

# Resuscitative Endovascular Balloon Occlusion of the Aorta Complications and its Management

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Numerous complications have been reported regarding the use of resuscitative endovascular balloon occlusion of the aorta (REBOA). Complications can be broadly classified into the following six categories: arterial access-related, REBOA catheter insertion-related, balloon positioning-related, balloon inflation-related, balloon deflation-related, and sheath placement and removal-related. REBOA operators must be knowledgeable about these possible complications and their management, along with its utility. A strong commitment to using REBOA safely and complication-free is essential to the skillful use of REBOA.

**Keywords:** Arteriovenous Fistula; Complications; Ischemia-Reperfusion Injury; Limb Ischemia; Pseudoaneurysm; REBOA

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## INTRODUCTION

Various restrictions exist when using resuscitative endovascular balloon occlusion of the aorta (REBOA). First, the time is limited. Immediate hemostasis is required; therefore, an excessively time-consuming procedure to use REBOA must be avoided. Second, the preprocedural evaluation is insufficient. REBOA placement is frequently required before the computed tomography (CT) scan. Tortuosity of the aorta, presence or absence of aortic injury, or precise hemorrhage location may be unclear during the procedure. Third, the assessment method for the procedure is limited. Whether or not REBOA is

placed in the appropriate position may be difficult to confirm without fluoroscopic guidance. Fourth, the condition of the patient is poor. If the patient is in severe hemorrhagic shock, the femoral artery may be impalpable and difficult to visualize using ultrasound. Consequently, vascular access may be challenging. Moreover, in patients with pelvic or femoral fractures, it may be difficult to use the right puncture site because of groin swelling or the use of pelvic compression devices such as SAM Pelvic Sling™, bed sheet wrapping, or Pelvic Binder™ [1]. Fifth, hands-on experience is insufficient. Low-volume centers have limited cases with indications for REBOA placement. Therefore, the operator may be required to use REBOA before acquiring sufficient hands-on experience.

It is inappropriate to think that some complications related to REBOA are inevitable or permissible because of the restrictions mentioned above. Complication rates for REBOA have been reported as 3.6–18% [2–5], and complication-related deaths have been reported as well [2]. Operators must be strongly committed to using REBOA safely and complication-free.

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### **Ethical Approval and Informed Consent**

Ethical approval was not required. Informed consent was not required.

### **ARTERIAL ACCESS-RELATED COMPLICATIONS**

The first on the list of procedure-related complications related to REBOA is arterial access-related complications. Femoral artery puncture must be performed accurately in the appropriate position. Retroperitoneal hemorrhage and intra-abdominal/retroperitoneal organ injury due to high puncture and mispuncturing of the superficial femoral artery or deep femoral artery due to low puncture are typical complications. Mispuncturing of the superficial femoral artery or deep femoral artery leads to sheath placement in a narrow artery, causing limb ischemia. Repeatedly puncturing the artery or mispuncturing the vein may lead to troublesome hemorrhage or arteriovenous fistula formation. Unsterile procedures and infrequent use of prophylactic antibiotics are associated with a greater risk of wound infection [6].

Ultrasound-guided puncture is recommended for accurate arterial access [6–8]. When ultrasound is used, the artery can be visualized and artery identification becomes easier, even when the pulse of the femoral artery is not palpable. It also allows the visualization of the bifurcation of the superficial and deep femoral arteries, making it possible to puncture above the bifurcation securely. However, ultrasound use does not necessarily ensure easy arterial access for any operator. Operators inexperienced in using ultrasound may adversely cause complications and require longer procedure time, so adequate training is required to skillfully perform ultrasound-guided puncture.

### **REBOA CATHETER INSERTION-RELATED COMPLICATIONS**

Typical complications associated with REBOA catheter insertion include guidewire management. Usually, when you advance the guidewire in the blood vessel, you should not feel any resistance, and when you do, you must not advance the guidewire any further. The risk is small if you are using a J-tip guidewire, but without fluoroscopic guidance, a totally unexpected movement of the tip of the guidewire may occur.

When you feel resistance advancing the guidewire, much attention is required since one of the following incidents may have occurred: migration into the contralateral common femoral artery, migration into the caudal vessels after forming a loop between the superficial and deep femoral arteries, aortic dissection, extravascular deviation, or migration into the deep circumflex iliac/inferior mesenteric/renal/superior mesenteric/celiac artery.

To ensure proper guidewire placement, operation under fluoroscopic guidance is the most reliable method,

but unless a hybrid emergency room is used, it is more likely that fluoroscopic guidance cannot be used during the early stages of trauma care. In such cases, a portable chest X-ray device or ultrasound must be used to check the position of the guidewire. Since the timing of the confirmation would be after the advancement of the guidewire, if you feel any unexpected resistance before advancing the guidewire to the length you planned using the landmark technique, you must sufficiently retract the guidewire to a certain length and re-advance the guidewire carefully.

