




A contemporary assessment of devices for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA): resource-specific options per level of care

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Abstract

Purpose Use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as adjunct for temporary hemorrhage control in patients with exsanguinating torso hemorrhage is increasing. Characteristics of aortic occlusion balloons (AOB) are diverse and evolving as efforts are made to improve the technology. It is important to select a device that fits the requirements of the medical situation to minimize the risk of failure and complications. The aim of this study is to appraise guidance in the choice of an AOB in a specific situation.

Methods We assessed 29 AOB for differences and outline possible advantages and disadvantages of each. Bending stiffness was measured with a three-point bending device.

Results Diameter of the AOB ranged from 6 (ER-REBOATM) to 10 (Coda[®]-46) French. However, some need large-bore access sheaths up to 22 French (Fogarty[®]-45 and LeMaitre[®]-45) or even insertion via cut-down (EqualizerTM-40). Bending stiffness varied from 0.08 N/mm (± 0.008 SD; Coda[®]-32) to 0.72 N/mm (± 0.024 SD; Russian prototype). Rescue BalloonTM showed kinking of the shaft at low bending pressures. The only non-compliant AOB is REBOA Balloon[®]. ER-REBOATM, Fogarty[®], LeMaitre[®], REBOA Balloon[®], and Rescue BalloonTM are provided with external length marks to assist blind positioning.

Conclusion In resource-limited settings, a guidewire- and fluoroscopy-free, rather stiff device, such as ER-REBOATM, Fogarty[®], and LeMaitre[®], is warranted. Of these devices, ER-REBOATM is the only catheter compatible with seven French sheaths and specifically designed for emergency hemorrhage control. Of the over-the-wire devices, Q50[®] has several features that facilitate use and reduce the risk of malplacement or vessel damage.

Keyword Aortic occlusion balloon catheter · REBOA · Resuscitation · Stiffness

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Background

The use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an adjunct for temporary hemorrhage control in patients with exsanguinating torso hemorrhage is increasing. In this technique, an occlusion balloon catheter is inserted, in most of the cases, into the femoral or brachial artery percutaneously or via surgical cut-down. It is then positioned into the aorta. There are two zones of occlusion, depending on the suspected site of injury. Zone I, between the left subclavian artery and the celiac trunk, is for the management of abdominal or retroperitoneal hemorrhage. Zone III occlusion, between the distal renal artery and the aortic bifurcation, is for the management of pelvic, junctional, or proximal lower extremity hemorrhage. Zone II, between the

celiac trunk and the distal renal artery, is considered as a zone of no occlusion [1–3]. By occluding the aorta above the level of injury, REBOA effectuates temporary distal hemorrhage control and centralizes blood flow. It thereby increases cardiac afterload and central aortic pressure, resulting in sustained perfusion of the brain and heart [4–6].

There are a variety of aortic occlusion balloon catheters (AOB) available with different physical characteristics and specifications. Demands of the AOB differ depending on the indication for REBOA and the circumstances under which REBOA should be performed. The use of REBOA in the fields of trauma and maternal fetal medicine is increasing, thus, consequently, its use in relatively austere settings. Therefore, it is important to select a device that fits the demands of the situation to maximize success and reduce the risk of complications.

The aim of this study is to provide an overview of the commonly used AOB and their specifications, characteristics, bending stiffness and possible advantages and disadvantages in their use to appraise guidance in the choice of an aortic occlusion balloon per medical situation.

Methods

In this review of available AOB, we assessed 29 AOB for differences, possible advantages and disadvantages based on current literature and experiences with REBOA. Considerations for catheter characteristics will be discussed for different levels of care from resource-limited settings where real-time fluoroscopy is not readily available and other equipment resources may be limited, to more normal levels of care where fluoroscopy and other resources are commonly available.

Exclusion criteria

AOB from manufacturers or distributors that could not be reached or were not able or willing to provide a sample are excluded from this overview since inclusion would infer missing information that will lead to a disparate comparison.

Specifications

The AOB are assessed for dimensions of the catheter and balloon, material of the balloon, compatible introducer sheath and guidewire, number of lumina, tip design, radiopacity, features that ease balloon volume control and positioning, and other special features that ease handling of the AOB.

Bending stiffness

To quantify the bending stiffness (BS) of the AOB, we developed a three-point bending device (MK01-60, Fig. 1). The catheter is placed against two ball bearings and force is applied perpendicular to the longitudinal axis of the catheter midway between the ball bearings. The proximal and distal ends of the catheter can move freely when force is applied to eliminate frictional influence on the measured force. Force is applied and measured at multiple sites of the catheter shaft. Also, since most catheters are packaged rolled up and consequently pre-curved, all catheters are measured in two directions (Fig. 2). The BS of the catheters is measured with and



Fig. 1 Three-point bending device (MK01-60) for measuring catheter bending stiffness. The catheter is placed against the two ball bearings and force is applied perpendicular to the longitudinal axis of the catheter midway between the ball bearings. The proximal and distal end of the catheter can move freely when force is applied. The force required to deflect the catheter 10 mm is measured with a digital force gauge

