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Anchoring Barbs and Balloon Expandable Stents: What is the Risk of Perforation and Failed Stent Deployment?

M.J. Bown [a], G.J. Harrison [b,*], T.V. How [c], J.A. Brennan [b], R.K. Fisher [b], S.R. Vallabhaneni [b], R.G. McWilliams [d]

[a] Department of Cardiovascular Sciences, University of Leicester, UK
[b] Department of Vascular Surgery, Royal Liverpool University Hospital, Prescot Street, Liverpool L7 8XP, UK
[c] Institute of Ageing and Chronic Disease, University of Liverpool, UK
[d] Department of Radiology, Royal Liverpool University Hospital, UK

WHAT THIS PAPER ADDS

- This study describes a possible modality of technical failure during advanced endovascular techniques. This complication has not been reported elsewhere, but happened once in our unit and we are aware of other reports. Failed stent deployment could result in target vessel loss manifesting as renal failure and mesenteric ischaemia. A safe, simple technique of utilisation of covered stents is shown to prevent this disasterous complication.

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ABSTRACT

Purpose: Balloon expandable stents may on occasion be deployed in close proximity to the anchoring barbs of endovascular grafts. The aim of this study was to determine the risk and effect of balloon perforation by anchoring barbs and to assess whether these risks are different if the balloon is protected by a covered stent mounted upon it.
Methods: A bench-top model was developed to mimic the penetration of anchoring barbs into the lumen of medium sized blood vessels. The model allowed variation of angle and depth of vessel penetration. Both bare balloons and those with covered stents mounted upon them were tested in the model to determine whether there was a risk of perforation and which factors increased or decreased this risk.
Results: All combinations of barb angle and depth caused balloon perforation but this was most marked when the barb was placed perpendicular to the long axis of the balloon. When the deployment of covered stents was attempted balloon perforation occurred in some cases but full stent deployment was achieved in all cases where the perforation was in the portion of the balloon covered by the stent. The only situation in which stent deployment failed was where the barb was intentionally placed in the uncovered portion of the balloon. This resulted in only partial deployment of the stent.
Conclusions: Balloon rupture is a distinct possibility when deploying balloon-expandable stents in close proximity to anchoring barbs. Care should be taken in this circumstance to ensure that the barb is well away from the uncovered portion of the balloon.

Introduction

Anchoring barbs attached to a supra-renal stent are used for fixation of many infrarenal aortic stent-grafts such as the Zenith (Cook Ireland Ltd. Limerick, Ireland) and Endurant (Medtronic, Galway, Ireland) abdominal endografts. The barbs are intended to engage the aortic wall and prevent migration. The barbs are arranged around the circumference of the bare metal anchor stent of the Zenith abdominal endograft. If one of the barbs opens at the ostium of an aortic sidebranch then the tip of this may not engage the aortic wall but lie in the lumen of the vessel (Figs. 1 and 2). There is thus the potential for luminal barbs to complicate the use of balloon expandable stents in such aortic side branches.

* Corresponding author. Tel.: +44 0151 7063447; fax: +44 0151 7065638.
E-mail address: garethjamesharrison@yahoo.co.uk (G.J. Harrison).

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There are several reasons why balloon expandable stents may be used in the vicinity of anchoring barbs. Firstly, they may be used during stent-graft deployment as an adjunctive procedure for visceral artery stenosis, or if visceral artery dissection has occurred as a complication of the procedure. Late deployment of stents through the anchor stent may be required because of stenotic disease in visceral arteries. The use of "chimney grafts",[1,2] requires that branch stents are placed alongside the anchoring stent and its accompanying barbs. A final situation is the use of fenestrated grafts or extension cuffs as management of proximal migration or gross neck dilatation.[3,4] Graft deployment will again potentially result in balloon expandable stents being inflated adjacent to anchoring barbs (Fig. 2).

Depending on the indication, either uncovered or covered visceral artery stents may be used in these situations. Perforation of the delivery balloon during attempted deployment may render the stent undeployable at a point of partial expansion. We are aware of anecdotal reports of balloon rupture during the deployment of branch vessel stents associated with the use of fenestrated proximal extensions and chimney grafts. This has also occurred once in our unit. The aim of this study was to determine the risk and effect of balloon perforation by anchoring barbs and to assess whether these risks are different if the balloon is protected by a covered stent mounted upon it.

