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Migration of Aortic Occlusion Balloons in an in vitro model of the human circulation

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ABSTRACT

Background: Aortic Occlusion Balloons (AOB) are used for hemorrhage control in hemodynamically unstable patients. Stability of an AOB is essential for reliable aortic occlusion. The primary aim of this study is to determine whether different types of AOB migrate after total, intermittent or partial occlusion in a porcine aorta positioned in an in vitro model.

Materials and methods: A porcine thoracic aortic section was positioned in a model of the human circulation. Primary and secondary migration was tested in Cook Coda™ 2–9.0-35-120-32 and 2-10-35-140-46, Cook Medical, USA; Rescue balloon™ Tokai RB-167080-E, Tokai Medical Products, Japan; Reliant™ AB46, Medtronic, USA; Russian prototype AOB; ER-REBOA™, Prytime Medical Devices, USA; LeMaitre™ 28 and 45 Aortic Occlusion Catheter, LeMaitre Vascular, USA. These AOB were tested in hypotensive, normotensive and hypertensive scenarios. Migration in total occlusion, intermittent occlusion and partial occlusion was recorded for all AOB.

Results: Limited primary migration occurred in all AOB after total occlusion. The Cook Coda™ 2–9.0-35-120-32 balloon showed maximal migration in 1 test cycle. No migration occurred during intermittent occlusion. Kinking occurs in various degrees but does not seem to prevent a successful occlusion of the aorta. No migration occurred during partial occlusion except in the Russian prototype AOB. In a partial occlusion scenario, distal perfusion occurred only with 5 ml remaining in all balloon types.

Conclusions: All AOB were successful in full aortic occlusion. Limited primary migration occurred in all AOB after total occlusion only the Cook Coda™ 2–9.0-35-120-32 balloon showed maximal migration once. No migration occurred during intermittent occlusion, during partial occlusion only the Russian prototype AOB migrated. Stiffness and size of the catheter are important factors in preventing migration and kinking.

Introduction

Controlling catastrophic bleeding is the major life saving skill in trauma and vascular surgery. Endovascular balloon occlusion of the aorta is a technique in which a compliant balloon is advanced into the aorta and then inflated, thereby obstructing blood flow into the distal circulation. [1] The principles of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) have been used as part of the endovascular and hybrid trauma and bleeding management (EVTM) concept in ruptured aneurysm patients and in patients with truncal and junctional injuries involving massive haemorrhage. [2,3] The REBOA concept has been used in the hospital setting, combat environments and even in the earliest phases of prehospital care [2,4,5]. Since the REBOA concept is a temporary procedure by definition, and serves as a bridge to definitive repair, transfer to a suitable treatment location is inherent. Stable balloon position in the desired zone is essential during resuscitation and transport. Currently, there is no evidence about properties of different types of Aortic Occlusion Balloons (AOB). It is not known if an AOB migrates during resuscitation (hypotensive), or if a patient becomes normotensive or even hypertensive and which factors contribute to the stability of the AOB. The primary aim of this

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study is to determine migration of different types of AOB after total, intermittent or partial occlusion in a porcine aorta positioned in an in vitro flow model and which factors, such as for instance catheter or balloon size or catheter stiffness, contribute to the stability of the AOB.

Methods

This study was conducted under a protocol reviewed and approved by the Dutch Ministry of Defense (MoD) and both the Institutional Review Board and Medical Ethical Committee of Alrijne Hospital, the Netherlands (NWMO 17-15, 17.409rt.tk).

Flow model

A male porcine thoracic aorta section of 30 cm section (20–23 mm outer diameter) was prepared on a side bench and intercostal arteries were ligated using 3-0 Prolene™ sutures (Ethicon, Somerville, NJ, USA). The aortic section was positioned in a validated model [6,7] functioning as an in vitro model of the human circulation (Fig. 1). Invasive continuous blood pressure measurements (Philips IntelliVue X2, Philips, Amsterdam, The Netherlands) were performed proximally and distally of the AOB. A 14 French sheath (Sentrant, Medtronic, Minneapolis, Minnesota, USA) was used as an introducer sheath.