Even if the guidewire is at the proper position, there are times when advancing the REBOA catheter over the wire becomes problematic. Severe tortuosity, arteriosclerosis, calcification of the aorta, and intravascular thrombus are the typical causes. When it is difficult to advance the REBOA catheter over the wire without confirming the proper guidewire location, this may be a signal that the guidewire position is not appropriate.

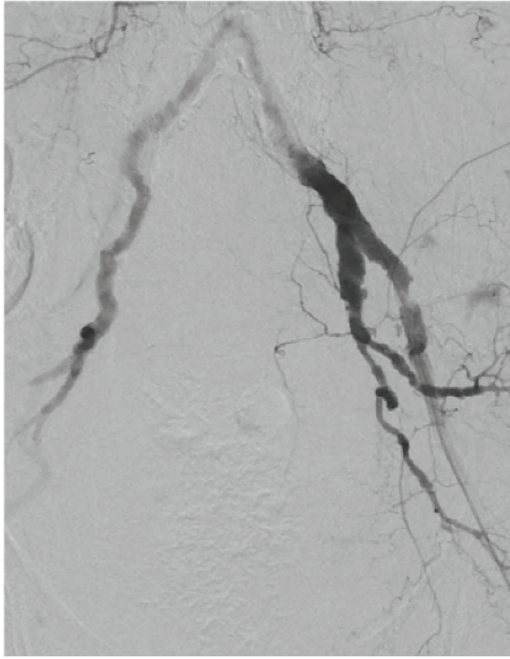
Do not adhere rigidly to the idea of using REBOA when you have trouble with arterial access or REBOA catheter advancement; always consider a different strategy. Causing substantial delay in hemostasis by insisting on carrying through a time-consuming procedure would be completely out of line. Always be flexible, and switching to resuscitative thoracotomy with aortic cross-clamping or even dropping the idea of aortic occlusion may be necessary sometimes.

### **BALLOON POSITIONING-RELATED COMPLICATIONS**

REBOA must be placed in either zone 1 or zone 3, depending on the purpose. Inappropriate balloon positioning may lead to various complications.

When REBOA is placed above zone 1 (i.e., between the left subclavian artery and the heart), not only is blood flow to the brain obstructed, but the afterload of the heart is significantly increased, causing myocardial dysfunction and lethal complications. Zone 2 placement blocks blood flow to the abdominal branches, causing bowel ischemia and renal dysfunction [9]. Zone 2 placement does not play any role in trauma care. By placing REBOA below zone 3 (that is, within the iliac artery region), the following complications could occur: complete limb ischemia on the side of placement, vascular injury or rupture [10], and hemorrhage exacerbation from abdominal and pelvic injuries (Figure 1).

To place REBOA at the appropriate position, checking the location of the guidewire and REBOA catheter using fluoroscopic guidance, a portable X-ray device, or ultrasound is helpful [10,11]. When using a small-diameter REBOA catheter, re-inserting the stylet before balloon inflation is mandatory to prevent downstream migration (Figure 2) [12]. It is important to remember that a certain degree of migration occurs even when a stylet is used. If the fixation of the sheath or REBOA



**Figure 1** (Reprinted with permission from reference [10].) Common femoral artery (CFA) rupture due to balloon inflation at CFA.

catheter is weak at the groin, the REBOA catheter could come out of the sheath, or in some cases, both the sheath and REBOA catheter could be pushed back; therefore, careful attention must be paid to the puncture site when inflating the balloon.

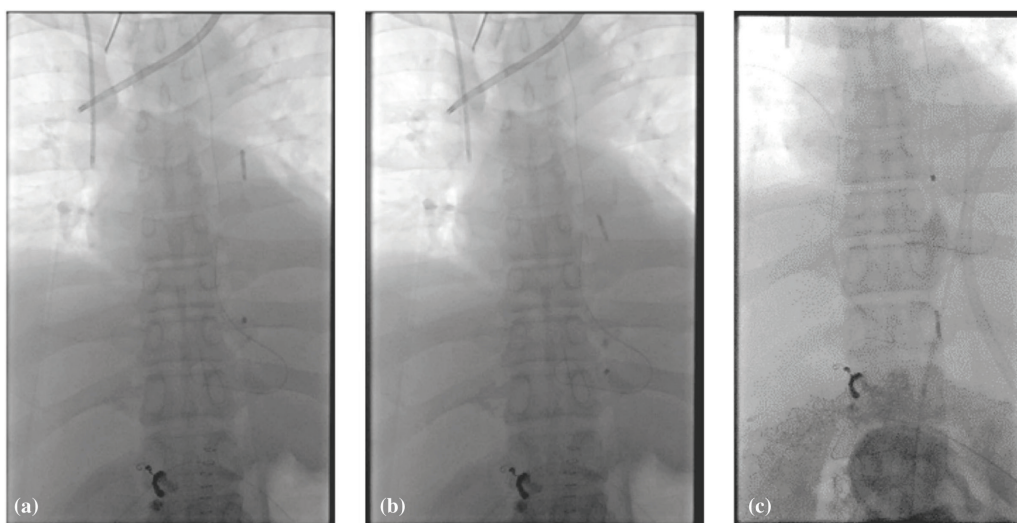
### BALLOON INFLATION-RELATED COMPLICATIONS

Typical examples of balloon inflation-related complications are vascular injury, vascular rupture, and balloon