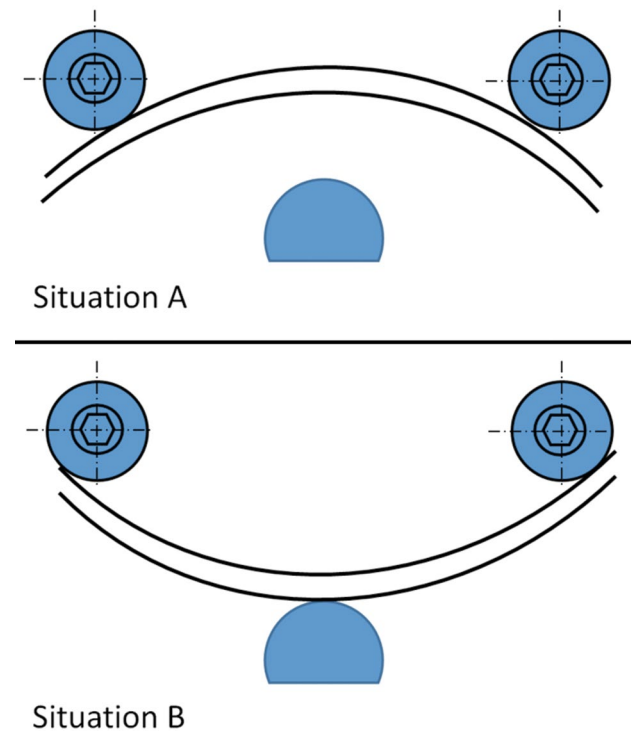


Fig. 2 Measurement directions of the catheters. Situation A: force is applied in the direction of the curvature of the catheter. Situation B: force is applied in the opposite direction. The catheter is turned 180°. In case of straight catheters, the same procedure is followed

without guidewire. Catheters without a supplied guidewire are measured with a standard 0.035 inch guidewire (Terumo (Tokyo, Japan) Radifocus® Guidewire M Standard Type 0.035", 150 cm).

The force (Newton) required to deflect the catheter 10 mm is measured with an ISO calibrated digital force gauge (PCE-DFG N 10, PCE Instruments, Meschede, Germany) with a capacity of 0–10 N (N), a resolution of 0.005 N and an accuracy of 0.1% of full scale. The BS is expressed in N/mm. Also, the mean stiffness/French is calculated [N/(mm Fr)].

The test bench is validated by repeating 8/21 (38%) of the measurements at different times. All measurements are performed at room temperature (21 ± 0.4 °C).

Results

Twenty-nine AOB from ten different manufacturers were assessed for variables. Each of these manufacturers provided samples for physical examination. Tables 1 and 2 list the specifications and characteristics of the AOB from these manufacturers. The mean BS and stiffness/French of the obtained catheters is presented in Table 3.

Three AOB were excluded due to various reasons. This involved the ResQ™ Occlusion Balloon Catheter (QxMédical, Montreal, Quebec, Canada), GORE® Molding & Occlusion Balloon (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA), and MIT aortic balloon (Minimally Invasive Technologies, Co. Ltd, Moscow, Russia). Reasons for not being able to include these AOB were: unable to reach the manufacturer, manufacturer was not able or willing to provide a sample or the (new) models were under development.

Aortic occlusion balloon catheters

Coda® Balloon Catheter (online resource 1)

Cook Medical, Bloomington, IN, USA, has an assortment of AOB with varying catheter and balloon sizes (Table 1). All catheters are double lumen. The Y-connector has indications for the balloon inflation port ("BALLOON") and wire entry ("DISTAL"). The balloon port is provided with a stopcock for balloon volume control (Table 2).

The Coda-32-LP has a maximum balloon inflation diameter of 32 mm. Its balloon length is 37 mm. The catheter is extremely flexible with a BS of 0.08 N/mm (± 0.008 SD) without guidewire and 0.11 N/mm (± 0.006 SD) with guidewire (Table 3).

The Coda-46 has a maximum balloon inflation diameter of 46 mm and a balloon length of 38 mm. It is slightly stiffer than the Coda-32-LP. Its BS is 0.12 N/mm (± 0.005 SD) without guidewire and 0.14 N/mm (± 0.010 SD) with guidewire (Table 3).

Equalizer™ Occlusion Balloon Catheter (online resource 2)

Boston Scientific, Marlborough, MA, USA, offers a wide range of the Equalizer™ Occlusion Balloon Catheter (Table 1). All catheters have two lumina. The balloon inflation port is marked with "BALLOON" and has a different color than the catheter itself. The central guidewire lumen is marked with "DISTAL" and is shorter than the balloon inflation port. The central lumen can also be used for infusion of contrast medium or medication. Both the balloon port and the central port have a luer-lock connector. There are no stopcocks pre-attached. The 40-mm balloon variants are not suitable for an introducer sheath, but have to be inserted bare via surgical cut-down. There are no length markings on the catheter shaft. According to the instructions for use (IFU), the catheter is designed for temporary vessel occlusion in various applications, including in patients requiring emergency control of hemorrhage (Table 2). The catheter's BS is 0.13 N/mm (± 0.032 SD) without guidewire and 0.16 N/mm (± 0.025 SD) with guidewire (Table 3). The Equalizer™ Occlusion Balloon Catheters are supplied with a syringe.

