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Proximal Scallop in Thoracic Endovascular Aortic Aneurysm Repair to Overcome Neck Issues in the Arch

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WHAT THIS PAPER ADDS

Proximal scalloped stent grafts appear to be an effective additional tool for TEVAR when dealing with short or angulated proximal necks. More prospective and multicentre studies have been initiated to confirm these results.

Objective: To evaluate initial experience with a custom made proximal scalloped stent graft for thoracic endovascular aortic repair (TEVAR) of aortic aneurysms involving the arch.

Methods: Between September 2012 and November 2014, patients presenting with a thoracic aortic aneurysm (TAA) with short or angulated neck were selected for treatment by custom made proximal scalloped Relay Plus stent grafts (ABS Bolton Medical, Barcelona, Spain). Prospectively acquired data relating to patient demographics, procedure details, clinical outcomes, and complications were analyzed retrospectively.

Results: Ten selected patients (50% male, mean age 77 ± 8 years) were treated using a thoracic custom made Relay Plus stent graft, three of whom underwent additional cervical supra-aortic trunk revascularizations. TAA were fusiform in four cases, saccular in three, and three patients were treated for proximal type I endoleaks after previous standard TEVAR. The graft was landed in zone 2 in 3 cases, in zone 1 in 4 cases, and in zone 0 in 3 cases. The custom made scallop was designed to preserve flow in the left subclavian artery in three patients, in the left common carotid artery in four, and in the innominate artery in three. No proximal type I endoleak occurred and proximal sealing was achieved in all cases, with a technical success rate of 100%. All targeted vessels were patent. During a mean follow up of 12 ± 5 months, no conversion to open surgical repair and no aortic rupture occurred. One patient died post-operatively from myocardial infarction and one patient suffered a stroke with complete recovery. One patient had a distal type I endoleak on the 6 month CT scan and is scheduled for distal extension. No paraplegia, retrograde dissection and no other aortic related complications were recorded.

Conclusions: Proximal scalloped stent grafts appear to be an effective additional tool for TEVAR of TAA when dealing with short or angulated proximal necks.

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INTRODUCTION

Although thoracic endovascular aortic repair (TEVAR) is now an established treatment for descending aortic aneurysms,[1] it is not so clear when considering the aortic arch. Management of the proximal landing zone remains challenging in cases of short proximal neck and severe angulation of the arch. During the last decade, short neck issues in TEVAR led surgeons to develop alternative techniques, such as hybrid arch repair with supra aortic debranching,[2] chimneys,[3] fenestrations,[4] and branches.[5] However, these procedures are still under evaluation and their results have been controversial.[6,7] In the era of exclusive endovascular solutions for aortic arch lesions, stent grafts designed with a proximal scallop may provide an interesting approach. The concept of the proximal scallop aims to increase the proximal landing zone in the inner curvature of the arch without compromising supra aortic trunk (SAT) patency, thereby reinforcing proximal sealing at its weakest point. This study reports a single center experience using a custom made proximal scalloped stent graft for TEVAR of aortic aneurysms involving the arch.

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METHODS

Between September 2012 and November 2014, selected patients presenting with thoracic aortic aneurysm (TAA) with short or angulated neck were selected for treatment by custom made proximal scalloped Relay Plus stent grafts (ABS Bolton Medical, Barcelona, Spain). TAA included short proximal landing zone $<$ 20 mm, significant angulation of the arch requiring up to 30 mm of proximal landing zone length, and patients with proximal type I endoleak after previous standard TEVAR. To be more specific, both in cases of fusiform and saccular lesions, it was considered that the minimum healthy aortic seal length had to be at least 15 mm from the expected position of the edge of the scallop, either distally or laterally (Fig. 1). All patients underwent high resolution computed tomography angiography (CTA) scan pre-operatively. All elective cases were discussed by a multidisciplinary team. Informed consent was obtained from all patients before intervention and data collection. After patient selection and approval, the custom made stent graft was ordered with a reinforced fenestration scallop to the left subclavian artery (LSA), the left common carotid artery (LCCA), or the innominate artery (IA). According to international recommendations,[8] extra-anatomic revascularization of SATs was performed when indicated, prior to stent graft implantation.