Aortic Occlusion Balloon

In total eight different AOB were tested from 6 different manufacturers; Cook Coda™ 2–9.0-35-120-32 and Cook Coda™ 2-10-35-140-46 from Cook Medical, Bloomington, Indiana, USA; Rescue balloon™ Tokai RB-167080-E from Tokai Medical Products, Kasugai, Japan; Reliant™ AB46 from Medtronic, Minneapolis, Minnesota, USA; Russian prototype AOB; ER-REBOA™ from Prytime Medical Devices, Boerne, Texas, USA; LeMaitre™ 28 Aortic Occlusion Catheter and LeMaitre™ 45 Aortic Occlusion Catheter from LeMaitre Vascular, Burlington, Massachusetts, USA. (Table 1). The following specification are described: maximum balloon diameter, maximum balloon volume, length of the balloon, minimum sheath size needed for introduction of the AOB.

Volume of Aortic Occlusion Balloon required for total occlusion

In order to determine the volume for total occlusion of the porcine aorta per AOB, the pressure in the model was first set to 70–80 mmHg and the AOB was then positioned in the mid section of the porcine aorta via the 14Fr introducer sheath. Subsequently, the AOB was inflated with tap water until the aorta was fully occluded. This was indicated by a pressure of 0 mmHg measured distally from the AOB. This procedure was performed for all types of AOB and correlated with the instructions for use (Table 2).

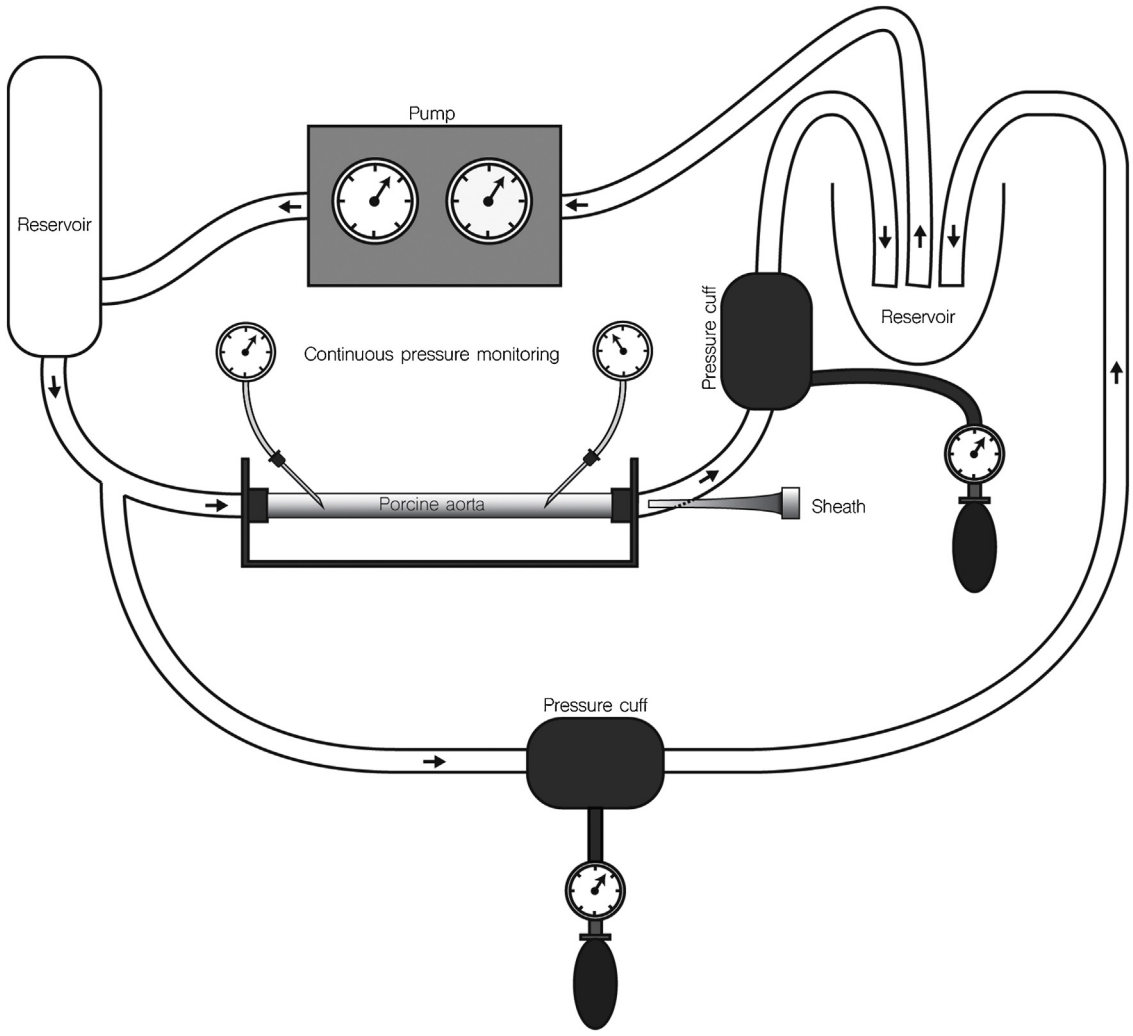

Fig. 1. In vitro model of the human circulation.