Table 1 Specifications of aortic occlusion balloon catheters for REBOA

| Aortic occlusion balloon | Max inflation \varnothing [mm] | Max inflation volume [mL] | Catheter \varnothing [Fr] | Required introducer sheath | Compatible GW \varnothing [inch] | Length [cm] | Lumina | Tip |
|---|----------------------------------|---------------------------|-----------------------------|----------------------------|------------------------------------|-------------|--------|-------------------------------|
| Coda [®] 2-9.0-35-100-32, Cook Medical | 32 | 30 | 9 | 12 Fr | 0.035 | 100 | 2 | Tapered flexible tip |
| Coda [®] 2-9.0-35-120-32, Cook Medical | 32 | 30 | 9 | 12 Fr | 0.035 | 120 | 2 | Tapered flexible tip |
| Coda [®] 2-10-35-140-46, Cook Medical | 46 | 60 | 10 | 14 Fr | 0.035 | 140 | 2 | Tapered flexible tip |
| Equalizer [™] Occlusion Balloon Catheter 17-105, Boston Scientific | 20 | 4.8 | 7 | 14 Fr | 0.038 | 65 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-107, Boston Scientific | 27 | 10 | 7 | 14 Fr | 0.038 | 65 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-109, Boston Scientific | 33 | 19 | 7 | 16 Fr | 0.038 | 65 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-111, Boston Scientific | 40 | 34.5 | 7 | Via cut-down only | 0.038 | 65 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-106, Boston Scientific | 20 | 4.8 | 7 | 14 Fr | 0.038 | 100 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-108, Boston Scientific | 27 | 10 | 7 | 14 Fr | 0.038 | 100 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-110, Boston Scientific | 33 | 19 | 7 | 16 Fr | 0.038 | 100 | 2 | Stiff tip |
| Equalizer [™] Occlusion Balloon Catheter 17-112, Boston Scientific | 40 | 34.5 | 7 | Via cut-down only | 0.038 | 100 | 2 | Stiff tip |
| ER-REBOA [™] , Prytime Medical Devices | 32 | 24 | 6 | 7 Fr | GW-free | 72 | 2 | Atraumatic P-tip [™] |
| Fogarty [®] Occlusion Catheter 62080814F, Edwards Lifesciences | 28 | 10 | 8 | 14 Fr | GW-free | 80 | 1 | Soft flexible blunt tip |
| Fogarty [®] Occlusion Catheter 62080822F, Edwards Lifesciences | 45 | 43 | 8 | 22 Fr | GW-free | 80 | 1 | Soft flexible blunt tip |

Table 1 (continued)

| Aortic occlusion balloon | Max inflation \varnothing [mm] | Max inflation volume [mL] | Catheter \varnothing [Fr] | Required introducer sheath | Compatible GW \varnothing [inch] | Length [cm] | Lumina | Tip |
|--|----------------------------------|---------------------------|-----------------------------|----------------------------|------------------------------------|-------------|--------|-------------------------|
| LeMaitre [®] 2107-80 Aortic Occlusion Catheter, LeMaitre Vascular | 28 | 15 | 8 | 14 Fr | GW-free | 80 | 1 | Soft flexible blunt tip |
| LeMaitre [®] 2107-81 Aortic Occlusion Catheter, LeMaitre Vascular | 45 | 50 | 8 | 22 Fr | GW-free | 80 | 1 | Soft flexible blunt tip |
| Q50 [®] Plus Q50-65P, QXMédical (Merit Medical) | 50 | 60 | 8 | 12 Fr | 0.038 | 65 | 3 | Tapered flexible tip |
| Q50 [®] Plus Q50-100P, QXMédical (Merit Medical) | 50 | 60 | 8 | 12 Fr | 0.038 | 100 | 3 | Tapered flexible tip |
| Q50X [™] Q50-65-X*, QXMédical (Merit Medical) | 50 | 60 | 8 | 10 Fr | 0.038 | 65 | 3 | Tapered flexible tip |
| Q50X [™] Q50-100-X*, QXMédical (Merit Medical) | 50 | 60 | 8 | 10 Fr | 0.038 | 100 | 3 | Tapered flexible tip |
| REBOA Balloon [®] 15, REBOA Medical AS | 15 | 8 | 6 | 6 Fr | 0.035 | 30/50/70 | 2 | Stiff tapered tip |
| REBOA Balloon [®] 20, REBOA Medical AS | 20 | 15 | 7 | 7 Fr | 0.035 | 30/50/70 | 2 | Stiff tapered tip |
| Reliant [™] Stent Graft Balloon Catheter, Medtronic | 46 | 60 | 8 | 12 Fr | 0.038 | 100 | 2 | Stiff tapered tip |
| Rescue balloon [™] OBS-01A, Tokai Medical Products | 40 | 40 | 7 | 7 Fr | 0.025 | 100 | 2 | Flexible tip |
| Russian prototype AOB, Minimally Invasive Technologies | 40 | 45 | 6 | 10 Fr | GW-free | 100 | 1 | J-tip |

AOB aortic occlusion balloon, *cm* centimeters, *Fr* French, *GW* guidewire, *mL* milliliters, *mm* millimeter

*Currently only available in the USA

ER-REBOA[™] (online resource 3)

The ER-REBOA[™] from Prytime Medical Devices, Boerne, TX, USA, is a 6-Fr, guidewire-free, double-lumen catheter (Table 1). The catheter shaft uses a concentric tube-in-tube design with inner elastic nitinol tube and outer plastic tube [7]. The inner lumen is used for arterial pressure monitoring with a pressure port distal from the balloon; the outer lumen is for balloon inflation. The ER-REBOA[™] has an atraumatic

P-tip[™] designed to resist accidental entry into aortic side branches [7]. A peel-away sheath facilitates insertion of the catheter. The maximum balloon inflation diameter is 32 mm and the length of the balloon is 48 mm. The catheter shaft has external length marks every centimeter and indications of every 5 cm to facilitate placement in situations without fluoroscopy (Table 2). Both the balloon inflation port and the arterial pressure port of the Y-connector have a flexible extension with stopcock to facilitate balloon volume control

