Narrative Review Article

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Present Strategy for REBOA Management After Catheter Placement: A Current Suggestion From the Japanese Society of DIRECT

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been accepted as a useful bridging tool to definitive hemostasis in refractory hemorrhagic shock. Although there is insufficient evidence of the target blood pressure under the utilization of REBOA, it may be reasonable to avoid excessive blood pressure elevation. Invasive blood pressure monitoring proximal to the aortic occlusion is desirable during REBOA. The zone of the aorta is selected and changed according to the location of injuries and the physiological conditions. The key to successful REBOA management is to set up an independent REBOA coordinator for systemic management. This review article aims to explain the procedures of proper REBOA management, so as to fill the knowledge gap between educational courses, which highlight the indications and safe procedures of the device, and the critical settings faced in clinical practice.

Keywords: *Resuscitative Endovascular Balloon Occlusion Of The Aorta (REBOA); Trauma; Hemorrhagic Shock; Management*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been accepted as a useful bridging tool to definitive hemostasis in refractory hemorrhagic shock [1–4]. Its use increases the proximal pressure and regulates distal arterial bleeding, while simultaneously inducing visceral organ hypoperfusion and leg ischemia. Although REBOA is a less invasive aortic occlusion method compared with resuscitative thoracotomy, it has a high probability of complications. There have been several reports confirming the negative impact of REBOA from analysis of the trauma database [5–7].

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Teaching of the standard procedures of REBOA have been widespread through educational programs internationally [8,9]. An educational workshop program has been created in each region or country, and the procedure is simple enough for even non-vascular surgeons or non-interventional radiologists to understand. Despite the rapid growth of the REBOA educational program, complications have been observed by inappropriate management during the REBOA placement even though the right procedures have been followed in the right patients.

REBOA is a device for creating a grace period until hemostasis is achieved. The REBOA educational programs mainly highlight the indications and safe procedures of the device. The management of REBOA, such as arterial blood pressure monitoring and the target blood pressure, the selection and alteration of the deployment zone, and the non-technical skills of the multidisciplinary trauma team, have not been focused on or discussed. The purpose of this review article is to explain the proper management of REBOA so as to fill

the knowledge gap between the educational courses and the critical settings faced in clinical practice.

MONITORING ARTERIAL BLOOD PRESSURE

Proximal Arterial Blood Pressure Monitoring

Invasive blood pressure monitoring proximal to the aortic occlusion balloon is desirable during REBOA utilization. In addition to non-invasive blood pressure alone, proximal invasive blood pressure monitoring would allow for more comprehensive management of partial REBOA. In the process of gradual balloon deflation from complete to partial inflation, hemodynamic changes could occur abruptly, and a proximal arterial blood pressure line facilitates a safe transition to partial REBOA. If the proximal arterial blood pressure drops too much, then the balloon volume should be gradually increased again to restore blood pressure to an acceptable level guided by the proximal arterial pressure. If a separate arterial blood pressure line is used, it should be secured as soon as the status of shock is detected, ideally before insertion of REBOA, but it can be done at the same time or in the operating room or the angiography room. Some REBOA catheters have a feature that allows blood pressure measurement by connecting a pressure line, so securing a separate arterial pressure line is not necessary when using these types of catheters. The REBOA catheter balloon volume should be adjusted to maintain appropriate blood pressure during aortic occlusion because the purpose of REBOA is to control distal bleeding, maintain proximal blood circulation, and avoid circulatory collapse until hemostasis is achieved. REBOA adjustment usually refers to the transition from complete aortic occlusion with REBOA to partial REBOA. However, when it is started with partial occlusion and circulation can be maintained, it can also mean adjustment from partial to complete occlusion. If the target blood pressure can be maintained with partial REBOA, the balloon volume should be maintained. If not, the gradual increase of the balloon volume should be performed in order for the appropriate blood pressure to be acquired.