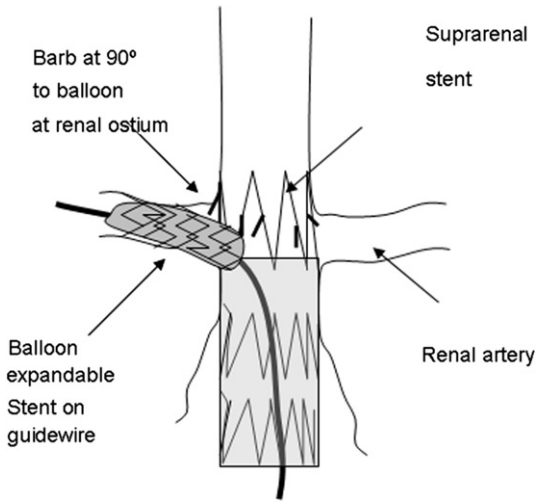

Figure 2. Anterior view of the supra-renal stent with barbs at 90° to a balloon expandable stent within the right renal artery.

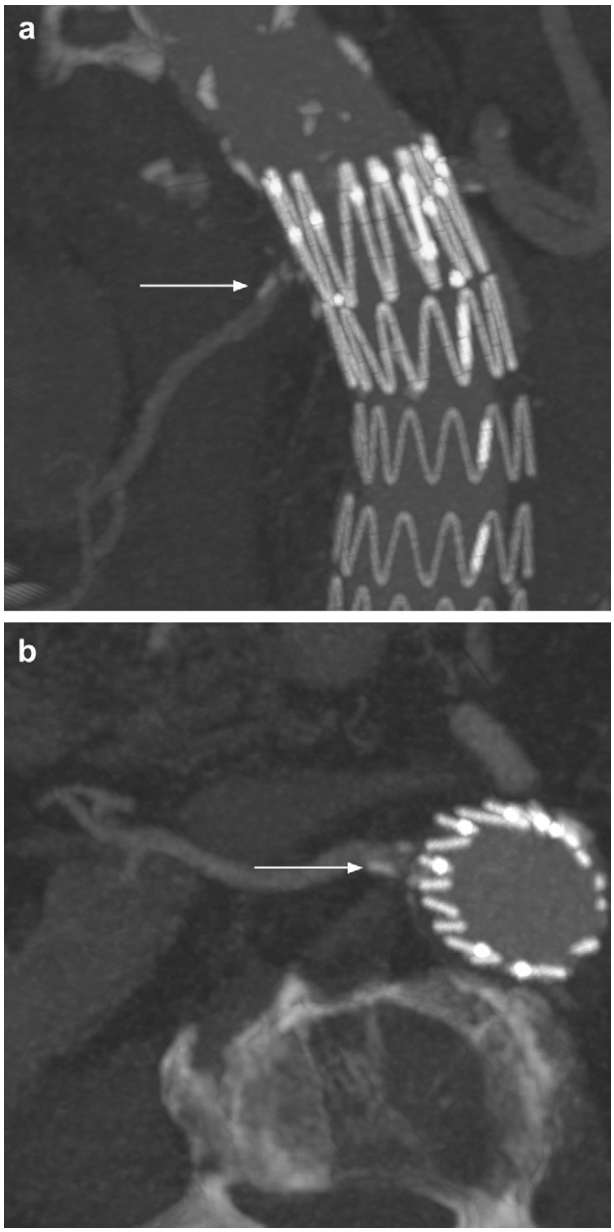

Figure 1. a) Coronal and b) axial computed tomography images of a Cook Zenith endograft showing the solder attaching the barbs to the top bare stent (arrow) in close proximity to the right renal artery. Image courtesy of Morten Vetrhus, Stavanger, Norway.