Table 2 Characteristics and features of aortic occlusion balloon catheters for REBOA

| Aortic occlusion balloon | Material | Features | Indications | Price* |
|--|-----------------------------------|--|---|--------|
| Coda® Balloon Catheter, Cook Medical | Compliant polyurethane | Radiopaque markers at the balloon to assist with positioning under fluoroscopy Distinctive balloon port and central lumen port Stopcock to facilitate balloon volume control | Temporary occlusion of large vessels To expand vascular prostheses | € 450 |
| Equalizer™ Occlusion Balloon Catheter, Boston Scientific | Compliant natural rubber latex | Radiopaque catheter shaft Radiopaque markers at the balloon to assist with positioning under fluoroscopy Distinctive balloon port and central lumen port Supplied with a syringe | Temporary occlusion of large vessels Including emergency control of hemorrhage | € 100 |
| ER-REBOA™, Prytime Medical Devices | Compliant thermoplastic elastomer | Guidewire-free External length marks every cm for positioning without fluoroscopy Radiopaque catheter shaft Radiopaque markers at the balloon to assist with positioning under fluoroscopy Pre-loaded peel-away sheath to ease insertion of the catheter's P-tip™ Built-in arterial pressure lumen Distinctive balloon port and central lumen port Stopcock to facilitate balloon volume control Available with convenience sets and access kits | Temporary occlusion of large vessels Monitoring of blood pressure Including emergency control of hemorrhage | € 1950 |
| Fogarty® Occlusion Catheter, Edwards Lifesciences | Compliant natural rubber latex | Guidewire-free Length marks every 10 cm to assist positioning without fluoroscopy Radiopaque catheter shaft Gate valve to facilitate balloon volume control | Temporary occlusion of large vessels | € 155 |
| LeMaitre® Aortic Occlusion Catheter, LeMaitre Vascular | Compliant natural rubber latex | Guidewire-free Length marks every 10 cm to assist positioning without fluoroscopy Radiopaque catheter shaft Stopcock to facilitate balloon volume control | Temporary occlusion of large vessels | € 135 |
| Q50® Stent Graft Balloon Catheter, QXMédical (Merit Medical) | Compliant polyurethane | Three lumina to allow quick inflation and deflation of the balloon Radiopaque markers at the balloon to assist with positioning under fluoroscopy Stopcock to facilitate balloon volume control | Temporary occlusion of large vessels To expand vascular prostheses | € 400 |

Table 2 (continued)

| Aortic occlusion balloon | Material | Features | Indications | Price* |
|--|---------------------------------------|---|---|--------------------|
| REBOA Balloon [®] , REBOA Medical AS | Non-compliant thermoplastic elastomer | One or two length marks on the catheter shaft to assist positioning without fluoroscopy Radiopaque markers at the balloon to assist with positioning under fluoroscopy Distinctive balloon port and central lumen port Available with a complete kit containing all materials needed for REBOA | Temporary occlusion of the aorta | €1350 [†] |
| Reliant [™] Stent Graft Balloon Catheter, Medtronic | Compliant polyurethane | Radiopaque markers at the balloon to assist with positioning under fluoroscopy Stopcock to facilitate balloon volume control | Temporary occlusion of large vessels To expand vascular prostheses or assist in the expansion of self-expanding stent grafts | € 180 |
| Rescue balloon [™] , Tokai Medical Products | Compliant polyurethane | Length marks every 5 cm to assist positioning without fluoroscopy Radiopaque markers at the balloon to assist with positioning under fluoroscopy Stopcock to facilitate balloon volume control | Temporary occlusion of large vessels Including emergency control of hemorrhage | NA |
| Russian prototype AOB, Minimally Invasive Technologies | Latex | Guidewire-free Radiopaque catheter shaft Stopcock to facilitate balloon volume control Rubber ring that can indicate migration | Temporary occlusion of large vessels | NA |

AOB aortic occlusion balloon, NA price information not yet available

*Approximate catalog price. Prices may vary based on regional differences, taxes, price agreements and changes over time

[†]Price for complete procedure kit. The balloon catheter is not sold separately

and fluid control of the arterial line. The balloon arm has a white stopcock and indicates “BAL”. The arterial pressure port comes with a red stopcock and indicates “ART”. The BS of the catheter is 0.43 N/mm (± 0.013 SD) (Table 3).

The ER-REBOA[™] is the most expensive catheter (Table 2). It is specifically designed for temporary hemorrhage control and resuscitation support in emergency settings. Convenience sets and access kits are available containing materials needed for arterial access, sheath placement and fixation of the catheter.

Fogarty[®] Occlusion Catheter (online resource 4)

The Fogarty[®] Occlusion Catheter from Edwards Lifesciences, Irvine, CA, USA, comes in two models suitable for aortic occlusion (Table 1). Both catheters are single-lumen, guidewire-free catheters with a blunt flexible tip. The catheters come with a removable stylet that increases body stiffness during placement of the catheter [BS 0.25 ± 0.011 N/mm with stylet versus 0.12 ± 0.007 N/mm

without stylet (Table 3)]. Marker bands assisting positioning without fluoroscopy are located on the catheter shaft every 10 cm, decreasing in number and width towards the balloon (Table 2). The catheter shaft itself is radiopaque. It does not have distinct radiopaque marker bands at the balloon. A gate valve with luer-lock connector is attached to the proximal end of the catheter (the inflation port). Closing the gate valve prevents the balloon from deflation. The catheters are supplied in a straight tube and are therefore not pre-curved.

