

Techniques for Performing Resuscitative Endovascular Balloon Occlusion of the Aorta

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Although resuscitative endovascular balloon occlusion of the aorta (REBOA) is a useful technique for achieving temporary hemostasis until radical hemostasis is achieved, it is necessary to understand and learn its correct use to avoid complications. The procedure of REBOA preparation, insertion, balloon inflation and deflation, and removal and the key points of the technique at each stage are described in this article. In addition, it expounds on the complications of REBOA and REBOA inflation time.

Keywords: Aortic Zone; Over-the-Guidewire Technique; External Landmark Method; Down Stream Migration; Partial or Intermittent REBOA; REBOA Management (REBOA Controller)

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INTRODUCTION

The use of REBOA catheters is mainly indicated for hemorrhagic shock. Even in hemorrhagic shock, if the bleeding points are in the head and neck region or chest, REBOA is not indicated, and resuscitative thoracotomy of aortic cross-clamping (RTACC) should be chosen. If REBOA is indicated, two people should perform balloon catheter insertion. Even if an operator is experienced, he/she cannot hold the catheter to stabilize its position while inflating the balloon. The operator and assistant must prepare for the insertion procedure on the sterile drape. This article demonstrates each procedural process of REBOA catheter insertion, balloon inflation, balloon deflation, and catheter removal. Commercially available REBOA catheters include wire-required devices and wire-free

devices. The over-the-wire technique reduces the risk of vascular injury due to catheters and is an essential procedure used universally in all endovascular procedures. The wire-free device can be inserted with a simple procedure, but the procedure for a wire-required device is a little more complicated and will be explained with emphasis.

Ethical Approval and Informed Consent

Ethical approval was not required. Written informed consent was not required.

ARTERIAL ACCESS

Early arterial access for trauma patients with hemorrhagic shock can lead to rapid access to REBOA and Interventional Radiology (IR). It has been reported that a 10-minute delay in arterial access reduces the survival rate by 10% [1]. So early access is critical. Arterial access can be divided into three methods: blind method (landmark method), ultrasound-guided method, and cut-down method, but the ultrasound-guided method is the first choice for arterial access, so we will explain how to perform ultrasound-guided arterial access. The sheath used for arterial access is a 4-Fr or 5-Fr sheath.

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ACCESS LOCATION

The femoral, brachial, and radial arteries are all used for access, but the femoral artery is most used in emergencies. The common femoral artery (CFA) branches into the superficial femoral artery (SFA) and the deep femoral artery (DFA), but the CFA should be punctured without fail. The CFA runs slightly medial to the midpoint of the inguinal ligament, between the inguinal ligament and the inguinal groove. If fluoroscopy is available, puncture at the level of the middle to one-third of the head of the femoral bone.

THE METHOD OF PUNCTURE AND SHEATH INSERTION

After confirming by ultrasound that the SFA and the DFA join to form the CFA, the puncture location is determined. After that, the area around the puncture site is disinfected, and local anesthesia is administered. The CFA is visualized in the axial or long axis by ultrasound and punctured. After confirming reversed blood flow, insert the guidewire to the CFA. If there is resistance, the mantle of the needle may not be positioned in the vessel, or it may have strayed into a branch vessel. No resistance will be felt if the guidewire is correctly placed in the vessel. Once the guidewire is inserted correctly, remove the mantle of the puncture needle. Confirm that the guidewire is protruding from the back end of the sheath. Grasp the guidewire to prevent it from straying into the body and place the sheath in the vessel.

FIXING THE SHEATH

The sheath is flushed with saline or heparinized saline, and then the sheath and skin are sutured and fixed.

MATERIALS FOR REBOA DEPLOYMENT

The items required to use the REBOA catheter are shown below:

- REBOA catheter kit (balloon catheter, stylet, suture with needle, needle holder, scalpel, syringe with lock, puncture needle, sheath dilator, guidewire, swab, disinfectant tray, drape)
- Ultrasound or fluoroscopy
- Saline or diluted contrast media: 20–40 ml (for balloon inflation)
- Saline or 5–10 U/min heparinized saline (for flushing the catheter)
- Suturing apparatus.