Methods

An experimental jig was developed to mimic anchoring barbs penetrating the lumen of a medium sized artery at varying luminal depths and angulation (relative to the long axis of the vessel) (Fig. 3). The artificial vessel was manufactured in-house from a soft silicone rubber (Dragon Skin™, Smooth-On, Bentley Chemicals Ltd, Kidderminster, UK) cast over a loose-weave cotton fabric tube with a luminal diameter of 7 mm and a vessel wall thickness of 1 mm. This was mounted on two open-ended tube connectors (internal diameter 4.8 mm and external diameter of 7 mm) that enabled access to the lumen. Unused barbs were harvested from Cook Zenith endovascular grafts and mounted in a clamp that could be moved axially and radially through the use of vernier screw gauges. A rotary stage with micrometer movement allowed the angle of the barb to be accurately positioned with respect to the vessel axis (Fig. 4). The tip of the barb was located through the vessel wall and referenced to a steel rod of diameter 4.7 mm which was placed concentrically through the connectors and the artificial vessel. Following the removal of the steel rod this was replaced with

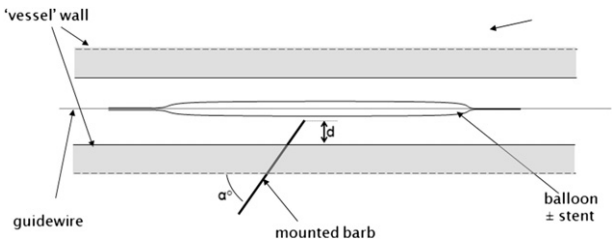

Figure 3. Diagram demonstrating the laboratory model used to test the balloons for potential perforation.

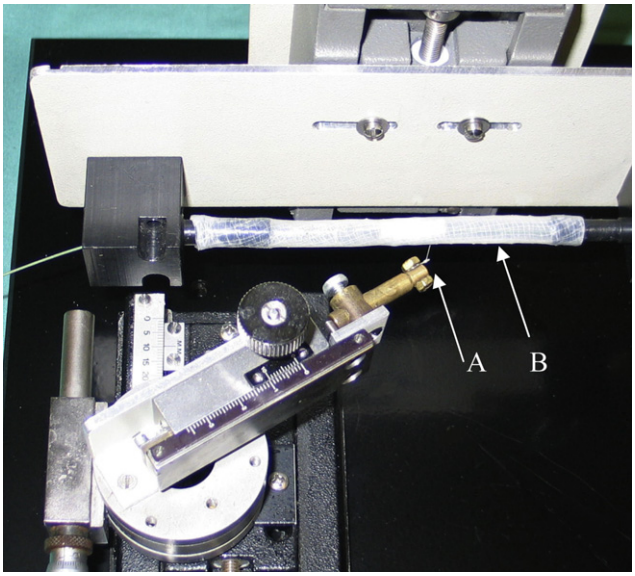

Figure 4. Photograph showing the experimental jig used in the experiment. The mounted barb ("A") can be seen just perforating the mock artery ("B").

Figure 5. Ex-vivo photograph of an Atrium Avanta V12 stent after inflation of the deployment balloon.

a 0.035 guidewire after first withdrawing the barb. The tip of the barb was then advanced through into the vessel so that it was 1 mm or 3 mm from the internal wall. The balloon or balloon with mounted stent was then passed over the guidewire and positioned relative to the barb position, usually with the barb at the central point of the balloon. Balloons were inflated with a pressure inflator (Excel Medical Products Fenton, MI, USA) using half-strength contrast medium (Iomeron 250, Bracco, High Wycombe, UK) warmed to room temperature. A removable expanded polystyrene back-support was incorporated into the model to allow testing of balloons with or without any resistance of the vessel to lateral movement. For every successive experimental test a fresh barb was used. At the end of each test the barbs were withdrawn from the model prior to removing the balloon from the model.

An initial experiment was designed to determine which combinations of variables resulted in perforation of balloons used alone (depth of vessel penetration, angle of barb, use of the back support). Each combination of variables was tested with 3 Atrium balloons from the Advanta V12 stent system (Atrium Europe, Mijdrecht, The Netherlands). The balloons are made from polyethylene terephthalate, specifically designed for stent delivery. For each test inflation the following data was recorded: visible balloon perforation within the model, visible leakage of contrast medium within the model, whether a pressure of 8 atm (Atm) was achieved within the model and the time 8 Atm was held for (up to 60 s), whether a pressure of 8 Atm was achieved after the balloon was removed from the model or the maximum pressure achieved after the balloon was removed from the model.

After determining a depth and angle of penetration that reliably caused balloon perforation a second experiment was performed to determine whether balloons with covered stents mounted upon them (Atrium Advanta V12 7 mm $\times$ 22 mm, Fig. 5) could be inflated and the stent safely deployed despite the high risk of perforation.

