

Short Communication

Update on FEVAR



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ABSTRACT

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1. Introduction

Management of juxtarenal and pararenal aortic aneurysm frequently presents a challenge. Open surgery for this condition is associated with devastating consequences. Endovascular approach has been developed by some of the device industries with better short- and long-term results. This is a Post-Market Surveillance Study for the Vascutek Custom Fenestrated Anaconda Stent Graft. Vascutek joined the Fenestrated programme in June 2010.

2. Methods

This is a web-based prospective multicentre observational post-market registry with the aim of monitoring clinical safety

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and efficacy of the device. This is a requirement from MHRA for vigilance of custom devices. The patient population included those who required a custom-made AAA device for juxtarenal aneurysms. The follow-up included clinical assessment, measurement of renal function and CT/ultrasound at predischarge or 30 days (if still hospitalised) and every year postimplant till 5 years. The endpoints were adverse events, overall mortality, AAA exclusion and target vessel patency.

3. Results

By the end of May 2015, a total of 968 devices were implanted world-wide, of which 307 were deployed in UK and 231 in Germany (Table 1). Two-third of the patients were hypertensive, 40% had ischaemic heart disease, 22% had chronic renal impairment and 9% had previous aortic surgery (Table 2).

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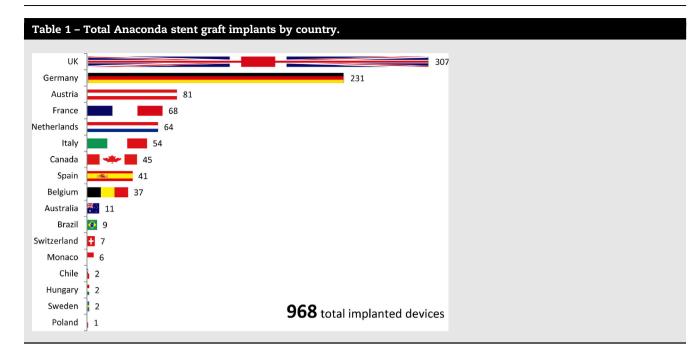
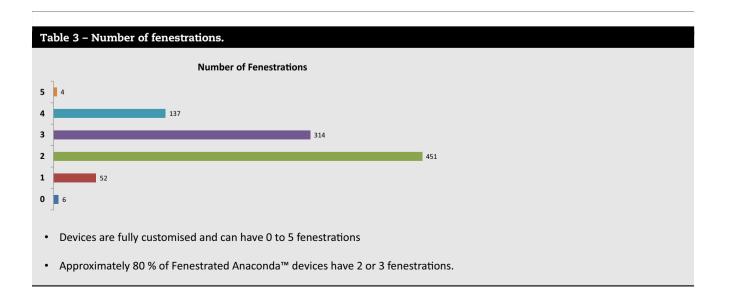


Table 2 – Patient demographics and reported comorbid- ities.		
Reported comorbidities	Ν	%
Diabetes	91	14
Hypertension	410	65
Current smoker	143	23
Ex smoker	229	36
Ischaemic heart disease	254	40
Congestive cardiac failure	57	9
Chronic renal impairment	137	22
Cerebrovascular disease	57	9
Prior aortic surgery	53	9
\bullet Age: Mean \pm SD: 74 \pm 7 years (N = 618); Range: 51–97 years.		

• Sex: 557 male (89%) (N = 628).

Forty-four patients were unfit for open surgery. The maximum diameter of the aneurysms was a mean of 62 ± 11 mm. 451 patients had 2, 314 patients had 3 and 137 patients had 4 fenestrations (Table 3). Bifurcated grafts were deployed in 584 (94.7%) of the 617 patients. Operating time in minutes was as follows: screening 69 ± 46 , procedure time 288 ± 114 (Tables 4 and 5). With regard to adverse events, 14 patients had cardiac events, 10 had renal complications, 8 patients suffered a stroke and limb ischaemia occurred in 4 patients. The overall mortality was 9.2% (57/618). Endoleaks were reported in 170/ 612 evaluable patients at the end of the procedure, and Type II accounting for majority of the endoleaks, reducing to 1 (Type II) at the end of 4 years. Aneurysm sac size had decreased in all the evaluable patients (Table 6). Target vessels were lost in 11/ 803 vessels at the end of 1 year (Table 7).



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