PREPARATION OF THE BALLOON CATHETER

Prepare the REBOA catheter itself before insertion. For non-fluoroscopic insertion, the landmark method is used to determine the insertion length of the catheter. When inserting under fluoroscopy, it is not necessary to determine the catheter insertion length in advance.

Over-Deflate the Balloon

Connect the empty locking syringe to the three-way stopcock of the balloon lumen and apply negative pressure to remove the air from the balloon (Figure 1). Test dilation of the balloon before insertion should never be performed as it breaks the neatly folded balloon, resulting in balloon injury.

Flush the Catheter Lumen

After removing the stylet, flush the catheter with heparinized saline (Figure 2). The stylet must be kept sterile

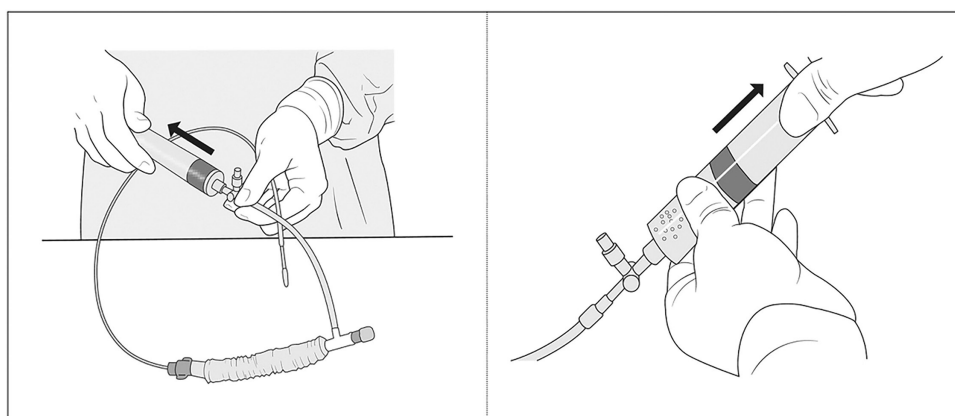


Figure 1 Removal of the air in the balloon. Connect the empty locking syringe to the three-way stopcock of the balloon lumen and apply negative pressure to remove the air in the balloon (do not remove the wrapping).

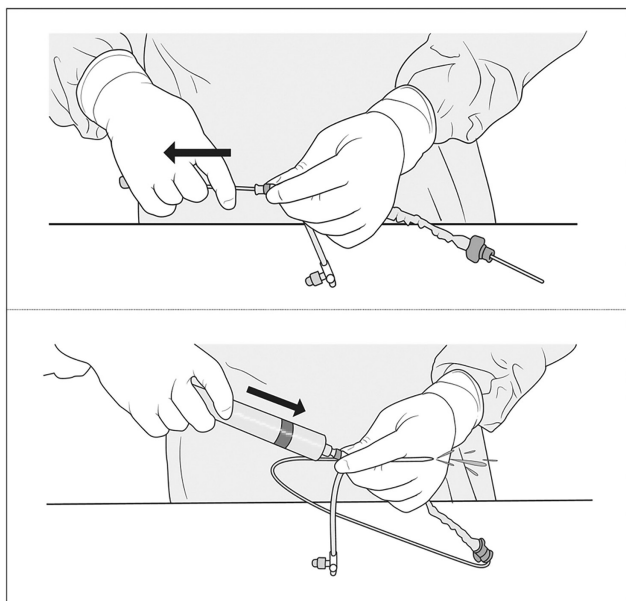


Figure 2 Flushing of the catheter. Remove the stylet once, and flush the catheter lumen.

as it will be used later. Be careful not to drop the stylet on the floor (as is often the case in an emergency).

Plan the Insertion Length

Plan the guidewire and balloon catheter insertion length according to the external landmark method under non-fluoroscopic conditions (Figure 3). The aortic zones are defined as Zones 1, 2, and 3 [2]. The target zone is selected based on the physiological state (hemorrhagic shock and impending cardiac arrest) and the assumed anatomical location of the injuries.