Table 1
Types of AOB used in the experiment.

Aorta Occlusion Balloon	max diameter (mm)	max volume (ml)	max length (mm)	sheath size (Fr)
Cook Coda™ 2-9.0-35-120-32	32	30	37	9
Cook Coda™ 2-10-35-140-46	46	60	38	10
Rescue balloon™ Tokai RB-167080-E	40	40	30	7
Reliant™ AB46	46	60	*	12
Russian balloon Catheter	40	50	*	6
ER Reboa™ Prytime	32	24	37	7
LeMaitre™ 28 Aortic Occlusion Catheter	28	15	*	8
LeMaitre™ 45 Aortic Occlusion Catheter	45	50	*	8

*not available; mm: millimeter, ml: milliliter, Fr: French size.

Table 2
Volumes used per type of AOB for total occlusion.

Aorta Occlusion Balloon	max volume Instructions for use (IFU) (ml)	IFU volume at 20-30 mm aorta diameter (ml)	volume used in test (ml)
Cook Coda™ 2-9.0-35-120-32	30	13-26	15
Cook Coda™ 2-10-35-140-46	60	16-25	20
Rescue balloon™ Tokai RB-167080-E	40	12-16	15
Reliant™ AB46	60	9-19	15
Russian balloon Catheter	50	*	20
ER Reboa™ Prytime	32	8-20	15
LeMaitre™ 28 Aortic Occlusion Catheter	15	*	15
LeMaitre™ 45 Aortic Occlusion Catheter	50	*	20

AOB: Aortic Occlusion Balloon; IFU: Instructions for use; ml: milliliter; *volume not available in IFU for range of 20–30 mm aorta diameter.

Measurement of migration

Total occlusion

The measurements consisted of three phases; 1. Hypotensive (70–80 mmHg), 2. Normotensive (100–120 mmHg) and 3. Hypertensive (160–180 mmHg).

Total occlusion was defined as the situation where the AOB was inflated and distal pressure was 0 mmHg. The hypotensive phase started with the positioning of a deflated balloon in the mid section of the porcine aorta and inflation of the AOB for total occlusion. After two minutes migration of the balloon was measured. The pressure was incrementally increased to a normotensive range (phase 2) and migration of the AOB was measured again during two minutes, subsequently the pressure was raised to a hypertensive range (phase 3) and migration was measured after two minutes. Migration was scored either as "primary migration", when the balloon migrated instantaneously in the hypotensive situation during insufflation, or as "secondary migration" when pressure increase resulted in pushing the AOB distally. Migration was scored in 5 mm increments either inside the porcine aorta and described as kinking or as migration outwards of the sheath, or as a combination of both (Fig. 2). This procedure was performed three times per AOB.