Device/stent graft

As reported by Alsafi et al.,[9] custom made scalloped stent grafts were designed on the basis of the CE marked Bolton Relay Plus, composed of self expanding nitinol stents sutured onto polyester vascular graft with proximal bare stent with capture. A curved nitinol catheter along the length of the stent graft supported the graft to place the scallop systematically on the upper side of the aortic arch, and to allow an easy positioning of the scallop around the origin of targeted SAT. In addition to radiopaque end markers, four more markers delineated the position of the scallop. The delivery system consisted of a series of coaxially arranged sheaths and catheters: a stiff hydrophilic introducer to deliver the device through the iliac arteries and a flexible sheath containing the stent graft, allowing the device to track through the tortuous course of thoracic aorta. If proximal readjustment was required, the delivery system allows distal tip recapture. Stent grafts were manufactured according to pre-operative CTA measurements, with a custom made scallop created in situ. Turnaround time from sizing to delivery was 3 weeks.

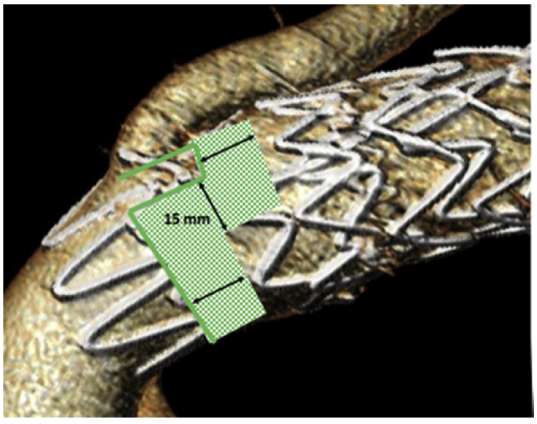

Figure 1. Diagram showing the minimum sealing length of 15 mm around the edges of the scallop.

Graft sizing

Procedure planning and device sizing were performed using a dedicated 3D vascular imaging work station (Vascular 4.2 software. 3mensio Medical Imaging BV, Bilthoven, The Netherlands) with centerline luminal reconstruction. The working landing zone included vessels around which the scallop fits. Scallops were custom made for each patient, according to the pre-operative CTA and 3D reconstructions. Three parameters were considered for their customization: width, length, and clockwise orientation of the targeted vessel. Generally, 20% oversizing of the stent graft, based on the proximal landing zone diameter, was recommended.

Technique

All procedures were performed under general anesthesia, through a surgical cutdown of the common femoral artery. The Relay Plus thoracic stent graft delivery system was inserted through a hydrophilic 60 cm, 22F to 24F sheath. Heparin 5000 IU, was administered at this point. Angiographic runs were performed through a pigtail catheter, introduced percutaneously through contralateral femoral or left brachial access and placed into the arch. The stent graft delivery system was inserted up to the mid descending thoracic aorta where the secondary sheath was further advanced into the arch. Using an arch angiogram, the distal marker of the scallop was aligned just distal to the targeted SAT (Fig. 2). Mean blood pressure at deployment was around 80 mmHg to optimize deployment accuracy. The steps of stent graft deployment were followed according to manufacturer instructions. Molding balloon angioplasty within the stent graft was optional. Completion angiograms were performed in all cases.

Follow up

Morphological follow up consisted of CTA scans before discharge, at 1 and 6 months, and yearly thereafter. A detailed clinical examination was performed during the hospital stay and at outpatient visits at 1 and 6 months, and yearly thereafter. Prospectively acquired data relating to patient demographics, procedure details, clinical outcomes, and complications were analyzed retrospectively.

RESULTS

Out of 88 TEVAR performed at the study institution during the study period, 10 selected patients (50% male, mean age 77 $\pm$ 8 years) were treated using a thoracic custom made Relay Plus stent graft. Patient characteristics and pre-operative conditions are presented in Table 1. Considering