Regardless of the balloon catheter position, the tip of the guidewire should be located at the root of the left subclavian artery, which has the second intercostal space as a landmark. The guidewire tip is placed at the second intercostal space, and the assistant holds the guidewire at the sheath entrance position to measure the distance.

The landmark in Zone 1 is the xiphoid [3], and in Zone 3, the umbilicus. The balloon is placed above the external landmark of the target zone. Higher placement (nipple level) is safer when the zone is targeted because balloon migration occurs after inflation. Note that the balloon, not the catheter tip, should be above the target external landmark when the distance is measured [4]. Do not insert the guidewire or catheter beyond the second intercostal space to avoid straying into or damaging the left subclavian artery or left common carotid artery.

When fluoroscopy is available, pre-insert measurement can be omitted. Recognize the target zone by the vertebrae level and confirm the movement of the wire or catheter.

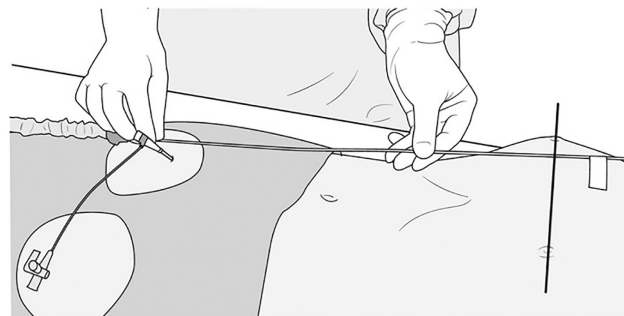


Figure 3 Determination of insertion length with the landmark method.

INSERTION OF THE REBOA CATHETER

Before inserting a REBOA catheter, upsize from a small (4–5 Fr) sheath to a larger (7–10 Fr) using a guidewire. After inserting the guidewire into the sheath for the REBOA catheter, advance the REBOA catheter to the target position using the over-the-guidewire technique. Remove the guidewire, reinsert the stylet to stiffen the shaft, and inflate the balloon.

Secure the Arterial Access and Upsize the Sheath

After securing the small initial (4-Fr or 5-Fr) arterial access, the sheath should be upsized when deciding to use REBOA. Use the appropriate size for the REBOA catheter; a 7-Fr sheath is provided for Rescue Balloon® and Rescue ER (Tokai Medical Products), and 10 Fr is for Block Balloon® (Senko Medical). Insert a guidewire (usually 0.035 inches) into a small short sheath to secure the arterial lumen and then remove the sheath. Then use the over-the-wire technique to upsize the sheath for the REBOA catheter. An oversized (an 8-Fr sheath for a 7-Fr catheter) sheath makes catheter removal through the sheath easier.

Insert the Guidewire

Insert the guidewire through the sheath. If the guidewire is in the artery, there is no resistance. If you feel even a little resistance, the guidewire might have stayed in an arterial branch or outside the vessel. Particular attention should be paid, especially to elderly patients. Never insert the REBOA catheter before confirming the wire in the aorta, even when you have to rush to deploy REBOA as soon as possible. This will avoid further aggravation, by iatrogenic injuries, in a life-threatening condition.

Without fluoroscopy, ultrasound, or radiography, the short sheath can be upsized using a guidewire [5]. When using a Rescue Balloon or Rescue ER catheter, the compatible guidewire is 0.025 inches, smaller than the most commonly used 0.035-inch wire. Recognize the compatibility of the guidewire and catheter before insertion.

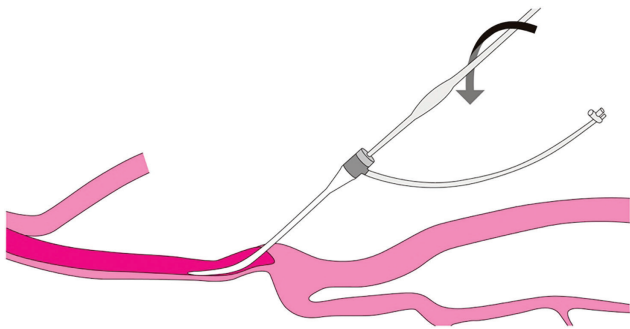


Figure 4 Insertion of the catheter for performing resuscitative endovascular balloon occlusion of the aorta. Insert while rotating clockwise in the sheath.