LeMaitre[®] Aortic Occlusion Catheter (online resource 5)

LeMaitre[®] Vascular, Burlington, MA, USA, offers two types of AOB suitable for REBOA (Table 1). Both models are guidewire-free, single-lumen catheters with an atraumatic flexible tip, and a two-way stopcock attached to the single lumen to maintain balloon inflation volume. Unique length markings are located on the catheter shaft every 10 cm to assist positioning without fluoroscopy (Table 2). There are no radiopaque marker bands located at the balloon; however,

Table 3 Bending stiffness of aortic occlusion balloon catheters for REBOA

| Aortic occlusion balloon | Overall mean BS w/o GW [N/mm] (\pm SD) | Mean BS/Fr w/o GW [N/(mm Fr)] | Overall mean BS w/ GW [N/mm] (\pm SD) | Mean BS/Fr w/ GW [N/(mm Fr)] | Overall mean BS w/ stylet [N/mm] (\pm SD) | Mean BS/Fr w/ stylet [N/(mm Fr)] | Guidewire |
|--------------------------|---|-------------------------------|--|------------------------------|--|----------------------------------|--|
| Coda-2-9.0-35-120-32 | 0.08 (\pm 0.008) | 0.009 | 0.11 (\pm 0.006) | 0.012 | n/a | n/a | Terumo Radifocus® Guidewire M Standard Type 0.035" |
| Coda-2-10-35-140-46 | 0.12 (\pm 0.005) | 0.012 | 0.14 (\pm 0.010) | 0.014 | n/a | n/a | Terumo Radifocus® Guidewire M Standard Type 0.035" |
| Equalizer™ 17-109 | 0.13 (\pm 0.032) | 0.019 | 0.16 (\pm 0.025) | 0.023 | n/a | n/a | Terumo Radifocus® Guidewire M Standard Type 0.035" |
| ER-REBOA™ | 0.43 (\pm 0.013) | 0.071 | n/a | n/a | n/a | n/a | n/a |
| Fogarty® 62080814F | 0.12 (\pm 0.007) | 0.015 | n/a | n/a | 0.25 (\pm 0.011) | 0.031 | n/a |
| LeMaitre® 2107-80 | 0.33 (\pm 0.013) | 0.041 | n/a | n/a | n/a | n/a | n/a |
| LeMaitre® 2107-81 | 0.33 (\pm 0.017) | 0.042 | n/a | n/a | n/a | n/a | n/a |
| Q50® Plus Q50-65P | 0.30 (\pm 0.061) | 0.037 | 0.34 (\pm 0.043) | 0.042 | n/a | n/a | Terumo Radifocus® Guidewire M Standard Type 0.035" |
| REBOA Balloon® 20 | 0.17 (\pm 0.036) | 0.024 | 0.30 (\pm 0.040) | 0.042 | n/a | n/a | SP Medical Accoat Guide Wire Seldinger Extra stiff, 0.035" |
| Reliant™ | 0.11 (\pm 0.016) | 0.014 | 0.14 (\pm 0.017) | 0.017 | n/a | n/a | Terumo Radifocus® Guidewire M Standard Type 0.035" |
| Rescue balloon™ | 0.23 (\pm 0.048) | 0.032 | 0.26 (\pm 0.051) | 0.038 | 0.47 (\pm 0.036) | 0.067 | Hydrophilic GW 0.025" |
| Russian prototype | 0.72 (\pm 0.024) | 0.119 | n/a | n/a | n/a | n/a | n/a |

BS bending stiffness, Fr French, GW guidewire, mm millimeter, N Newton, n/a not applicable, SD standard deviation, w/ with, w/o without

the catheter shaft itself is radiopaque. The catheters are not pre-curved since they are supplied in a straight tube.

The LeMaitre® 2107-80 has a maximum balloon inflation diameter of 28 mm and is compatible with a 14-Fr introducer sheath. The balloon length is approximately 20 mm. BS is 0.33 N/mm (\pm 0.013 SD) (Table 3).

The LeMaitre® 2107-81 has a maximum inflation diameter of 45 mm and is compatible with a 22-Fr introducer sheath. Its balloon length is 24 mm. It has a BS of 0.33 N/mm (\pm 0.017 SD) (Table 3).

Q50® Stent Graft Balloon Catheter (online resource 6)

QXMédical, Montreal, Quebec, Canada, manufactures four types of the Q50® Stent Graft Balloon Catheter that are either compatible with a 12-Fr introducer sheath or a 10-Fr sheath (Table 1). The difference in introducer sheath compatibility is due to a different balloon wrapping of the Q50® PLUS and the Q50X™. With a maximum balloon diameter of 50 mm, the Q50® is the largest occlusion balloon. It has a length of approximately 40 mm. The Q50® Stent Graft

Balloon Catheters are the only AOB with three lumina. It has two balloon inflation lumina to allow quick inflation and deflation of the balloon. The third lumen is intended for a guidewire. The balloon inflation port has an extension tube with a stopcock to prevent balloon deflation (Table 2). Q50[®] distributor Merit Medical (South Jordan, UT, USA) offers a lockable syringe (VacLok[®] Negative Pressure Syringe) to facilitate balloon volume control. BS is 0.30 N/mm (± 0.061 SD) without guidewire and 0.34 N/mm (± 0.043 SD) with guidewire (Table 3).

REBOA Balloon[®] (online resource 7)

REBOA Medical AS, Norway, offers a broad range of the REBOA Balloon[®] catheter (Table 1). It is the only AOB with a non-compliant balloon. It consists of a thermoplastic elastomer (DEHP free and latex free). The maximum diameter of the balloon with standard injection volume avoids aortic wall rupture since over-inflation is not possible. However, it does impose a risk of rupturing the aorta in patients with a smaller aortic diameter. In situations where the aortic diameter is in excess of the occlusion balloon diameter, the balloon will not provide occlusion or hemorrhage control.

