Fenestration of Aortic Stent Grafts—In Vitro Tests Using Various Device Combinations

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ABSTRACT

Purpose: To evaluate the response of various stent grafts after needle fenestration and sequential dilation with standard percutaneous transluminal angioplasty (PTA) and cutting balloons and sealing of the fenestration with a side branch stent graft.

Materials and Methods: Five commercially available aortic stent grafts (Endurant, Gore TAG, Talent, Valiant, and Zenith) were fenestrated with a needle. The fenestrations were sequentially dilated up to 10 mm with PTA balloons or cutting balloons. The residual diameter stenosis and visual appearance of the fenestration was estimated after each dilation. The joint between the main prosthesis and a side branch stent graft, placed through the fenestration, was visually assessed.

Results: Stent grafts responded variably after fenestration and balloon dilation; the holes were round or oval with smooth, fringed, frayed, or torn edges. Talent and Valiant fabrics were easiest to dilate, whereas Zenith was the most resilient. Dilation with a cutting balloon led to fully open fenestrations in all stent grafts. Good apposition of the side branch stent graft to the main prosthesis was achieved unless fenestration was located in close proximity to a stent strut.

Conclusions: The balloon-based technique, especially the cutting balloon, fully opened the fenestrations up to 10 mm, and the fenestrations could be successfully covered with side branch stent grafts. Various graft fabrics responded variably to balloon dilation, however, which may have significant impact on the clinical in situ fenestration of individual aortic stent grafts.

ABBREVIATIONS

EVAR = endovascular aortic repair, PTA = percutaneous transluminal angioplasty

Endovascular aortic repair (EVAR) is evolving at a rapid pace. The technique was first introduced by Parodi et al (1) and Volodos et al (2) in the early 1990s and has since expanded and is used in the treatment of a wide variety of aortic pathology, including aortic aneurysms, dissections, and traumatic ruptures. The technique is feasible for the repair of the thoracic and abdominal aorta. EVAR offers an alternative to surgical therapy; it is a minimally invasive technique that seems to be better tolerated (3,4).

Endovascular aortic repair has some limitations. Major side branches of the aorta (brachiocephalic trunk, carotid arteries, celiac trunk, superior mesenteric artery, renal arteries) cannot be covered without serious consequences. If covering side branches is anticipated, preoperative revascularization is usually necessary to prevent significant complications. A short proximal neck (ie, the distance between the proximal end of the fabric and aneurysm is $\leq$1.5 cm) is associated with a higher risk of complications and the eventual failure of the therapy (5,6). Hybrid procedures and prefabricated fenestrated stent grafts can partly overcome the problems associated with this. Some manufacturers provide customized fenestrated stent grafts to incorporate renal and mesenteric arteries. The same approach has been applied for the treatment of aortic arch diseases and includes sealing of the fenestration with a stent graft into the side branch artery. Customized stent grafts depend on excellent preoperative imaging, graft planning, and manufacturing. Successful device use requires that fenestrations are carefully aligned with the vessel ostia before the device is deployed. With tortuous anatomy, this alignment can be extremely challenging, and proper sealing of fenestrations may not be achieved. Customized stent grafts are also very expensive and are unavailable for acute syndromes.

Anecdotal cases of in situ fenestration of stent grafts have been published. Needle-based (7–11) or laser (12) techniques have been used to create the fenestration, which is then dilated with either a cutting balloon or ordinary percutaneous transluminal angioplasty (PTA)

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Residual Stenosis and Visual Appearance of Various Fabrics after Sequential Dilation with a Standard Percutaneous Transluminal Angioplasty Balloon

Graft Type, Graft Material	Balloon 2.5 mm Residual Diameter Stenosis	Visual Appearance	Balloon 4 mm Residual Diameter Stenosis	Visual Appearance
Endurant, woven polyester	65% stenosis	Small, round hole	53% stenosis	Round hole
Gore TAG, multilayer ePTFE/FEP	54% stenosis	Small, round hole	27% stenosis	Round hole
Talent, woven polyester	45% stenosis	Small, round hole	Fully open at 26 atm	Horizontal tear
Valiant, woven polyester	60% stenosis	Small, oval hole	Fully open at 24 atm	Transversal tear
Zenith, PET (woven polyester)	53% stenosis	Barely visible round hole (elastic recoil)	58% stenosis	Small, round hole (elastic recoil)

ePTFE = expanded polytetrafluoroethylene, FEP = fluorinated ethylene-propylene, PET = polyethylene terephthalate.