If it is difficult to insert the guidewire or if it is not possible to confirm the guidewire in the aorta, an approach from the contralateral femoral artery or left brachial artery may be performed at the same time. However, resuscitative thoracotomy with aortic cross-clamping or definitive hemostasis without aortic occlusion should always be considered.

Insert REBOA catheter with Over-the-Guidewire Technique

Remove the stylet from the catheter and flush the lumen with saline. Keep the stylet sterile and never drop it on the floor, even in a hectic resuscitation situation. Insert the guidewire first, followed by the catheter. The guidewire tip always precedes the catheter. These procedures are referred to as the over-the-guidewire technique. The catheter is advanced to the position measured using the external landmark method. Since the balloon wrapping is folded clockwise, rotating the catheter clockwise makes insertion smooth while inserting the REBOA catheter (Figure 4).

Make sure to grasp the end of the guidewire to avoid leaving the entire catheter in the artery. Keep the position of the guidewire tip to avoid staying in the carotid or subclavian artery or cardiac cavity when it is inserted deeply. If the guidewire is unintentionally dislodged, the catheter is more advanced than the guidewire, a risk factor for vascular injury. The operator or the assistant should grasp the guidewire during the entire procedure to ensure reliable guidewire manipulation. This is one of the reasons why a two-person maneuver is recommended. In particular, hydrophilic-coated guidewires require attention because they can be easily dislodged.

Replace the Guidewire with the Stylet

Never inflate the balloon immediately after catheter insertion. This is the biggest pitfall. Remove the guidewire and replace it with the stylet to stiffen the shaft before balloon inflation, preventing downstream migration. (Figure 5) The balloon moves significantly distally,

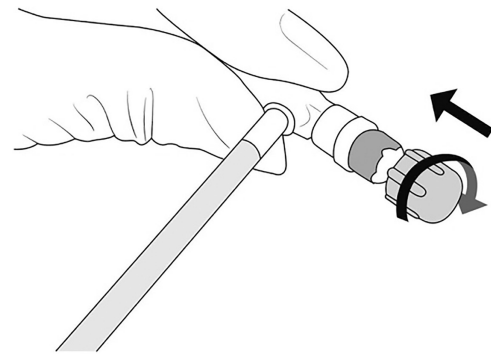


Figure 5 Insertion of the stylet. Before inflation of the balloon, replace the guidewire with a stylet.

especially in the small-profile catheter [6]. If the balloon is inflated without the stylet, the REBOA catheter will bend under arterial pressure. Once the catheter bends, the lumen collapses, and the stylet may not be inserted. If the catheter is bent more severely, it may not be removed from the sheath.

INFLATION OF THE BALLOON AND FIXATION OF THE CATHETER

Inflate a balloon to occlude the aorta. After inflation, the REBOA catheter may migrate, or the sheath may deviate. Fix both the catheter and sheath and the sheath and skin to prevent migration. An exclusive physician (REBOA controller) who is dedicated to monitoring the REBOA should manage the REBOA from the start of inflation to the removal of the catheter.

Inflate the Balloon Safely

With an assistant grasping the sheath and catheter, the operator slowly injects saline (or diluted contrast medium) through the balloon lumen. The three-way stopcock is locked when the inflation balloon volume reaches the target. There are three methods for determining the injection volume: 1) inflate until the tactile feedback is met; 2) observe the proximal arterial pressure; 3) the distal arterial pressure disappears [7]. The proximal pressure is usually measured in the radial artery. The distal pressure can be measured through the contralateral sheath or the side port of the oversized sheath. Balloon overinflation may cause iatrogenic aortic injuries. Distal pressure measurements can decrease the risk of overinflation [8].

Suppose that the operator inserts the REBOA catheter alone. An experienced operator may be able to grasp both the catheter and sheath with the left hand while inflating the balloon with the right hand. However, a third hand is required when it is time to lock the stopcock. Hence, an assistant is essential during the procedure.

