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The Endovascular Sealing Device in Combination with Parallel Grafts for Treatment of Juxta/Suprarenal Abdominal Aortic Aneurysms: Short-term Results of a Novel Alternative

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WHAT THIS PAPER ADDS

The novel technique described, combining the endovascular aneurysm sealing (Nellix) device and separate parallel grafts to ensure blood flow to visceral vessels is a potential option for patients with complex aortic aneurysms and is potentially disruptive for expensive customized solutions.

Background: The chimney technique using parallel grafts offers an alternative to fenestrated or branched endovascular solutions for juxtarenal and suprarenal aneurysms. Endograft deployment proximal to the renal or visceral ostia is combined with parallel stents to the aortic side branches. Application of the chimney technique using the Nellix device (Ch-EVAS) may offer some potential advantages with respect to the seal between the endograft and the parallel grafts. This study aimed to investigate the feasibility and efficacy of the Nellix endovascular aneurysm sealing (EVAS) system in conjunction with parallel grafts for the treatment of juxtarenal and suprarenal aneurysms.

Methods: A prospective evaluation of patients treated for juxtarenal and suprarenal non-ruptured aortic aneurysms using Ch-EVAS was undertaken in a single vascular unit. Patients were treated with this technique if they were unsuitable for either open repair or a custom-made complex branched/fenestrated endograft. Procedural, postoperative morbidity, and mortality data were recorded.

Results: Between March 2013 and April 2015, 28 patients were treated with Ch-EVAS. The median age was 75 years (range 60–87 years) and the median aneurysm diameter 66 mm (IQR 60–73 mm). Eight patients underwent suprarenal aneurysm repair including parallel grafts in the superior mesenteric artery and renal arteries. Five patients had a double chimney configuration; all the other patients were treated with a single chimney configuration. There was one 30-day or in-hospital mortality in a patient with a symptomatic aneurysm (4%) and three further deaths within 1 year of follow-up. One proximal type I endoleak and one type II endoleak occurred. Four patients underwent a reintervention. One patient experienced a transient ischemic attack and two patients suffered from a minor stroke (7%), therefore the total number of cerebrovascular complications was 11%. No patient required postoperative renal replacement therapy.

Conclusions: Ch-EVAS appears to offer a feasible solution for juxtarenal and suprarenal aneurysms with adverse morphology. In this short-term follow-up endoleak rates were low and re-intervention rates were acceptable. Outcomes over extended follow-up will determine the application of this novel technique and better define which patients and aneurysm morphology can be treated effectively.

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INTRODUCTION

Endovascular treatment options have emerged as a promising alternative to conventional open repair for patients with juxtarenal and suprarenal aneurysms. Available reports suggest fenestrated or branched solutions are associated with reduced perioperative mortality compared with open aneurysm repair.[1,2] In parallel with endovascular aneurysm repair (EVAR) in the infrarenal aorta, fenestrated and branched solutions are not universally applicable with respect to aortic morphology, and custom-made endografts are of limited utility in urgent or emergency cases.

The chimney graft technique was introduced as an alternative to fenestrated or branched stent grafts for preserving blood flow to aortic side branches in the sealing

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zones of aortic stent grafts. Short- and mid-term clinical outcomes of this technique have been reported and highlight the risk of gutter endoleak, between the chimney grafts and aortic endograft.[3–12]

The introduction of the novel technique of endovascular aneurysm sealing (EVAS) with the Nellix system (Endologix, Irvine, CA, USA) offers the potential to mitigate these risks by achieving a better seal at the level of the chimney grafts, and a better incorporation of the chimney grafts into the aortic endoprosthesis. Preliminary evidence to support the applicability of EVAS with chimney grafts (Ch-EVAS) from an in vitro model[13] have been confirmed by reports of successful treatment of juxtarenal aneurysms with this configuration.[14,15] Clearly, these studies provide limited information on the durability of Ch-EVAS across a range of aortic morphology. The present study describes an early experience of Ch-EVAS for the treatment of complex juxtarenal and suprarenal aneurysms in a single centre.