The REBOA Medical AS balloon catheters are available with a 15-mm (6-Fr) or 20-mm (7-Fr) balloon diameter. The catheters can only be ordered as a complete kit containing all materials needed for REBOA, including a guidewire (SP Medical Accoat Guide Wire Seldinger Extra stiff, J3 mm tip, PTFE coated, 150-cm length, 0.035-inch diameter). The catheters have a coaxial double-lumen design. The balloon inflation port is marked with "BALLOON" and is longer, and has a different color than the guidewire lumen (Table 2). According to the IFU, the catheters can be placed without fluoroscopic guidance. To aid positioning without fluoroscopy, the 50-cm catheters have a shaft marking at 30 cm from the distal tip. The 70-cm catheters have single line marking at 30 cm from the distal tip and a double line at 50 cm from the distal tip. The BS of the 7-Fr catheter is 0.17 N/mm (± 0.036 SD) without guidewire and 0.30 N/mm (± 0.040 SD) with guidewire (Table 3).

Reliant[™] Stent Graft Balloon Catheter (online resource 8)

The Reliant[™] Stent Graft Balloon Catheter from Medtronic, Minneapolis, MN, USA, is a flexible double-lumen catheter with a BS of 0.11 N/mm (± 0.016 SD) without guidewire and 0.14 N/mm (± 0.017 SD) with guidewire (Table 3). The balloon has a maximum inflation diameter of 46 mm and a length of approximately 37 mm (Table 1). There are no length markings on the catheter shaft. The balloon inflation port of the Y-connector has a flexible extension with a three-way stopcock to assist in balloon volume control (Table 2).

Rescue Balloon[™] (online resource 9)

The Tokai Rescue Balloon[™] OBS-01A from Tokai Medical Products, Aichi, Japan, is a small-sized, double-lumen 7-Fr catheter (Table 1). It can be used with a 0.025-inch guidewire that is provided with the catheter. After balloon positioning, the guidewire can be removed and a stylet can be inserted to provide additional catheter stiffness [BS 0.47 \pm 0.036 N/mm with stylet versus 0.26 \pm 0.051 N/mm with guidewire (Table 3)]. The BS of the catheter is 0.23 N/mm (± 0.048 SD). Length marks that assist with positioning without fluoroscopy are located on the catheter shaft every 5 cm (Table 2). A double mark is located 55 cm from the tip of the catheter. The balloon inflation port has a flexible extension with a stopcock to prevent deflation of the balloon during the procedure.

The catheter tends to kink and when kinked, it remains plastically deformed. Careful handling of the catheter to prevent kinking prior to insertion is important.

Russian prototype aortic occlusion balloon (online resource 10)

The Russian prototype AOB from Minimally Invasive Technologies, Co. Ltd, Moscow, Russia, is a small-sized 6-Fr catheter (Table 1). The deflated balloon requires a 10-Fr sheath. Despite the small diameter, it is the stiffest catheter with a BS of 0.72 N/mm (± 0.024 SD) (Table 3). The maximum inflation diameter of the balloon is 40 mm and its length is approximately 34 mm. The catheter has a built-in J-tip guidewire which cannot be removed from the catheter. It also has a rubber stop ring that can be used to indicate initial introduction depth and possible subsequent migration of the catheter (Table 2). There are no length markings on the catheter shaft. The transition from catheter shaft to guidewire tip is visible with fluoroscopy.

Discussion

There is a wide variety of AOB available and specifications, and characteristics are diverse. With the increasing use of REBOA in the field of trauma, maternal fetal medicine and iatrogenic surgical hemorrhage, it is important to choose a device that fits the demands for the best success rate for a patient in need of urgent hemorrhage control. However, there is no consensus on the desired specific features of the AOB. This article provides an overview of the currently available AOB with their specifications, characteristics and bending stiffness, and possible advantages and disadvantages in their use after extensive review of the catheters. Cautious recommendations for selecting an AOB are done based on this review, current literature and experience with REBOA.

Only three AOB, the Equalizer™, ER-REBOA™, and Rescue balloon™ have specifically indicated in their IFU that it is intended for use in patients with massive bleeding. Suitability for partial aortic occlusion is not described in any of the IFUs. All catheters are small caliber catheters. Required introducer sheath size and the catheters BS, however, vary widely. We found that the guidewire-free devices are generally stiffer than the over-the-wire catheters and a standard guidewire only adds minimal extra stiffness. Catheter stiffness, including a stiff catheter tip, might increase the risk of dissection or rupture of the aorta during placement [8]. On the other hand, Onishi et al. described a case of a loop formation of an AOB in the aorta presumably due to a more flexible small caliber catheter [9]. Borger van der Burg et al. also demonstrates an association between catheter stiffness and migration of the aortic occlusion balloon [10]. In their study, minor primary migration during insufflation is observed in all devices. Only the Cook Coda® Balloon Catheter and the Russian prototype AOB showed subsequent migration under higher pressures. Comparing these findings with our results, we can conclude that the most flexible and the stiffest catheters migrated while fully inflated, suggesting there is an optimum in catheter stiffness regarding the risk of balloon migration. The stiff catheter (Russian prototype AOB, BS 0.72 N/mm (± 0.024 SD)) showed outward migration at the sheath; while, migration of the highly flexible catheters (9 Fr Coda® with BS of 0.08 N/mm (± 0.008 SD) and 10-Fr Coda® with BS of 0.012 N/mm (± 0.005 SD)) was due to kinking of the catheter in the aorta which was not visible at the sheath. Theoretically, outward migration or kinking of the catheter is also possible in patients in whom restoration of blood pressure leads to an increase in aortic diameter and consequently loss of contact surface between the balloon and aortic wall, while downward pressure on the catheter is increasing. By general rules, the axial force a catheter can resist is limited by the buckling force. The buckling force depends on the BS as well as the aspect ratio (relation between length, area, and moment of inertia) of the catheter. A catheter with a high BS is more resistant to kinking due to in vivo axial pressure. However, the buckling force of most catheters will be negligible due to the large aspect ratio. The flexible Reliant™ catheter (BS 0.11 (± 0.016 SD)) did not show secondary migration in the study of Borger van der Burg et al. This supports the theory that frictional force between the balloon and aortic wall is of importance in preventing migration or kinking of the catheter. Despite the observed migration, all catheters achieved total aortic occlusion and can be used for REBOA. However, in vivo kinking of the catheter shaft can lead to an improper occlusion location when fluoroscopy is not available to confirm the position of the balloon [9–11]. In resource-limited settings where real-time fluoroscopy is not readily available, such as the obstetrics delivery room, intensive care

