The Journal of Emergency Medicine, Vol. ■, No. ■, pp. 1–9, 2018

0736-4679/$ - see front matter

https://doi.org/10.1016/j.jemermed.2017.12.044

Original Contributions

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA USING A LOW-PROFILE DEVICE IS EASY AND SAFE FOR EMERGENCY PHYSICIANS IN CASES OF LIFE-THREATENING HEMORRHAGE

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□ **Abstract—Background: Bleeding from hemorrhagic shock can be immediately controlled by blocking the proximal part of the hemorrhagic point using either resuscitative thoracotomy for aortic cross-clamping or insertion of a large-caliber (10–14Fr) resuscitative endovascular balloon occlusion of the aorta (REBOA) device via the femoral artery. However, such methods are very invasive and have various complications. With recent progress in endovascular treatment, a low-profile REBOA device (7Fr) has been developed. Objective: The objective of this study was to report our experience of this low-profile REBOA device and to evaluate the usefulness of emergency physician–operated REBOA in life-threatening hemorrhagic shock. Methods: Ten patients with refractory hemorrhagic shock underwent REBOA using this device via the femoral artery. All REBOA procedures were performed by emergency physicians. The success rate of the insertion, vital signs, and REBOA-related complications were evaluated. Results: Median age was 54 years (interquartile range 33–78 years). The causes of hemorrhagic shock were trauma (n = 4; 1 blunt and 3 penetrating), ruptured abdominal aortic aneurysm (n = 3), and obstetric hemorrhage (n = 3). Two patients had cardiopulmonary arrest upon arrival. REBOA procedure was successful in all patients, and all became hemodynamically stable to undergo definitive interventions after REBOA. There were no REBOA-related complications. The mortality rate within 24 h and 30 days was 40%. Conclusions: This REBOA device was useful for emergency physicians in life-threatening hemorrhagic shock because of its ease in handling and low invasiveness.**

□ **Keywords—aortic occlusion; hemorrhagic shock; resuscitation; endovascular; trauma**

INTRODUCTION

In case of life-threatening hemorrhagic shock, bleeding must be controlled immediately to maintain cerebral and coronary circulation. In such situations, resuscitative thoracotomy for aortic cross-clamping (ACC) or insertion of a large-caliber intra-aortic balloon occlusion (IABO) catheter (10–14Fr) via the femoral artery is often needed (1). In animal models of hemorrhagic shock, the central arterial blood pressure, carotid blood flow, and brain oxygenation were increased by ACC and IABO (2,3). Furthermore, many recent clinical reports have suggested the use of IABO as an effective and efficient method to manage hemorrhagic shock, particularly trauma cases (4–12). Several reports have also suggested the use of IABO in the emergency setting as an alternative to ACC (2,11,12).

RECEIVED: 8 July 2017; FINAL SUBMISSION RECEIVED: 7 December 2017;
ACCEPTED: 17 December 2017

The concept of resuscitative endovascular balloon occlusion of the aorta (REBOA) in the emergency setting is not new. The method was first reported in 1954 during the Korean War (13). Despite the potential advantages of the less-invasive REBOA over ACC, REBOA has not been widely adopted into clinical practice. Moreover, REBOA seemed to have a recession in the 1990s and early 2000s because it required complex and special skills at the time, and its use of a large-caliber IABO catheter has possible vascular complications. No adequate REBOA devices existed for hemorrhagic shock in the emergency setting at that time. Nevertheless, endovascular treatment has progressed remarkably in recent years, and in 2013, a new REBOA device (Rescue Balloon [RB]; Tokai Medical Products Inc., Aichi, Japan) has been developed in Japan. It is thinner and has a lower profile (7Fr) compared with conventional large-caliber REBOA catheters (10–14Fr), is less invasive, and is easier for the emergency physician (EP) to handle. Fewer REBOA-related complications compared with conventional devices have been reported (4).