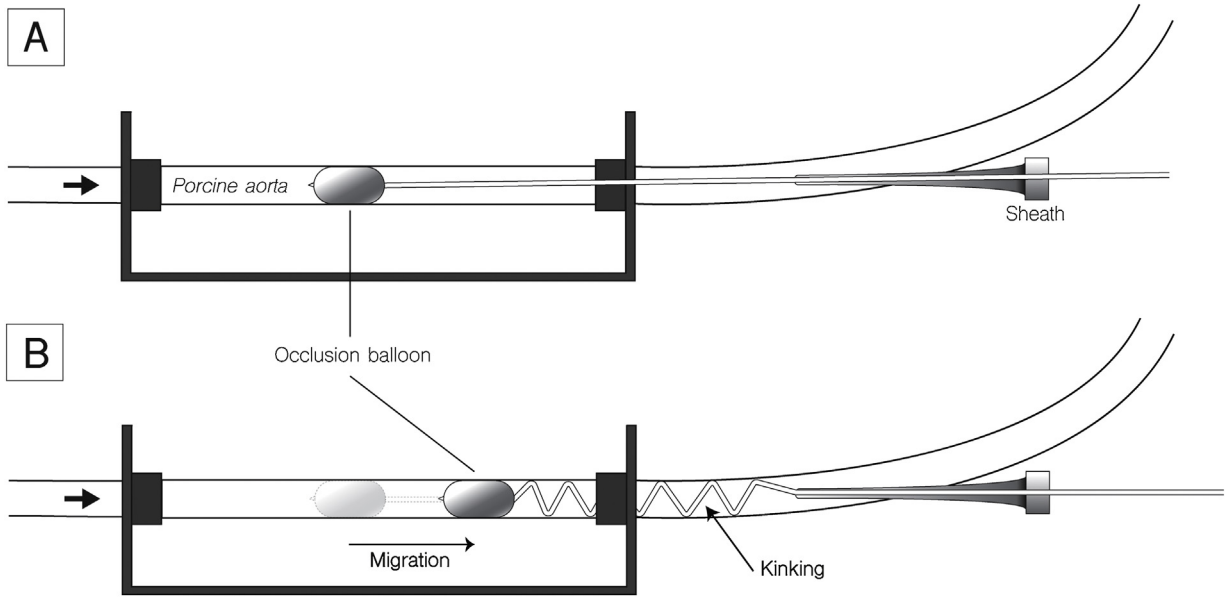

Fig. 2. Migration and kinking of Aortic Occlusion Balloon. A: total occlusion without migration, B: total occlusion with migration and kinking within the model.

Intermittent occlusion

After each test cycle, the balloon was fully deflated resulting in intermittent occlusion. Migration during intermittent occlusion was measured in between test cycles.

Partial occlusion

After the final test cycle, the pressure was set to 120 mmHg with an insufflated balloon in position. Distal pressure in this situation was 0 mmHg. The volume of the balloon was deflated in 5 ml steps. Changes in proximal and distal pressures where recorded for each balloon and migration was registered during this scenario.

Statistical analysis

Statistical analyses were performed in collaboration with a statistician, using the Statistical Package for the Social Sciences (SPSS®, Version 24, IBM Corporation, Armonk, New York). All baseline information of the subjects and subsequent follow up data were registered in an electronic data file (Microsoft Excel® and SPSS®).

Results

In the Cook Coda 2–9.0-35-120-32 balloon there was 0–5 mm primary migration and zero additional migration at 100–120 mmHg. In the hypertensive scenario there was maximal migration of 80 mm after 90 s in one of the three test cycles. This migration was classified as kinking (Fig. 2), with no outward migration registered at the sheath. In this kinked position of the balloon and catheter, we were unable to deflate the balloon. This was only possible after introduction of a stiff guidewire into the catheter. In the other two test cycles this phenomenon of extreme kinking and migration was not observed, although limited kinking and migration occurred. The Cook Coda™ 2-10-35-140-46 also showed kinking of the catheter, but this did not inhibit the deflation of the balloon. The catheters of the Cook Coda™ AOB were characterized by a low stiffness, which resulted in kinking of the catheter. The Reliant™, LeMaitre™ 28, LeMaitre™ 45 and ER-REBOA™ showed no additional migration after primary migration during insufflation. During the test with the Russian prototype AOB a 10–15 mm primary migration was recorded in the hypotensive scenario, 0–5 mm additional migration occurred in the normotensive scenario and an additional 5 mm migration in the hypertensive scenario. Total migration was 20 mm, with 10 mm outward migration at the sheath. There was 0 mm migration in all of the different AOB types during intermittent aortic occlusion (Table 3).

The migration and proximal and distal pressure changes during the partial occlusion are described in Table 4. After the first of 5 ml deflation no proximal or distal pressure changes were recorded and no migration occurred. The Cook Coda™ 2-10-35-140-46 and the LeMaitre™ 45 balloon showed proximal pressure changes with only 10 ml balloon volume, but no distal pressure changes were measured. In the final step, in which only 5 ml remained in the balloon, a drop in proximal pressure and a raise in distal pressure was noted in all AOB indicating restoration of distal perfusion. No migration occurred except in the Russian prototype AOB. Russian prototype AOB showed 10 mm outward migration at the sheath with 5 ml balloon volume and 120 mmHg proximal pressures.