Results

At least three separate balloons were tested at each combination of the following variables: depths of 1 mm and 3 mm luminal penetration, angles of 90° and 45°, and with, and without a back support. Individual results for each group of variables are shown in Table 1. This demonstrates that perforation of balloons occurred at all combinations of variables. Only an angle of 90° with a back support to the vessel caused every balloon to perforate. Overall, balloon perforation occurred in 14 of 25 balloons. When reinflated with contrast medium outside the model, 11 of these fourteen balloons showed leakage as a single jet implying a simple circular perforation. In three cases there were jets in multiple angles implying that the material had probably split. Nine of the 14 balloons that perforated did not reach their rated inflation pressure for stent deployment within the model.

Since perforation was seen in all cases where the barb was perpendicular to the long axis of the balloons with the back support of the model in place (irrespective of the depth of vessel penetration) this barb position was chosen to test whether covered stents mounted on balloons could still be deployed despite the high risk of perforation. In all cases where the barb was positioned at the mid-point of the stent, successful stent deployment was achieved (Table 2). This was despite perforation during stent deployment of 3 of the 3 balloons tested at a barb penetration depth of 1 mm and 1 of the 3 balloons tested at a barb penetration depth of 3 mm. In all of these experimental stent deployments complete deployment of the stents was confirmed by measurement of the external diameter of the stent within the vessel. Further experiments were performed to determine whether the position of the barb in relation to the longitudinal position of the stent and balloon affected stent deployment (all previous deployments performed with the barb at the mid-point of the stent). In one case the barb was positioned at one end of the balloon, at a depth of 1 mm but still within the limits of the stent. In this case, perforation of the balloon occurred, but only following successful stent deployment. Following this the barb was positioned at one end of the balloon but outside of the portion covered by the stent (Fig. 5). In this case the balloon was perforated at an early stage of inflation which precluded further balloon inflation and resulted in only partial stent deployment. This was the only situation where incomplete stent deployment occurred. To test the possibility that a perforated balloon within a deployed stent may impinge on the exposed barb causing the perforation and preclude removal of the balloon a stent was deployed in the model prior to positioning the barb. Following deployment of the stent, and with the balloon still inflated the barb was advanced 3 mm into the lumen of the vessel causing the balloon to rupture. The balloon

Table 1
Results of testing bare balloons.

Angle of barb (°)	Depth (mm)	Back support used	Pressure achieved in model (Atm)	Time held (s) (without continuous inflation)	Visible perforation	Visible leakage	8 Atm achieved in model	8 Atm achieved outside model	Maximum pressure outside model (Atm)	*n* balloons in group	*n* perforated
90	1	No	8	60	No	No	Yes	Yes	8		
90	1	No	8	0	Yes	Yes	Yes	No	6	3	1
90	1	No	8	60	No	No	Yes	Yes	8		
90	1	Yes	8	0	Yes	Yes	Yes	No	3		
90	1	Yes	8	0	Yes	Yes	No	No	6	3	3
90	1	Yes	8	0	Yes	Yes	Yes	No	6		
90	3	No	8	60	No	No	Yes	Yes	12		
90	3	No	8	60	No	No	Yes	Yes	12	4	2
90	3	No	4	0	Yes	Yes	No	No	4		
90	3	No	8	60	Yes	Yes	Yes	Yes	12		
90	3	Yes	4	0	Yes	Yes	No	No	6		
90	3	Yes	4	0	Yes	Yes	No	No	6	3	3
90	3	Yes	4	0	Yes	Yes	No	No	4		
45	1	No	8	0	Yes	Yes	Yes	Yes	8		
45	1	No	8	60	No	No	Yes	Yes	12	3	1
45	1	No	8	60	No	No	Yes	Yes	12		
45	1	Yes	6	0	Yes	Yes	No	No	4		
45	1	Yes	8	60	No	No	Yes	Yes	12	3	1
45	1	Yes	8	60	No	No	Yes	Yes	12		
45	3	No	8	60	No	No	Yes	Yes	12		
45	3	No	8	60	No	No	Yes	Yes	12	3	1
45	3	No	6	0	Yes	Yes	No	No	6		
45	3	Yes	8	60	No	No	Yes	Yes	12		
45	3	Yes	4	0	Yes	Yes	No	No	3	3	2
45	3	Yes	7	0	Yes	Yes	No	Yes	10		

was then withdrawn manually which demonstrated that this was possible although the balloon was destroyed in the process.