Fix the Catheter and Sheath to Avoid Migration

After the three-way stopcock is locked, the sheath and catheter are secured. After balloon inflation, the catheter is subjected to aortic pressure. If the catheter itself is not secured, it exits the sheath. Fix both the catheter and sheath and the sheath and skin to prevent migration. Suture or adhesive tape should be used for secure fixation. The tape may be better as a temporary fixation, considering possible correction of the balloon catheter after radiography or fluoroscopy.

Tips for the Management of Balloon Inflation

Liquid for the balloon injection

The preferred liquid to be injected into the REBOA balloon is saline or a two-fold diluted iodine contrast medium. The visibility of the balloon with fluoroscopy is much better when using a contrast medium. On the other hand, the contrast may make it difficult to remove the catheter through the sheath because of incomplete deflation due to its viscosity. The undiluted contrast medium makes balloon images too dense with fluoroscopy.

Occlusion time

Balloon inflation should be performed immediately if the patient is in hemorrhagic shock that requires REBOA. The delayed decision for REBOA may induce hemodynamic collapse and cardiac arrest. Immediate definitive hemostasis must be achieved, and the duration of aortic occlusion should be as short as possible. Although there is insufficient evidence, balloon inflation is considered when the systolic blood pressure is below 70 mmHg [1]. Complete Zone1 REBOA should not be used if patients cannot proceed to a hemorrhage control within 15 min. Total occlusion time over 30 min is associated with increased ischemic complication and risk of mortality [9–12]. There is also no sufficient evidence of an acceptable duration of aortic occlusion. As a possible solution to ischemic sequelae, partial or intermittent REBOA is utilized to allow extended occlusion time.

Early definitive hemostasis and shorter aortic occlusion duration should always be considered.

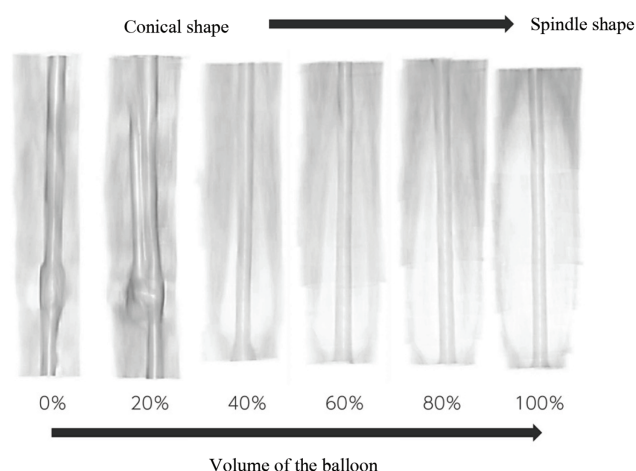


Figure 6 Changes in balloon shape due to balloon inflation volume.

Inflation volume and balloon shape

The relationship between the injection volume and balloon diameter differs depending on the REBOA product used, as shown in Table 1. Therefore, this relationship should be understood in advance. When the balloon is inflated, the balloon first becomes conical. With a further injection, the balloon starts to contact the aortic wall. The aortic occlusion effect increases according to the area of contact with the aortic wall. The balloon shape changes to a spindle shape as the contact area increases (partial REBOA). Finally, inflation results in a complete REBOA (Figure 6) [7]. Thus, the arterial pressure on the proximal side does not necessarily increase in proportion to the balloon injection volume (Figure 7) [7].

Management of the aorta occlusion

If proximal pressure monitoring has already been placed in the radial or brachial artery, the balloon is inflated gradually while checking the response of the pressure elevation. Elevation in proximal arterial pressure can determine sufficient aortic occlusion. The balloon should be inflated while palpating the radial pulse when proximal arterial pressure is not obtained. The contralateral femoral artery pressure can also judge complete occlusion

Table 1 Relationship between inflation volume and balloon diameter/shape.

	Balloon Diameter		
	20 mm	25 mm	30 mm
Inflation volume of the balloon (1)*	10 ml	15 ml	20 ml
Inflation volume of the balloon (2)**	25 ml	35 ml	45 ml

The diameters of the thoracic aortic and abdominal aortic arteries are generally $\phi 25$ – 30 mm and $\phi 20$ – 25 mm, respectively. In the shock state, the aortic diameter becomes smaller. *Rescue Balloon® (Tokai Medical Products). **Block balloon® (Senko Medical).