Discussion

Limited primary migration was recorded in all AOB after total occlusion in hypotensive, normotensive and hypertensive pressure scenarios. No migration occurred during intermittent occlusion or during partial occlusion except in the Russian prototype AOB. However, the observed migration was not hemodynamically relevant. The catheters of the Cook Coda™ AOB were characterized by a low stiffness, which resulted in kinking of the catheter. The Cook Coda™ 2–9.0-35-120-32 balloon showed one maximal migration out of three test cycles during the hypertensive scenario. Since we wanted to include the full range of pressure scenarios in this in vitro study we included the hypertensive scenario. It is not likely that, with proper indication for REBOA, such a hypertensive scenario would easily occur in reality. Interestingly, kinking of the catheter did not lead to a migration of the catheter at the level of the sheath and consequently a proper position is unsure if no fluoroscopic or alternative modality for checking the AOB position is used during insufflation. Anzai et al. [8] describes migration of a prototype AOB in a canine model, this AOB was able to resist a pressure of about three times that of normal blood pressure. The Russian prototype AOB showed primary migration during inflation and outward migration at the level of the sheath during the three pressure scenarios. In the partial AOB scenario, the Russian prototype AOB showed outward migration. The Russian prototype AOB has the smallest diameter and can be introduced through a 6Fr introducer sheath. It has the highest stiffness of all catheters tested. The smaller catheter diameter causes an increase in inflation time. During this inflation time, the balloon is more susceptible to primary migration due to a windsack phenomenon. Due to its stiffness the catheter did not show kinking, but migrated outward at the level of the sheath. Since this can be noted, the AOB can be repositioned to the required zone. There was no relevant migration during intermittent AOB. In the partial AOB scenario, there was a distal pressure increase with a minimal balloon volume of 5 ml in all balloons tested. It seems that with minimal balloon volumes, total occlusion of the aorta is still present and no distal perfusion occurs. Although this was beyond the scope of this study, it is an interesting finding and it confirms our skepticism towards the

Table 3
Migration in hypo-, normo- and hypertensive scenarios for total ABO and intermittent ABO.

Aorta Occlusion Balloon Migration (mm)	Total ABO 70-80 mmHg	Mean / SD	Total ABO 100-120 mmHg	Mean / SD	Total ABO 160-170 mmHg	Mean / SD	Intermittent ABO 120 mmHg	Mean / SD
Cook Coda™ 2-9.0-35-120-32	0-5	2.5/0.0	0	0.0/0.0	0-80	20.0/40.0	0	0.0/0.0
Cook Coda™ 2-10-35-140-46	5-10	7.5/0.0	0	0.0/0.0	0-15	5.0/8.7	0	0.0/0.0
Rescue balloon™ Tokai RB-167080-E	0-5	2.5/0.0	0	0.0/0.0	0	0.0/0.0	0	0.0/0.0
Reliant™ AB46	0-5	2.5/0.0	0	0.0/0.0	0	0.0/0.0	0	0.0/0.0
Russian balloon Catheter	10-15	12.5/0.0	10-15	14.2/2.9	20	20.0/0.0	0	0.0/0.0
ER Reboa™ Prytime	0-5	2.5/0.0	0	0.0/0.0	0	0.0/0.0	0	0.0/0.0
LeMaitre™ 28 Aortic Occlusion Catheter	0-5	2.5/0.0	0	0.0/0.0	0	0.0/0.0	0	0.0/0.0
LeMaitre™ 45 Aortic Occlusion Catheter	0-5	2.5/0.0	0	0.0/0.0	0	0.0/0.0	0	0.0/0.0

mmHg: millimeters of mercury; mm: millimeter; AOB: Aortic Occlusion Balloon; ABO: Aortic Balloon Occlusion; SD: standard deviation.

Table 4
Balloon volume, proximal and distal pressures and migration in partial aortic occlusion in a normotensive scenario (120 mmHg).