METHODS

Study population

A prospective evaluation of patients treated for juxtarenal and suprarenal non-ruptured aortic aneurysms using the Nellix system and parallel grafts was undertaken in a single Vascular Unit in the United Kingdom. Patients selected for Ch-EVAS were morphologically unsuitable for either a bifurcated endograft or custom-made fenestrated/branched endograft. Patients were deemed to be of prohibitive risk for open surgery. During the study period 17 patients were treated with a custom-made branched device and 23 patients underwent fenestrated repair for a juxtarenal or suprarenal aneurysm. Our tertiary vascular centre receives a large volume of referrals from centres with experience in open and fenestrated repair of complex aneurysms; hence patients that are unsuitable for these techniques make up a large proportion of our practice. Two major reasons for these referrals are either morphological unsuitability (angulation, iliac diameter) or acute aortic pathology warranting immediate surgery with an off-the-shelf solution.

The institutional EVAS programme started in March 2013 after commercialization of the endograft following the award of a CE mark. All patients with non-ruptured juxtarenal/suprarenal abdominal aortic aneurysms (AAAs) treated with the Nellix device and parallel grafts between March 1, 2013, and April 1, 2015 were included in the present series. Data were recorded prospectively and included demographics, aneurysm morphology, procedural details, and early surveillance outcomes. Specific ethics approval for this study was not required because the analyses undertaken used data collected for routine clinical care (UK National Research Ethics Service guidance).

Endovascular procedure and follow-up

The technique used for EVAS changed during the study period as experience was gained, complications were reported globally, and the procedure was refined. The current procedure utilized in our centre is briefly described. A 3D workstation (3mensio Medical Imaging BV, Bilthoven, The Netherlands) was used to define pre-procedure aortic morphology with emphasis on the centerline distance between the sealing zone and the aortic bifurcation (used for calculation of device length) and the volume of the flow lumen between sealing zone arteries and iliac bifurcations (used to estimate polymer fill volume).

Ch-EVAS was planned to obtain a sealing zone of parallel-sided aorta of 20 mm length and 20–30 mm diameter. The number of chimneys utilized for this purpose varied from one to three according to aortic morphology.

A percutaneous puncture was made in the common femoral arteries and two Proglide (Abbott Vascular, Abbott Park, IL, USA) closure devices deployed.[16] The left axillary artery was exposed and cannulated with a sheath commensurate with the number of planned parallel grafts (1 or 2 7F Ansel sheath(s) for a single/double chimney configuration, three flexor Ansel sheaths for 3 chimneys). Unfractionated heparin (5,000 units) was administered intravenously. Two 14F sheaths (Cook Medical, Bloomington, IN, USA) were inserted over Lunderqvist wires (Cook Medical) via the femoral arteries, and a calibrated angiogram was obtained to supplement information provided by preoperative planning and define the lengths of the Nellix system required. The technique used for deploying the Nellix system has been described in detail previously.[17]

Through the axillary approach, the renal arteries with or without the superior mesenteric artery were cannulated; balloon-expandable (Advanta V12; Atrium Medical Corporation/Maquet Cardiovascular, Hudson, NH, USA) or self-expendable covered stents (Fluency; C.R. Bard Incorporation, Tempe, AZ, USA) were deployed with the proximal stents just proximal to sealing zone. The Nellix devices were inserted through the common femoral artery bilaterally, and advanced over a wire into a position at the sealing zone (Fig. 1A). The stent-grafts were positioned at the level of the sealing zone and stents deployed by simultaneous inflation of the Nellix balloons to 7 atm (Fig. 1B). The endobag was inflated with an aqueous polyethylene glycol–based polymer (Fig. 1C). During balloon expansion of the Nellix device and all stages of subsequent polymer injection, the parallel stent-grafts were supported by continuously inflated balloons.

If there was a failure of sealing or if pressures in the endobags were lower than 180 mmHg on saline instillation (<1 mL to create a hydraulic column into the endobag), further polymer was added to the endobags at this stage, defined by secondary “pre-fill” volumes.

Completion angiography was used to define aneurysm seal and patency of the system. In the presence of adverse angulation between the EVAS stent-graft and the iliac vessel wall, additional uncovered bare metal self-expandable stents were deployed (Zilver, Cook Medical). In some cases the longest Nellix endograft (180 mm) was not sufficient to effect a seal in the iliac arteries and so covered endografts were used to bridge between the distal end of the Nellix endograft and the sealing zone in the iliac arteries (see Table 2).

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