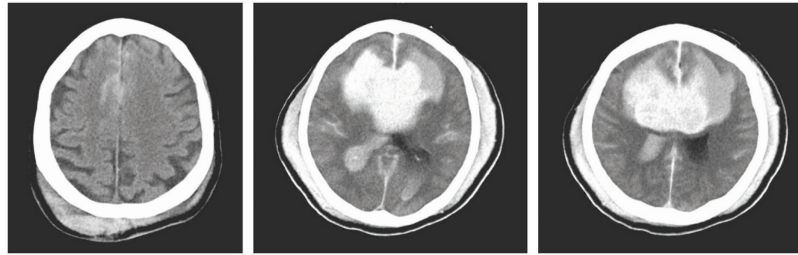
rupture due to overinflation [13]. Since proximal blood pressure and blood flow rapidly increase after inflation, there is a possibility of worsening proximal hemorrhage (Figure 3) [14]. In particular, careful attention should be paid to patients with head or chest injuries. In addition, injuries that were not apparent due to shock may become evident by increased blood pressure and blood flow.

To prevent complications, it is essential to monitor blood pressure proximal to the site of occlusion. Balloon inflation must be performed cautiously while closely monitoring the proximal blood pressure. You should not blindly continue to inject the balloon when there is no observable responsive increase in blood pressure. In severe shock, even if the position of the balloon is appropriate and the balloon is already fully inflated, proximal blood pressure may not change, and continuing to inject in the balloon may cause vascular injury or balloon rupture due to overinflation. If it is possible to monitor the distal pressure, confirming the disappearance of pulse pressure would make it easier to avoid overinflation and appropriately manage partial REBOA. In animal studies, it has been shown that after the balloon volume reaches 60% of the volume needed for complete occlusion, even if the balloon is continuously injected, the proximal mean blood pressure remains unchanged [15].

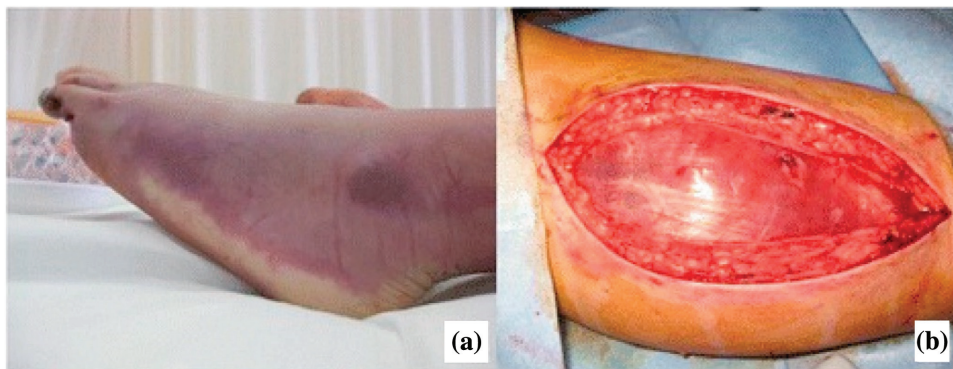
Do not put too much trust in the strength of push-back you feel from the injection. If the circumstances permit, to decide the adequate injection volume, monitor the proximal blood pressure and the distal blood pressure, or use diluted contrast to inflate the balloon and check the balloon shape under fluoroscopy. By using a wide-diameter sheath (e.g., 8-Fr sheath for 7-Fr catheter), sheath pressure can be used to monitor the distal arterial pressure and estimate the degree of occlusion.



**Figure 2** Examples of downstream migration. (a,b) Balloon is inflated after re-inserting the stylet. A certain degree of downstream migration occurs even if the stylet is inserted and the catheter is fixed. (c) The tip of the catheter turned over and migrated immediately after removing the stylet during an attempt to measure the proximal arterial pressure from the catheter.



**Figure 3** (Reprinted with permission from reference [14].) Cerebral hemorrhage significantly worsened after inflating the balloon.



**Figure 4** (Reprinted with permission from reference [17].) Compartment syndrome due to limb ischemia necessitating a relaxing incision.