unit, remote areas (such as military treatment facilities) or out-of-hospital REBOA, catheters with medium to high stiffness are, therefore, a safer option. These include the ER-REBOA™, LeMaitre®, or Fogarty® with stylet. Obtaining plain radiographs directly before and after balloon inflation to confirm balloon position can be an alternative for fluoroscopic guidance. However, real-time fluoroscopic guidance is always preferred to monitor possible migration or over-inflation with consequent rupture of the balloon or aorta.

In environments with limited equipment resources or supporting staff that are not familiar with endovascular materials, the complete procedure kits from REBOA Medical AS (REBOA Balloon®) or Prytime Medical Devices (ER-REBOA™) are beneficial. When considering health care costs as limited resource barrier, the ER-REBOA™ (approximately 1950 euro) can be a barrier, especially in middle- to low-income countries. To explore the need for REBOA in such countries, we are currently preparing a study into non-compressible truncal hemorrhage in the Republic of South Africa (RSA), one of such countries with a high trauma caseload. Through an international collaborative program [12], we have already used REBOA in several trauma cases in the RSA over the last years.

Our results provide evidence that a standard guidewire only adds minimal extra stiffness to the catheter, so this should not be an argument to choose an over-the-wire device. Moreover, guidewire-free devices itself are generally stiffer than the over-the-wire catheters and are provided with a flexible atraumatic tip to prevent aortic punctures. With the advent of REBOA-specific devices that house features of wire stiffness within the catheter, it is no longer advisable to use over-the-wire catheters for REBOA in emergency situations, especially those in which real-time fluoroscopy is not available. When fluoroscopy is available, an over-the-wire device can be considered to aid and confirm correct positioning, especially in middle-aged and elderly patients in whom tortuosity of blood vessels is more prevalent. REBOA via brachial artery access should not be performed without guidewire and fluoroscopic guidance given the higher risk of misplacement of the catheter. Of the over-the-wire devices, the Q50® has several features that facilitate use and reduce the risk of malplacement or vessel damage (medium stiff, sufficient balloon diameter, flexible tip), especially when combined with the VacLok® syringe.

The tested catheters are small caliber catheters ranging from 6 to 10 Fr. Required introducer sheath size, however, varies from 6 to 22 Fr with the LeMaitre® 45 mm Aortic Occlusion Catheter and Edwards Fogarty® 62080822F Occlusion Catheter, or even insertion via surgical cut-down only (Boston Scientific Equalizer™ with 40 mm balloon). The difference in catheter diameter and required sheath size is due to a larger diameter of the balloon or balloon wrapping, or to an increased balloon diameter after inflation and

deflation of the devices. Devices compatible with a small introducer sheath are the ER-REBOA™ (7 Fr), Tokai Rescue Balloon™ (7 Fr), and REBOA Medical AS REBOA Balloon® 15 and 20 (6 Fr and 7 Fr, respectively). It is known that larger sheath sizes require either surgical repair of the access site after sheath removal or access site closure with a large-bore vascular closure device (VCD), while the smaller ones can be removed without surgical repair. Percutaneous access and access site closure might be elegant considering it reduces wound complications at the access site [13, 14]. Also, femoral access site complications, such as dissection, pseudo-aneurysm, embolism or limb ischemia are associated with the larger sheath sizes [15, 16]; whereas, Teeter et al. [17] describe no access-related complications in their series with 7-Fr introducer sheaths. Hence, in the era of new, small diameter REBOA-specific devices, it is no longer advisable to use a catheter larger than 7 Fr to perform this procedure in emergent situations, especially those in which vascular surgery consultation is not readily available. Furthermore, some large-bore VCDs such as the Perclose Proglide® and Prostar XL® (Abbott Vascular, Santa Clara, CA, USA) or the MANTA™ VCD (Teleflex Incorporated, Wayne, PA, USA) predominantly require either a preclose technique or pre-procedural depth measurement, thereby increasing time to vascular access, while early and quick vascular access and bleeding control is essential to improve outcome of the hemorrhagic trauma patient. The InClosure VCD (InSeal Medical, Caesarea, Israel) and PerQseal (Vivasure Medical, Galway Ireland) do not require any preparation before the main procedure. With the smaller sheath sizes, the femoral artery puncture site can be closed either with direct pressure or with an Angio-Seal™ (up to 8 Fr; Terumo, Tokyo, Japan) or EXOSEAL® or MYNXGRIP® (up to 7 Fr; Cordis, Santa Clara, CA, USA). These VCDs do not require any pre-procedural preparations. Khan et al. described an alternative route for vascular access [18]. In their case, the aorta was punctured directly to place an ER-REBOA™ during laparotomy of a patient in extremis from multicavity penetrating trauma. With this hybrid approach quick vascular access is achieved without making unnecessary additional wounds. Their technique was successful in achieving hemodynamic stability.