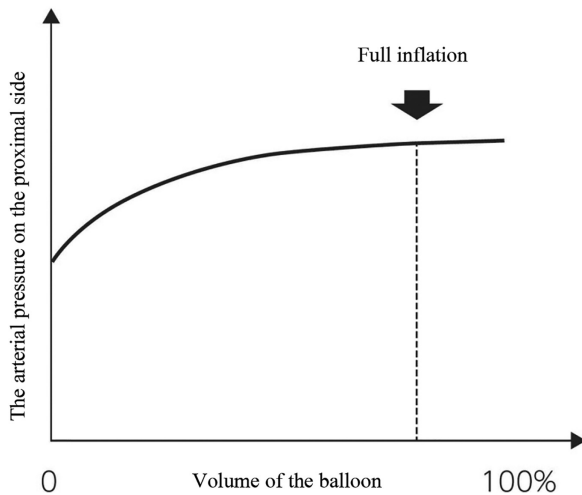


Figure 7 Changes in balloon diameter and proximal arterial pressure with balloon inflation.

when the pulse pressure disappears. When no arterial pressure is available, resistance to contact with the aortic wall is the only way to determine a complete aortic occlusion. However, tactile feedback may be challenging to recognize and is often overinflated. In patients with hemorrhagic shock, a decreased aortic diameter results in complete occlusion with a smaller volume than expected.

DEFLATION OF THE BALLOON

When hemodynamics become stable, consider using partial REBOA to reduce distal ischemia. Once the circulation is stable and definitive hemostasis is achieved, fully deflate the balloon.

Aortic occlusion time with REBOA is preferably as short as possible. When hemodynamics stabilizes and bleeding control is achieved, deflation should be attempted as soon as possible. The balloon inflation volume has to be gradually deflated by 1–2 ml while observing the arterial pressure of the upper limbs. For balloon deflation, cooperation between the physician in charge of REBOA management (REBOA controller), the hemostatic surgeon (interventional radiologist or surgeon), and the anesthesiologist is crucial. The REBOA controller may be a concurrent post as a commander for overall trauma treatment or an anesthesiologist proficient in managing REBOA. However, it may be challenging to serve concurrently as a hemostatic surgeon. The blood pressure always drops during balloon deflation. When balloon deflation occurs, particularly from complete aortic occlusion, the blood pressure often drops sharply because the vascular bed distal from the REBOA increases rapidly even if the blood volume is filled before balloon deflation.

Removal of the REBOA Catheter

If definitive hemostasis is achieved and hemodynamics become stable after complete deflation, remove the

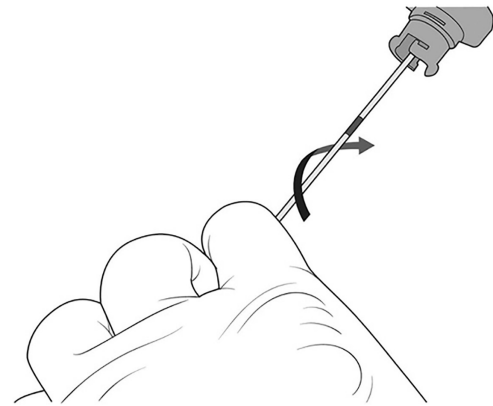


Figure 8 REBOA catheter removal practice. The REBOA catheter can be removed smoothly by turning the entire catheter clockwise while holding the sheath.

REBOA catheter as soon as possible. Consider leaving the catheter when the re-collapse is expected, or a massive transfusion is still required after hemostasis. Keep evaluating the injury and correcting the coagulopathy. Consider the risk of thrombus formation and then remove or leave the catheter.

Through or Together with the Sheath

Removing only the REBOA catheter from the sheath is ideal but not always possible. There is less risk of vascular damage if the catheter can be removed as it exits the sheath. Moreover, it is possible to avoid difficulty in manual compression for achieving hemostasis after sheath removal when the patient's coagulation is not normal.