Among trauma patients with hemorrhagic shock, it is generally recommended that excessive blood pressure elevation is avoided prior to completion of hemostasis. [10]. The purpose is to suppress the increase in bleeding by permitting low blood pressure [10–12]. This also prevents dilutive coagulopathy and hypothermia by avoiding over-infusion of extracellular fluid to maintain blood pressure. Table 1 shows the advantages of blood pressure elevation and unsuitable situations when it should be avoided. Avoiding excessive blood pressure elevation decreases the amount of bleeding and blood transfusion, and may also avoid unnecessary aggravation of intracranial, cervical, and thoracic hemorrhages. This concept could be beneficial to the management of those hemorrhages. Meanwhile, severe traumatic brain injury requires elevated blood pressure to maintain cerebral perfusion pressure [13]. Partial REBOA should be titrated to avoid excessive blood pressure elevation, and intracranial pressure monitoring should give us helpful information to enable the achievement of goal-directed partial REBOA management in hemorrhagic shock cases associated with traumatic brain injury.

Table 1 The advantages of excessive blood pressure elevation and unsuitable situations when it should be avoided.

Advantages	*Unsuitable situations*
Reduce blood loss	Traumatic brain injury
Reduce overall IV fluid administration	The elderly*
Reduce blood product utilization	
Reduce dilutional coagulopathy	
Avoid hypothermia caused by excessive IV fluid administration	

**Excessive blood pressure elevation should be avoided in the elderly as well, but cerebral perfusion will likely be inadequate compared to younger patients, and setting the target blood pressure too low may be dangerous. IV, intravenous.*

For proximal arterial blood pressure monitoring during REBOA, arterial blood pressure lines, such as in the radial and brachial arteries, are secured in the upper limbs. In patients with shock status, successful arterial puncture is a challenge because of collapsed vessels. An arterial blood pressure line is required to manage patients with REBOA; however, the arterial line is only a means of monitoring and not a treatment. Definitive hemostasis should be prioritized rather than taking time to secure a proximal arterial pressure line. When securing a radial arterial pressure line is difficult before surgery or angiography, it should be performed alongside definitive hemostasis by abducting the arm (Figure 1). A non-invasive continuous hemodynamic measurement system is an option; however, it may not demonstrate accurate numerical calculations in severe shock.

Distal Arterial Pressure Monitoring

Distal arterial blood pressure monitoring is not as desirable as proximal monitoring. However, it would be easier to determine a complete occlusion if the distal arterial pressure can be monitored. Partial occlusion is better than complete occlusion for maintaining organ perfusion, such as, for example, in intestinal ischemia in Zone 1 management and lower limb ischemia in Zone 3 management [15]. If organ perfusion, especially intestinal ischemia, is not considered, the prognosis would be poor even if hemostasis is achieved. By measuring the distal blood pressure, we may be able to manage the distal organ perfusion more carefully. However, a quantitative organ perfusion method has not yet been established, and further investigation is needed. The disappearance of the distal pressure after balloon inflation accurately indicates complete occlusion. The method of distal

(a) (b)

Figure 1 Ingenuity is needed when it is difficult to secure the invasive arterial pressure monitoring line of the upper limbs. (**a**) Initiate IR with the patient's right upper limb extended. (**b**) During IR, the emergency physician or anesthesiologist in charge of general care continues to secure the invasive arterial pressure monitoring line of the upper limbs.

arterial blood pressure monitoring is as follows: (1) the use of an additional arterial sheath in the contralateral femoral artery (via bilateral femoral arterial access); (2) the use of a side port of an oversized arterial sheath (e.g., 8 Fr or a larger sheath for a 7 Fr REBOA catheter).

HOW TO CHOOSE THE AORTIC ZONES PROPERLY

Differences in balloon placement or zones affect the magnitude of hemodynamic changes and the severity of ischemic intensity during REBOA management.

Zone 1 should be selected if the anatomical location of the assumed injury is intra-abdominal or causes retroperitoneal bleeding, or Zone 3 if it can be localized to the pelvis area (Figure 2). Often, a zone cannot be selected depending on the situation because REBOA is often used in clinical settings where no prominent bleeding site can be identified or in a physiologically disrupted state on the verge of cardiac arrest [16]. Although Zone 3 is anatomically reasonable for pelvic trauma, direct embolization should be performed instead of Zone 3 REBOA if the patient is not in imminent cardiac arrest and angioembolization is available immediately. Here, it should be recognized that there is a significant difference between Zones 1 and 3 in blood flow and blood pressure increase on the proximal side of the occlusion.