balloon. Sealing of fenestrations has been done with covered stents or plain metallic stents. There are two alternatives for intraoperative graft fenestration: *(a)* Retrograde fenestration is done from the target vessel to the graft lumen. *(b)* Antegrade fenestration is done from the graft lumen to the branch vessel. In the retrograde technique, access to the branch vessel is necessary. The technique has been tested as a repair method for aortic arch vessels in experimental in vitro and animal models (9,13), and a few patient cases have been published (7,8,12). The retrograde technique cannot be easily used in visceral arteries, however.

Several concerns remain regarding the acute and long-term effects of different techniques. It is unclear how various graft materials behave when they are dilated. Dilation of the fenestration may cause a tear in the fabric that enlarges and leads to an endoleak and eventually to rupture of the aneurysm. A durable technique for sealing the fenestration still needs to be determined. The purpose of this experimental study was to test the fenestration of various commercially available stent grafts in vitro. The specific aim was to clarify how various fabrics perform when dilated sequentially with a standard PTA balloon or a cutting balloon. The joint between the main prosthesis and a side branch stent graft, placed through the fenestration, was visually assessed.

MATERIALS AND METHODS

Commercially available stent grafts from three manufacturers were tested: Zenith (William Cook, Baereskov, Denmark); Gore TAG (W.L. Gore, Flagstaff, Arizona); and Valiant, Talent, and Endurant (Medtronic Inc, Minneapolis, Minnesota). For the first test, a small hole was created with a 22-gauge needle, and the hole was sequentially dilated with 2.5-mm and 4-mm coronary PTA balloons (Maverick; Boston Scientific, Natick, Massachusetts) and 7-mm and 10-mm peripheral PTA balloons (Opta Pro Cordis, Miami Lakes, Florida). Stent grafts were manipulated by hand, and balloons were placed manually through the hole created with a needle. With each balloon, the pressure was gradually increased until the balloon was fully open with no waist caused by the prosthesis.

The prospective goal was to create a fenestration with diameter of 10 mm. Fenestrations were assessed visually by two observers and recorded on x-ray images. For the second test, a hole created in the fabric with the needle was dilated with a 5-mm cutting balloon (Boston Scientific). Results were recorded as before. Residual diameter stenosis caused by the fabric was measured from x-ray images of the balloon. A 6-mm/38-mm Advanta V12 (Atrium Medical; Hudson, New Hampshire) stent graft was placed through the fenestration and dilated. The joint between the main prosthesis and the side branch stent graft was assessed visually for evidence of possible gaps. Finally, an additional fenestration was created in the Talent prosthesis puncturing the hole as close as possible to the stent strut.

RESULTS

Fenestration with a Standard Balloon

Results from the radiologic and visual assessments after standard balloon dilation are summarized in the **Table**. Creation of a fenestration was easiest with Talent and Valiant grafts. There was no residual stenosis at the balloon profile after dilation with a 4-mm diameter balloon up to 26 atm (Talent) and 24 atm (Valiant). The fenestration widened with low pressure during dilation with 7-mm and 10-mm balloons. Gore TAG and Endurant grafts resisted 2.5-mm and 4-mm balloon dilation. The waist of the balloon disappeared after dilation with a 7-mm balloon up to 12 atm, and there was no difficulty widening the fenestration up to 10 mm. The fabric of the Zenith stent graft was most resilient and resisted, to some degree, all dilation attempts; a residual diameter stenosis of 29% remained even after dilation with the largest 10-mm balloon (**Figure 1**).

Visually, the hole created in the Gore TAG endoprosthesis was very clean-cut. The hole was slightly oval, and the