When you cannot see an increase in blood pressure after inflation, if the position of the REBOA catheter has not yet been checked, the possibility is that the position of the balloon is inappropriate. Always deflate the balloon before adjusting the position of the REBOA. Otherwise, the large balloon could erratically enter an unintended vessel and cause unnecessary ischemia. Moreover, by pushing the REBOA catheter under high pressure, the REBOA catheter could abnormally bend inside the vessel.

By using partial REBOA or intermittent REBOA in combination with total occlusion, or by changing the balloon position from zone 1 to zone 3 after controlling for intra-abdominal hemorrhage, it should be possible to minimize the degree of ischemia-reperfusion injury. However, regardless of the strategy you decide to take on, keep in mind that a longer occlusion time is the most significant cause of an unfavorable prognosis. Rush for hemostasis and make every effort to shorten the occlusion time.

### BALLOON DEFLATION-RELATED COMPLICATIONS

By deflating the balloon and thereby releasing aortic occlusion, a rapid decrease in afterload, rebleeding, and ischemia-reperfusion injury can occur. Massive amounts of metabolites due to ischemia-reperfusion injury (e.g., nitrogen oxide and inflammatory mediators) are released, and vasodilation, refractory hypotension,

hyperkalemia, and acidosis can rapidly develop [6]. Since rapid expansion of the vascular bed and vasodilation occur simultaneously, in the worst case, circulatory collapse could occur, which may cause cardiac arrest. In such cases, salvage of the patient may fail even if the balloon is reinflated [8,16].

If hemostasis is not yet achieved at the distal area of the occlusion, deflation of the balloon would immediately cause rebleeding. Therefore, as a general rule, deflation should be performed after the hemorrhage has been controlled. However, to minimize the effect of ischemia-reperfusion injury, the strategy of using partial REBOA before complete hemostasis or intermittent REBOA could be considered as an option. Since deflation could immediately cause cardiac arrest, the timing of deflation should not be solely decided by the REBOA controller alone; it should be considered and shared with the entire team.

When deflating the balloon, carefully and gradually draw 1 to 2 ml while monitoring the blood pressure in the upper limb. Since the vascular bed expands rapidly, be prepared to administer a sufficient amount of fluid or blood. Vasodilation due to ischemia-reperfusion injury could occur concurrently, and vasopressors may also be necessary. If circulation collapses, or if the hemorrhage becomes uncontrollable in the operative field, the balloon may need to be reinflated immediately. It is essential for the operator, REBOA controller, and anesthesiologist to work hand in hand to regulate the situation appropriately.

## SHEATH PLACEMENT AND REMOVAL-RELATED COMPLICATIONS

After using REBOA, the sheath may be left in place for prompt arterial access, as a measure in case of rebleeding. However, it should be noted that thrombus formation and limb ischemia could occur when the sheath is left in place. Large sheaths, small blood vessels, and long-term placement all contribute to a greater risk of limb ischemia. Limb ischemia could cause the following: compartment syndrome necessitating a relaxing incision (Figure 4) [17], thromboembolism necessitating a thrombectomy or lower limb amputation [18,19].

Therefore, you should always bear in mind the possibility of these complications occurring after sheath placement, and you should continue to pay close attention to the blood flow and the appearance of the skin of the limb where the sheath is placed. Confirming the pulse wave on the oximeter is a convenient method of evaluation. If it is likely that a complication has occurred, it should be promptly evaluated using contrast-enhanced CT, ultrasound, or angiography. Although the use of small sheaths (7-Fr) minimizes the complication rate of sheath-related complications, including limb ischemia [20–22], complications still occur using 7Fr sheaths [8,23–25]. To take measures for thromboembolic events, continuous diluted heparin administration from the sheath may be considered [8,26].

If the sheath is considered unnecessary, it should be removed as soon as possible. Optimally, this should be done after the completion of hemostasis and after coagulopathy has improved. The most commonly used method of hemostasis after sheath removal is adequate manual compression. Using hemostatic devices or performing surgical vessel repair may be considered, depending on the operator's experience. Coagulopathy and low platelet count at the time of sheath removal, inappropriate compression position, insufficient compression pressure, and short compression time may all cause pseudoaneurysm formation, and delayed massive hemorrhage can occur.

If the position of the sheath was inappropriate or if the vein was mispunctured, an arteriovenous fistula could form after sheath removal. If these complications occur, covered stent insertion, percutaneous thrombin injection, or surgical angioplasty including patch angioplasty should be considered, in consultation with vascular surgeons and interventional radiologists. Adequate experience is required to manage sheath-related procedures complication-free.

## CONCLUSIONS

REBOA operators must be knowledgeable about the possible complications and their management, along with its utility. A strong commitment to using REBOA safely and complication-free is essential to the skillful use of REBOA.

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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

TS was responsible for drafting, editing, and submission of the manuscript. KT, KI, 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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