Bayer et al. reported that Zone 1 occlusion caused a significantly higher elevation in systolic blood pressure than Zone 3 occlusion [17]. Therefore, the proper use of zones should be decided upon from an anatomical viewpoint and according to the physiological conditions.

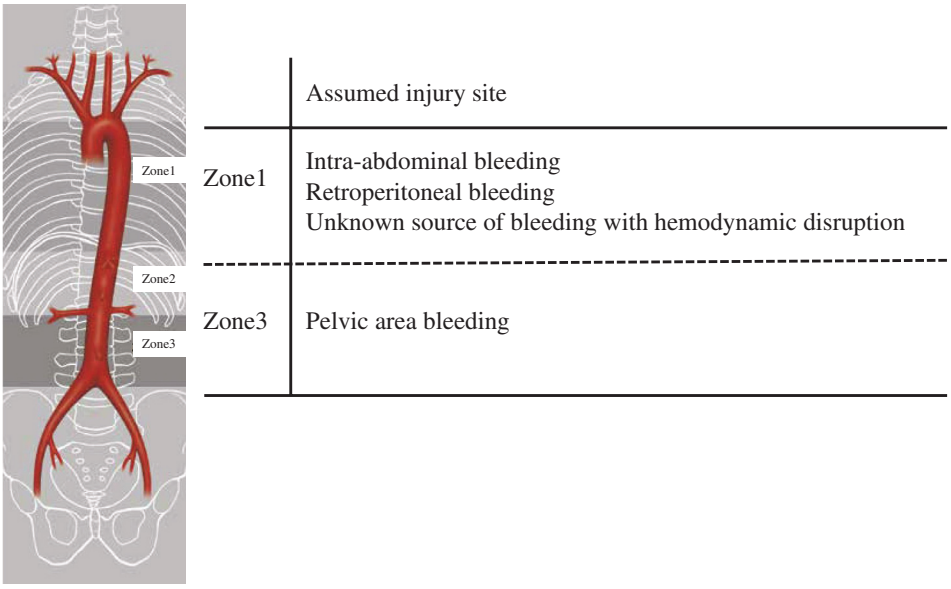

Figure 2 Aortic zone selection according to the injury site. Figure modified from Morrison et al. [14].

For example, if a patient has a single pelvic fracture but has an urgent cardiac arrest, it would be pragmatic and reasonable to choose Zone 1 instead of Zone 3. On the other hand, Zone 1 occlusion causes a wide range of blood reduction and vigorous ischemic intensity in the whole body. The permissible occlusion time is considered to be within 20 to 30 minutes. Moreover, this permissible occlusion time may be less than 20–30 minutes if the patient is in cardiac arrest, because there would have already been a period of time with no blood flow prior to the inflation of the REBOA balloon, which must also be included in the overall ischemia time. Resuscitative thoracotomy should be considered in the cardiac arrest case with chest injury.

REBOA may be contraindicated if the injury is associated with the proximal side of the balloon occlusion. REBOA may cause rapid proximal hypertension and promote bleeding. There are reports of increased bleeding due to head and chest injuries [18,19]. Johnson et al. reported that the use of REBOA did not exacerbate head trauma in a hemorrhagic shock model with head trauma in swine when circulating blood volume was reduced [20]. Bailey et al. also reported intermittent REBOA prolonged the intracranial hypertension after occlusion, using a model of penetrating head trauma with unreduced circulating blood volume [21].

There is no clear evidence that the use of REBOA in patients with proximal injury is associated with improved or worsened outcomes. However, there is no doubt that the use of REBOA in the presence of head, neck, and chest trauma should be carefully selected.

CHANGE OF THE BALLOON POSITION

The position (aortic zone) of the REBOA balloon may be changed. When the injured site is unspecified, and the patient is in impending cardiac arrest, a balloon is tentatively placed in Zone 1. If subsequent X-rays of the chest and pelvis and FAST examination reveal that the injury site is at the pelvic area, the balloon should be moved to Zone 3. In cases where the initial Focused Assessment with Sonography for Trauma (FAST) is negative and the pelvis is injured, the balloon should be placed in Zone 3. When intra-abdominal bleeding increases and FAST becomes positive, or hemodynamics becomes more unstable, the balloon can be moved to Zone 1 (Figure 3).