Further, there is an advantage in that it can be prepared for reinsertion when the patient is in a state of shock again owing to rebleeding. Therefore, we recommend removing the REBOA catheter while leaving the sheath. When removing the Rescue Balloon® and Rescue Balloon®-ER catheter, the 9-Fr sheath is recommended, but empirically, the 8-Fr sheath can be used to remove the catheter safely. In many cases, the REBOA catheter can be removed through a 7-Fr sheath using the following techniques.

Deflate the Balloon Completely

Incomplete deflation of the balloon causes the removal of the REBOA catheter from the sheath to fail. It is vital to aspirate the lumen of the balloon catheter completely. In particular, when a contrast medium is used for balloon inflation, a small amount of contrast medium may remain because of its high consistency.

Remove the Catheter

It is easier to remove the REBOA catheter from the sheath by pressing it and slowly rotating it clockwise (Figure 8). In Rescue Balloon® and Rescue Balloon®-ER,

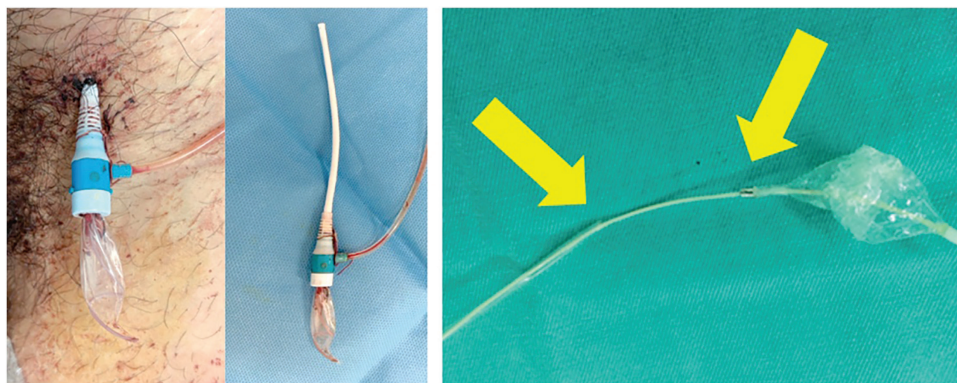


Figure 9 A case of balloon rupture due to forcible removal of the resuscitative endovascular balloon occlusion of the aorta catheter from the sheath. Left, ruptured balloon. Right, balloon damaged during catheter removal, and the end of the balloon moved to the tip (arrows).

the catheter marker can be confirmed when the balloon reaches the tip of the sheath. If there is any resistance at the time of removal, do not forcibly pull it out. This forcible procedure can lead to balloon rupture and damage to the catheter (Figure 9). Not only will the balloon be ruptured, but the shape of the sheath tip will be deformed, making it impossible to remove the REBOA catheter as it leaves the sheath. Therefore, first, if any resistance is present, check if the balloon is sufficiently deflated. Second, return the catheter into the artery, and change the shape of the balloon by inflating it slightly. Then, try to remove the REBOA catheter again using the above method.

Sheath Removal and Hemostasis Achievement

In principle, manual compression is selected for hemostasis in the case of a 7-Fr sheath. The sheath is removed to cause pulsatile bleeding for a moment while the SFA is compressed, and then complete compression is initiated. This process aims to brush away the thrombus around the sheath to not flow into the lower limbs. Consider removing the catheter when hemostasis is completely achieved, and the patient's coagulopathy is corrected. Manual compression should be maintained for approximately 20 min. In contrast, sheaths of ≥ 10 -Fr require compression for ≥ 30 min, and the use of hemostatic devices or surgical procedures can also be considered. Because each hemostatic device has its characteristics for use, manual compression is considered more reliable if the user has little experience with these hemostatic devices.

Follow-up After Catheter Removal for Access-Related Complications

After sheath removal, follow-up should be performed while paying attention to the occurrence of complications such as hematoma at the puncture site, pseudoaneurysm, iatrogenic arteriovenous fistula, and lower

extremity arterial thrombosis. If an arterial branch in the inguinal region was penetrated at the time of REBOA insertion, a large hematoma might expand after sheath removal, which may require endovascular treatment.