Another feature that has to be taken into account is the balloon diameter. Maximum balloon diameter of the devices varies from 15 mm (REBOA Balloon® 15) to 50 mm (Q50® Stent Graft Balloon Catheter). The diameter of the occlusion balloon must be sufficient for total aortic occlusion, considering a smaller diameter is required for zone III occlusion than for zone I occlusion. Since most catheters carry a compliant balloon, the larger balloon diameters are also suitable for smaller aortic diameters. The REBOA Balloon® from REBOA Medical AS is the only device with a non-compliant balloon. Since non-compliant balloons have

standard injection volumes, it may avoid over-inflation and subsequent rupture of the balloon or aortic wall. However, if the diameter of the aorta is smaller than the diameter of the non-compliant balloon, the balloon can create a tear in the aortic wall [19]. Furthermore, when the diameter of the aorta exceeds the diameter of the non-compliant balloon, no proper hemorrhage control will be established. The choice for a compliant or non-compliant balloon should be carefully considered based on the possible advantages and disadvantages and preference of the providing physician. Profound data on balloon material properties, such as compliance and the frictional properties of balloon surface, are missing and should be a topic of interest in the development of new, REBOA-specific devices.

All catheters have features that ease correct positioning. When fluoroscopy is available, radiopaque marker bands located at the balloon assist in positioning of the balloon. Especially, markers at the distal and proximal end of the balloon are helpful to visualize the proper inflation location. Catheters without markers located at the balloon but with a completely radiopaque catheter shaft are also helpful in positioning the balloon, assuming the balloon is near the distal end of the catheter. However, the exact occlusion zone cannot be confirmed unless balloon inflation occurs with a contrast medium. Consequently, inflation could occur in or overlapping the wrong aortic zone.

When fluoroscopy is not available, as in out-of-hospital REBOA or other resource-limited settings, devices with external length marks on the catheter shaft enable correct positioning of the balloon without imaging. Placement depths can be estimated before insertion of the catheter using anatomical landmarks such as the suprasternal notch, mid-sternum, xiphoid process or umbilicus [20, 21]. The ER-REBOA™ facilitates accurate positioning with a length mark every cm and the exact length indicated with numbers every 5 cm. The Tokai Rescue Balloon™, LeMaitre® Aortic Occlusion Catheters and Edwards Fogarty® Occlusions Catheters have length marks every 5 or 10 cm to assist positioning without fluoroscopy. The REBOA Balloon® has length marks at 30 and 55 cm to allow a standardized placement depth. It thereby might reduce procedure time. Standardized placement depth and the use of anatomical landmarks are based on average body measures from predominantly low-volume studies [20–24]. It may, however, lead to inadequate balloon positioning in an unknown number of patients. Therefore, future research should focus on further objectifying these population-based average body measures to help reduce the chance of improper balloon positioning in the field.

There are limitations in this study. The bending stiffness of the catheters is measured at room temperature and not at body temperature. Material properties may alter in higher temperatures; thus, bending stiffness might differ at body

temperature. However, room temperature lies within the temperature range indicated on the catheters. In vivo longitudinal or axial stiffness can also be important; whereas in our study, bending stiffness was measured perpendicularly. However, the axial force from the catheter on the inflated balloon is in most cases negligible compared to the friction force between balloon and the inner wall of the artery, because of the large aspect ratio of the catheter. Also, a number of AOB are missing from this overview due to various reasons. To avoid a disparate comparison due to missing information, we chose to exclude these AOB. In addition, some of the devices might not be available in all countries due to regulatory restrictions.

Conclusion

Although there is a wide variety of AOB available, in resource-limited settings, a medium-stiff to stiff device that can be placed without guidewire and fluoroscopy guidance is warranted. Catheters such as the ER-REBOA™, Fogarty®, and LeMaitre® are, therefore, advised. Of these devices, the ER-REBOA™ is the only catheter compatible with a small 7-Fr sheath and specifically designed for hemorrhage control in emergent settings and should, therefore, be preferred. Complete procedure kits for the REBOA Balloon® or ER-REBOA™ are beneficial, especially in environments with limited equipment resources. When fluoroscopy is available, an over-the-wire device should be considered to aid and confirm correct positioning. Of the over-the-wire devices, the Q50® has several features that facilitate use and reduce the risk of malplacement or vessel damage.

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Author contributions SMV, BLSBB, PJEMV, GAHK, TER and RH prepared the study set-up. SMV and PJEMV developed the test bench and collected the data. SMV, BLSBB and RH prepared the manuscript. SMV and PJEMV prepared the tables and figures. SMV, BLSBB, PJEMV, GAHK, TER and RH contributed to the final version of the paper.

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Data availability The data that support the findings of this study are available from the corresponding author, SMV, upon reasonable request.

Compliance with ethical standards


Conflict of interest Cook Medical, Bloomington, IN, USA; Boston Scientific, Marlborough, MA, USA; Prytime Medical Devices, Boerne, TX, USA; Edwards Lifesciences, Irvine, CA, USA; LeMaitre Vascular, Burlington, MA, USA; Merit Medical, South Jordan, UT, USA; REBOA Medical AS, Norway; Medtronic, Minneapolis, MN, USA; Tokai Medical Products, Aichi, Japan; Minimally Invasive Technologies, Moscow, Russia, provided the catheters used for this study. No other support was provided. S.M. Vrancken, B.L.S. Borger van der Burg, P.J.E.M. Vrancken, G.A. Kock and R. Hoencamp report no proprietary or commercial interest in any product mentioned or concept discussed in this article. Dr. Rasmussen is an inventor of REBOA and REBOA-like technology and is part of patents that have been declared and approved in several countries in this topic area. He has no relevant financial relationships to medical device industry in this topic area to disclose. The authors declare that there are no conflicts of interest that could inappropriately influence (bias) their work. We confirm that this submission has not been published elsewhere.

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