Before moving the balloon's position, it is necessary to deflate the balloon in advance. Moving the REBOA catheter without deflation may cause iatrogenic aortic injury and spread mural thrombus resulting in the embolism of the visceral organs and lower extremities.

To move from Zone 1 to Zone 3, the catheter should be pulled to Zone 3 after deflation. However, it is necessary to confirm whether the balloon is precisely located in Zone 3 by fluoroscopy or X-ray. More care must be taken when changing from Zone 3 to Zone 1. There is concern about the cleanliness of reinserting a catheter that is outside the sheath and is no longer sterile. The procedure differs depending on whether the REBOA catheter is a wire-free device.

ER-REBOA™ (PryTime Medical Inc., Boerne, USA) and COBRA-OS™ (FrontLine Medical Technologies Inc. London, Canada) are wire-free devices. As with regular insertion, movement to Zone 1 must be made while paying attention to vascular damage. However, we should be aware of the risks of vascular injuries and the inability to advance the catheter when there is severe aortic tortuosity due to arterial calcification.

Rescue Balloon® (Tokai Medical Products, Aichi, Japan), Rescue Balloon®-ER (Tokai Medical Products, Aichi, Japan), Block Balloon™ (MERA, Tokyo, Japan), REBOA Balloon Kit™ (REBOA Medical, Norway) have a guide wire and are inserted by the over-the-wire technique. If the stylet is inserted, it should be removed once, the guidewire inserted, and the catheter then advanced to Zone 1. When REBOA is placed whilst in the emergency department, the guidewire is often not brought into the operating room. The guidewire may have already been scrapped or placed in an unclean field after implantation. When performing interventional radiology after placement of REBOA whilst in the angiography suite, the catheter may be safely advanced with fluoroscopy. Although not ideal, there may be cases where the catheter is blindly advanced. The risk of vascular injury by the tip of the catheter must be reduced as much as possible. In particular, when using a catheter (Tokai, MERA) that increases the rigidity of the shaft with the stylet, the stylet should be pulled out a few centimeters and the procedure undertaken

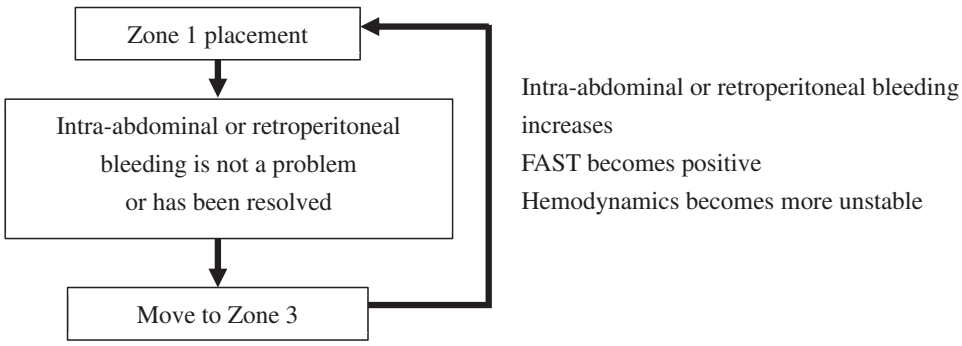

Figure 3 Flowchart of changing aortic zone.

slowly, with attention being paid to the fact that there is no resistance with its advancement.

A SYSTEM-WIDE MULTIDISCIPLINARY APPROACH – THE ROLE OF THE REBOA COORDINATOR

Zakaluzny et al. reported that REBOA was more than a tool or a technique, but rather a system-wide multidisciplinary approach that spans numerous institutional disciplines and requires a management capability [22]. Specifically, an organizational chart is developed with the REBOA coordinator at the center, as shown in Figure 4, and practical methods are introduced with a checklist (Table 2) for each job and situation. Facilitating the communication of information between job categories and departments through simulations of REBOA insertions and other means will lead to the success of REBOA [23].