We expect that the low-profile catheter has many advantages compared with ACC and large-caliber REBOA devices in the emergency setting. The objectives of this study are to report our experience of this low-profile REBOA device and to evaluate the usefulness of EP-operated REBOA in life-threatening hemorrhagic shock.

MATERIALS AND METHODS

Patients and Study Setting

This retrospective study analyzed the data of 10 patients with all-cause hemorrhagic shock (systolic blood pressure [SBP] < 90 mm Hg; shock index [SI]; ratio of heart rate [HR] to SBP > 1.0 after fluid resuscitation with > 1.0 L Ringer solution) who underwent REBOA using a low-profile (7Fr) REBOA device in our ED of the tertiary care center, Kyorin University Hospital (Tokyo, Japan) between June 2014 and September 2016. We obtained the informed consent from patients or their family.

REBOA Device (Rescue Balloon)

We used the low-profile (7Fr) REBOA device (RB). This REBOA device is an all-in-one package (Figure 1A) that includes a 19-G puncture needle (Seldinger type), a 30-mL syringe, a 0.035-inch guide wire (80 cm) for sheath insertion, a J-shaped 0.025-inch balloon catheter guide wire (145 cm, femoral approach; 240 cm, brachial approach), a 7Fr sheath (11 cm) dilator, and a balloon catheter (insertable length, 80 cm) reinforced by an internal stiff wire stylet. The balloon catheter has a double-lumen for the guide wire or internal stiff wire stylet and has 2 radio-opacity markers on the catheter tip to confirm the position of the balloon catheter by fluoroscopy or portable radiography (Figures 2A and B). The balloon is made of polyurethane and has high compliance (balloon length, 60 mm; diameter, 16 mm [8 mL] to 40 mm [40 mL]) (Figure 1B).

Intervention for REBOA Using This Low-Profile REBOA Device

At our institution, if a patient progresses into all-cause hemorrhagic shock in the prehospital setting, the EP routinely inserts a 5Fr, 10-cm sheath in the common femoral artery (CFA) by ultrasonography (US) guidance on arrival. Furthermore, initial fluid resuscitation is started with 1 L Ringer solution. If a patient with hemorrhage below the chest (e.g., abdominal trauma, pelvic fracture, gastrointestinal hemorrhage, ruptured abdominal aortic aneurysm [rAAA], obstetrics bleeding) is transient or is not responding, REBOA using RB is performed by exchanging the femoral sheath to a 7Fr sheath with sheath guide wire. If the patient is responding, the femoral sheath is used for continuous arterial pressure monitoring. For REBOA patients, subxiphoid-focused abdominal US is used to confirm that the balloon catheter guide wire is inside the supraceliac aorta (Figure 2C) and then the balloon catheter is inserted. The final positioning of the balloon catheter is checked by portable radiography or fluoroscope (Figures 2A and B). The balloon is inflated in zone I, between the left subclavian and celiac trunk, after exchanging the balloon catheter guide wire to the internal stiff wire stylet. Because of the narrow shaft catheter, the inflated balloon is caudally pushed back without reinforcement of an internal stiff wire stylet. The balloon positioning is adjusted at a suitable zone after determining the bleeding point (14). Balloon inflation time should be within 30 min of the time from starting the complete blockage of the aorta (complete occlusive REBOA method), and then the balloon is gradually deflated, maintaining 90 mm Hg SBP for 5 minutes (i.e., partial occlusive REBOA method, which allows examination by enhanced computed tomography; the distal region of the balloon should also be evaluated adequately). This balloon technique is repeated until definitive hemostasis is obtained by surgical or endovascular treatment. The sheath is removed after the recovery of patient's hemodynamics and coagulopathy. Hemostasis of the puncture site is by manual compression for 30 min, and the patient must have an 8-h bed rest, with the inguinal part fixed by compressed gauze with an elastic tape. All REBOA procedures above were performed by EPs in our institution who were not specialists of radiology or vascular surgery. At our institution, senior EPs with experience in REBOA teach our junior EPs and residents to perform US-guided CFA punctures on occasions when any arterial accesses from CFA are performed. They also train our junior EPs and