Discussion

Early and late interventions after the primary deployment of abdominal and thoracic endografts may result in the need to deploy balloon expandable stents adjacent to anchoring barbs. Depending on the indication, either uncovered or covered balloon expandable stents may be used. For example, uncovered stents would normally be considered for atherosclerotic visceral artery stenosis requiring treatment at some point after deployment of a Zenith abdominal endograft. Covered stents are likely to be considered in conjunction with fenestrated cuffs and chimney grafts.[1–4] We are aware of anecdotal reports of balloon rupture during the deployment of branch vessel stents, including once in our unit. We acknowledge that balloon perforation by anchoring barbs is therefore an important but infrequent clinical scenario.

Our in vitro experiment has further confirmed the possibility and importance of balloon perforation. Not all balloons were perforated even when the barb protruded 3 mm into the vessel and we observed that on some occasions the barb was pushed aside by the inflating balloon without perforation. The angle at which the barb interacts with the long axis of the balloon influences the likelihood of perforation which is more likely at 90 than 45 degrees. It is unlikely that the pre-operative imaging will be good enough to allow the operator to accurately assess the exact position of the barb. The position of the barbs of the Zenith anchor stent at CT is inferred from the more visible solder which attaches these to the struts of the bare metal stent (Fig. 1).

The experimental model may not simulate the in vivo situation where the barb is situated in the lumen of the ostium of the renal

Table 2
Results of testing covered stents mounted on balloons in model.

Angle of barb (°)	Depth (mm)	Pressure achieved in model (Atm)	Time held (s) (without continuous inflation)	Visible perforation	Visible leakage	8 atm achieved in model	8 atm achieved outside model	Maximum pressure outside model (Atm)	Stent successfully deployed	*n* balloons in group	*n* perforated
90	1	8	0	Yes	Yes	Yes	No	4	Yes		
90	1	10	0	Yes	Yes	Yes	No	6	Yes	3	3
90	1	10	0	Yes	Yes	Yes	No	6	Yes		
90	3	12	60	No	No	Yes	Yes	12	Yes		
90	3	12	60	No	No	Yes	Yes	12	Yes	3	1
90	3	8	0	Yes	Yes	Yes	No	3	Yes		

artery or other aortic branch (Fig. 2). As the barb is unsupported by a vessel wall in vivo it may be more likely to be deflected sideways by the balloon without perforation. The experimental model with a back support preventing displacement of the 'artery' may not mimic the in vivo situation where some displacement may be expected. However, it should be noted that balloon perforation occurred in 5 of 13 tests without the back support. Another potential explanation why balloon perforation has not previously been reported is that covered stents are commonly used in chimney endografts.[2,5]

For reasons of cost, we used standard balloons to mimic the use of uncovered balloon expandable stents. It is a weakness of the study design that we have not assessed the protection that the struts of the bare stent may afford the balloon as it is inflated. We would expect that the limited surface area of the balloon that is covered by metal struts would not significantly change the results. Also, the presence of a bare stent which is external to the balloon should not alter the flexibility of the balloon material and consequently the resistance to balloon perforation should not be affected.

Only the Atrium Advanta V12 covered stent was used in these experiments and we cannot extrapolate our results to other covered stents. These results can neither be extrapolated to the Endurant graft (Medtronic, Minneapolis, USA) which has shorter and thicker barbs made of Nitinol. It may be that these thicker barbs do not displace and could be more likely to cause balloon rupture.

We were encouraged that all the covered stents could be inflated to their nominal inflation pressures despite perforation where that perforation was in the section of balloon covered by the fabric of the covered stent. It is important to state that when the uncovered balloon was perforated at the tail of this system then attempted stent deployment was unsuccessful. It should be noted that despite perforation most of the bare balloons could be inflated to the nominal pressure in the experimental model but this was not always the case.

In conclusion, we recommend that operators consider the possibility of balloon rupture when deploying balloon expandable stents adjacent to the barbs of Zenith stent grafts. If there are barbs at the level of intended balloon inflation then, based on our experimental data, we recommend the use of an Atrium covered stent. We also recommend that the stent is positioned so that the uncovered balloon tails of this Atrium stent are not adjacent to the level of a barb.

Conflict of Interest

None.

Funding Source

Balloon expandable stents and balloons were supplied by Atrium Europe, Mijdrecht, The Netherlands. No other external funding was received.

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