traumatic patients. Furthermore, the ER-REBOA™ catheter might be a potential addition to ACLS in the management of NTCA. Additional studies for further modification of optimal patient selection are needed, fundamental in the use of any procedure, to further investigate, evaluate and define the effectiveness and optimal role of REBOA.

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GUEST EDITOR COMMENTARY on:

Endovascular Resuscitation with Aortic Balloon Occlusion in Non-Trauma Cases: First use of ER-REBOA in Europe, by David McGreevy, et al.

I read with great interest the article by McGreevy et al., published in this first issue of the JEVTM, reporting the first European experience with ER-REBOA™ in a non-traumatic setting. Without a doubt, wide-spread awareness and the experience gained has resulted in expanded use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in various indications [1, 2]. This article demonstrates that a simple procedure and thinking "out of the box" may save the lives of dying people.

I have several comments.

Firstly, as we understood from the paper, REBOA was performed in various hospital sites: the operating room, the angio-suite and even in the intensive care unit. Does this mean that the hospital team made the decision to equip the entire hospital with endovascular balloon sets or was this done as a part of a planning study? In some described cases there is no exact information regarding the blood product replacement. In patient 1, the aortic occlusion was performed after 9 units of Packed Cells (PC), while patient 3 received 22 units of PC before balloon insertion. Such information is missing regarding the other patients. Was the REBOA performed too early or too late? How will the above described patients be managed next time?

Regarding partial REBOA: there are some very interesting studies evaluating the effectiveness of partial aortic balloon occlusion [3–5]. Is its use related to balloon type or volume/pressure inflation numbers? However, there has been no clear parameter or recommendation recently published regarding how to perform this procedure in the "live scenario" of a middle-of-the night bleeding patient.

Timing of REBOA: in this study, as in most previously published studies, the authors report an almost immediate increase in systemic blood pressure. However, in this study after achieving the target in patient 2, total occlusion was performed for only 2 minutes, which was then changed to partial occlusion for an additional 11 minutes. In patients 4 and 5, the inflation time was also very short. The question that I want to raise for possible reader discussion: how far do we need to go with REBOA? Does it make sense to make such efforts, to achieve a reasonable blood pressure in a critically ill patient and 10 minutes later to deflate the balloon, probably paying the price of repeat rapid deterioration? Is blood pressure the single parameter which we use to come to a decision? From my personal veteran trauma surgeon point of view, I am never "in a rush" with my patients. In this way, one can make the best decisions. If 30 minutes has been shown to be a safe time, either for total or partial occlusion, I would try to receive the maximum information about all possible physiologic parameters within this time span. Furthermore, I believe that future research will help to define "markers" for possible aggravation after REBOA deflation.

I think that authors' conclusion that REBOA may be a part of advanced cardiac life support is too premature. This study was performed only on patients with severe bleeding and even described cardiac arrest resulting from hemorrhage. On other hand, I think we should think together regarding where the timing of REBOA should be placed within a massive blood transfusion protocol. This is a highly appreciated pioneer paper. The use of REBOA in non-trauma bleeding patients has only begun to be investigated. There are too many questions and too few answers. The contribution of this paper has opened a great perspective for fruitful discussion and the exchange of ideas within the pages of this journal.

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