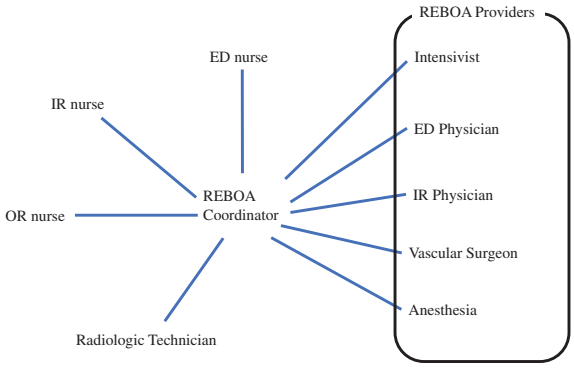

Figure 4 Organizational chart with the REBOA coordinator at the center. The REBOA coordinator can be a concurrent post, but it must not be covered by the operator of the surgery or interventional radiologist. Figure modified from Zakaluzny et al. [22]. OR, Operating Room. IR, Interventional Radiology. ED, Emergency Department.

The role of the REBOA coordinator includes the following: (1) timekeeping of the occlusion time, (2) adjustment of the balloon in-flows such as partial REBOA and intermittent REBOA, and (3) management with attention to the prevention of REBOA catheter removal and deviation during patient transfer. In addition, the REBOA coordinator should consciously and closely coordinate with the surgical operators, intervention radiologists, and anesthesiologists. The REBOA coordinator can serve as a physician in any specialty as long as he or she understands these essentials. Emergency physicians, anesthesiologists, trauma surgeons, and InterVentional Radiology (IVR) physicians are all candidates. The role of the REBOA coordinator is significant because the aim is to shorten the occlusion time and reduce the occlusion intensity. Since the role of this REBOA coordinator requires the ability to make

Table 2 Check list for REBOA implementation (adapted from Zakaluzny et al. [22])

Management Team

- Supervised by the chief of medical staff (the REBOA coordinator)
- Plan a comprehensive nurse-driven and provider supported quality assurance program
- Assure buy-in for additional resources needed in terms of call schedules and other purchases (i.e., fluoroscopy compatible operating room tables, digital X-ray machines)

Establish a core of providers interested and in agreement on implementation

- Adopt an algorithm for REBOA use
- Determine which catheter to use
- Establish plans for femoral artery access and specific devices for kits including hands-on practice to assure compatibility
- Establish what should be in a cut-down tray

Implementation in the Operating Room (OR)

- Establish REBOA kits and assure they are maintained
- Establish cut-down trays and assure they are maintained
- Assure OR fluoroscopy capability including OR beds
- Coordinate educational program with nurse/technicians in the OR

Implementation in the Emergency Department

(1) Meet with critical providers to determine how REBOA will be implemented in resuscitations
    - Decide which providers will be gaining access and placing catheters; and assure appropriate training scheduled
    - Establish provider roles and responsibilities during a resuscitation if REBOA is being placed, including establishing who will continue the resuscitation

(2) Meet with providers and nurses
    - Establish the roles for nurses and radiological staff during REBOA placement
    - Confirm the treatment flow (checking the location of REBOA and the treatment procedure) after the start of REBOA

comprehensive judgments for vital signs and surgical field conditions, emergency physicians and anesthesiologists will likely take on this role. It would be desirable to have a dedicated REBOA coordinator, but realistically, there are not usually enough human resources. If the surgical operator or the intervention radiologist is also the REBOA coordinator, the management of REBOA may be neglected, and the occlusion time and intensity may not be sufficiently controlled. Therefore, if there is a shortage of human resources, then it is suggested that staff with a broad perspective, such as the commander of the overall trauma care or the operative assistant as a director, should also serve as the REBOA coordinator.

LIMITATIONS

There is no definite evidence for monitoring arterial pressure or changing the balloon position. The recommendation is mainly based on the expert recommendation of the Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical Care, and Trauma (DIRECT), which has an extended history regarding REBOA placement or management.

CONCLUSION

In the management of REBOA, invasive blood pressure monitoring proximal to aortic occlusion is desirable, and when securing a radial arterial line is difficult, some ingenuity is required. The zone of the aorta is selected and changed according to the anatomical injury site and physiological conditions. The key to successful REBOA management is to set up an independent REBOA coordinator for systemic management.

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Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.
(2) The authors declare that they have read and abided by the JEVTM statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

Conflicts of Interest

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

YK was responsible for drafting, editing, and submission of the manuscript. TM critically appraised the manuscript. YK, ST, TM, and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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