Aorta Occlusion Balloon	Remaining Balloon volume (ml)	RR prox-distal (mmHg)	Migration (mm)	Remaining Balloon volume (ml)	RR prox-distal (mmHg)	Migration (mm)	Remaining Balloon volume (ml)	RR prox-distal (mmHg)	Migration (mm)
Cook Coda™ 2-9.0-35-120-32	10	120-0	0	5	80-30	0	n/a	n/a	n/a
Cook Coda™ 2-10-35-140-46	15	120-0	0	10	116-0	0	5	90-30	0
Rescue balloon™ Tokai RB-167080-E	10	120-0	0	5	60-50	0	n/a	n/a	n/a
Reliant™ AB46	10	120-0	0	5	80-30	0	n/a	n/a	n/a
Russian balloon Catheter	15	120-0	0	10	120-0	0	5	90-45	10
ER Reboa™ Prytime	10	120-0	0	5	80-55	0	n/a	n/a	n/a
LeMaitre™ 28 Aortic Occlusion Catheter	10	120-0	0	5	95-15	0	n/a	n/a	n/a
LeMaitre™ 45 Aortic Occlusion Catheter	15	120-0	0	10	115-0	0	5	90-30	0

ml: millliter; RR prox/distal:pressure proximal/distal of AOB; mm: millimeter; n/a: not applicable.

partial balloon occlusion concept. [9,10] In cases of prolonged transportation times of the patient and the necessity for distal perfusion of the organs and limbs, it is only with very small balloon volumes that this desired distal perfusion can occur. In a clinical situation it will be very difficult to titrate the required balloon volume for achieving partial balloon occlusion and intermittent occlusion might therefore be an alternative. Obviously, this is only recommended when intermittent balloon occlusion is hemodynamically tolerated by the patient, as the initial goal of an AOB is to stop the bleeding.

There are several limitations in this in vitro study. The use of a porcine flow model does not fully represent reality. The diameter of the porcine thoracic aorta can be smaller than in humans. On the other hand, this model provided standardization. Ideally migration of AOB is tested in a human (cadaver) flow model. Furthermore, the test cycle we used was 6 min long. Since only limited migration occurred during the initial phase of the test cycles we did not prolong the test period. A longer test period might alter our findings.

Conclusion

Limited primary migration occurred in all the tested types of AOB after total occlusion. The Cook Coda™ 2–9.0-35-120-32 balloon showed one maximal migration out of three test cycles during the hypertensive scenario, but this was not repeated. No migration occurred during intermittent occlusion or during partial occlusion except in the Russian prototype AOB. Stiffness and catheter size seem to be important factors in preventing migration. Kinking occurs in various degrees but does not seem to prevent a successful occlusion of the aorta. Balloons on catheters with smaller diameters are harder to inflate, increasing the windsack phenomenon with increased primary migration. Partial occlusion of the aorta only occurs in very minimal balloon volumes and is therefore hard to titrate. Total occlusion or intermittent occlusion were not associated with migration and are advised. Based on our study results, future research used focus on in vivo or cadaver flow models.

Disclaimer

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense, Dutch or United States government. Several authors are employees of the Dutch or United States government.

Contribution of the authors

B.L.S. Borger van der Burg and R. Hoencamp prepared the study set-up. B.L.S. Borger van der Burg, R. Hoencamp, C.Y. Wong and J.J.W.M. Brouwers performed the study and collected the data. B.L.S. Borger van der Burg, C.Y. Wong and J.J.W.M. Brouwers, and R. Hoencamp prepared the manuscript, B.L.S. Borger van der Burg and C.Y. Wong prepared the tables and figures. B.L.S. Borger van der Burg, C.Y. Wong and J.J.W.M. Brouwers, J. Van Schaik, T.E. Rasmussen, J.F. Hamming and R. Hoencamp contributed to the final version of the paper.

Disclosure

Cook Medical, Bloomington, Indiana, USA; Tokai Medical Products, Kasugai, Japan; Medtronic, Minneapolis, Minnesota, USA; Russian prototype AOB; Prytime Medical Devices, Boerne, Texas USA; LeMaitre Vascular, Burlington, Massachusetts, USA provided the catheters used for this study. Medtronic, Minneapolis, Minnesota, USA provided the introducer sheaths. No other support was provided.

Conflict of interest statement

Cook Medical, Bloomington, Indiana, USA; Tokai Medical Products, Kasugai, Japan; Medtronic, Minneapolis, Minnesota, USA; Russian prototype AOB; Prytime Medical Devices, Boerne, Texas USA; LeMaitre Vascular, Burlington, Massachusetts, USA provided the catheters used for this study. Medtronic, Minneapolis, Minnesota, USA provided the introducer sheaths. No other support was provided. B.L.S. Borger van der Burg, J. Van Schaik, J.J.W.M. Brouwers, C.Y. Wong, T.E. Rasmussen, J.F. Hamming and R. Hoencamp report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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