In Case of Leaving the REBOA Catheter or the Sheath

A shorter time of aortic occlusion and arterial sheath placement can reduce REBOA-related complications and access-related complications. However, in patients with recurrent unstable hemodynamics due to insufficient hemostasis after complete balloon deflation or those dependent on massive transfusion or anticoagulant therapy, keeping the REBOA catheter indwelling with balloon deflation is possible. If the patient's hemodynamics deteriorate during the night shift when definitive treatment is not available immediately, we can inflate the deflated REBOA again. The long-term indwelling of artificial materials induces a thrombus around the REBOA catheter or the arterial sheath, and this thrombus causes distal embolization, such as lower limb ischemia. Therefore, when we reuse the REBOA catheter, we must consider patient safety and decide on a case-by-case basis, considering the advantages and disadvantages. We have no high-quality evidence for the concrete time when the deflated REBOA catheter can be left in place. If only the REBOA catheter is removed and the arterial sheath is left in place, we can avoid the risk of thrombus around the REBOA catheter. However, because of the risk of clot formation in the lumen of the arterial sheath, the arterial sheath should be used for blood pressure monitoring or continuous flow injection.

COMPLICATIONS

In using REBOA, it is necessary to consider the complications that may occur during each process. The incidence of complications from REBOA use is 3.6–18%, and deaths due to complications have been reported in some cases [13–17].

Complications with Arterial Access

The most common complications are retroperitoneal hematoma and intra-abdominal and retroperitoneal organ injury due to high puncture and mispuncture of SFA and DFA due to low puncture. The mispuncture of SFA may lead to being a risk of lower limb ischemia.

Complications with Insertion of the REBOA Catheter

If the guidewire strays into a branch of the aorta, it may cause branch artery damage, arterial dissection, or extravasation. Even if the guidewire is positioned correctly, the REBOA catheter may not be inserted if there is vascular tortuosity, atherosclerosis, or calcification. If REBOA catheter insertion is impossible, do not hesitate to change tactics. For example, switch to RTACC and so on.

Complication with Position of REBOA Catheter

If the REBOA catheter is positioned between the left subclavian artery and the heart beyond Zone 1, it will block the cerebral arterial flow and cause myocardial damage. Balloon in Zone 2 will cause intestinal ischemia and renal damage due to blockage of blood flow in the abdominal branch. If the REBOA catheter is placed below Zone 3, that is, in the iliac artery, which may cause complete limb ischemia, vascular injury, or rupture of the limb artery. To prevent downstream migration of the catheter, always remember to reinsert the stylet before balloon inflation.

Complication with Balloon Inflation

Since balloon overinflation can cause vascular injury and balloon rupture, it is necessary to avoid the overinflation of the balloon while monitoring blood pressure. Moreover, keep in mind that if the injuries are central than the balloon inflation site, increased arterial pressure on the central side may exacerbate bleeding.

Complication with Balloon Deflation

Deflation of the balloon can lead to rebleeding and ischemia-reperfusion injury. Caution should be exercised because the ischemia-reperfusion injury may cause refractory hypotension, hyperkalemia, and metabolic acidosis [10]. When deflating the balloon, it is essential to monitor the upper extremities' blood pressure and do so slowly and gradually in 1–2 ml increments while using adequate fluids, blood transfusions, and vasopressor.

Complication with Indwelling Sheath

In some cases, patients are admitted to the intensive care unit with the sheath in place to prevent rebleeding after removing the REBOA catheter. Leaving the sheath in

place for a long time may cause vascular embolism or ischemia in the lower limb, which leads to reduction incision for compartment syndrome or thrombectomy for thromboembolism [18,19]. After sheath indwelling, continuous observation of the lower extremity on the side of indwelling is essential to check for ischemia.

CONCLUSIONS

Although REBOA is a valuable technique for controlling bleeding until radical hemostasis is achieved, it is essential to use it appropriately to avoid complications from insertion to removal. We must understand and master the appropriate techniques for REBOA use.

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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. SS, KR, 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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