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Original Article

Jotec E-Ventus BX Stent Graft Deployment in the FEVAR and Iliac Branch Device: Single Centre Experience

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Objectives: To evaluate the outcomes of the E-ventus BX balloon-expandable stent graft system (Jotec, Hechingen, Germany) implanted as bridging stent grafts during fenestrated endovascular aortic repair (FEVAR) and the iliac branch device (IBD) of complex aneurysms.

Methods: This was a single centre retrospective analysis prospective study including all consecutive patients treated by FEVAR and the IBD performed with E-ventus BX stent grafts as bridging stents. Demographics of patients, the diameter and length of the bridging stent grafts, technical success, reinterventions, occlusions, post-operative events, and imaging (computed tomography [CT] scan and ultrasound) were prospectively collected in an electronic database. Follow-ups were performed with clinical assessment and a CT angiogram scan at four weeks after discharge followed by a duplex ultrasound every six months for two years and then a yearly duplex scan afterwards.

Results: Between June 2015 and October 2017, 40 consecutive patients (three females) were treated with custom made fenestrated endografts and the iliac branch device for complex aneurysms, using the E-Ventus BX stent graft. All 82 E-Ventus BX stent grafts were successfully delivered and deployed. There was no in-hospital mortality. The early bridging stents patency rate was 97.6% (80 out of 82). The two-target vessel post-operative occlusion was secondary to kink of the renal stents and failure for re-lining of the renal artery. Of the two patients, only one needed permanent dialysis. On the late follow-up (after 30 days), two other patients demonstrated a renal stent occlusion, with one treated successfully with re-lining of the stent and the other patient treated conservatively. Neither of them needed permanent dialysis. A follow-up was maintained for 36 patients until April 2018 with a median follow-up of 18 months. All bridging stents E-Ventus BX stent grafts remained patent (78 out of 82, 95.1%).

Conclusion: E-Ventus BX stent grafts used as bridging stents during FEVAR and the IBD are associated with favourable outcomes at the mid-term follow-up. Long-term follow-up is required to confirm these promising results.

Keywords: aortic aneurysm, E-Ventus, FEVAR, IBD, bridging stents

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Introduction

An endovascular aneurysm repair (EVAR) has a distinct perioperative mortality advantage as compared to an open repair for asymptomatic abdominal aortic aneurysms (AAA),[1] although the range of the standard 'off-the-shelf' devices can only treat approximately 70% of patients. The presence of an inadequate proximal sealing zone (juxtarenal AAA) was addressed by the development of bespoke stent-grafts (fenestrated endovascular aneurysm repair or FEVAR) which have been available since 1999.[2]

The simplest structure that can be added to an endovascular graft to allow for blood flow to a branch vessel is a fenestration (or hole) through the graft material. Challenges arise when this fenestration has to be aligned with the branch vessel during deployment and in maintaining this alignment with the vessel during the life of the endovascular repair to ensure long-term branch patency.[3]

The first fenestrated repair was reported by Park in 1996, and he used a device modification to incorporate an accessory renal artery in a patient with an infrarenal aneurysm.[3] Additionally, these fenestrations are made in the graft corresponding to the ostia of the visceral vessels, and covered stents are placed through both to maintain flow into the target vessel and the integrity of the seal.[2]

FEVAR is a validated option for treating complex aortic aneurysms.[4,5] Studies have demonstrated that the use of fenestrated stent grafts have comparable perioperative mortality rates to conventional stents used in EVAR, in addition to high immediate and mid-term target vessel patency rates with a low rate of secondary interventions.[6]

Another key philosophy from surgery translated into endovascular techniques is the preservation of normal anatomy whenever possible.[7] The first use of an iliac branch device to maintain the flow to the internal iliac artery was performed successfully in Perth, Australia in 2001. Initial attempts at iliac branch repair paralleled early approaches to complete infrarenal AAA repair with a unibody (single piece) bifurcated endovascular prosthesis. Similar to the experience with AAA repair, the device implantation was simpler, and the device sizes required to treat varying patient anatomy were reduced by a modular approach. Finally, the graft design was similar to that of a standard iliac leg extension with a small branch added a few centimetres from the proximal end of the graft.[8]

The development of an iliac branch device (IBD) in 2001 offered a strategy to deal with an inadequate distal seal zone (aneurysmal common iliac artery).[9] The flow to the hypogastric vessel is preserved by placing a bifurcated iliac limb component with a covered stent placed to connect the short internal limb of the graft to the hypogastric vessel.[9] Long-term follow-ups of the iliac branch devices are also encouraging.[10]

Clinical studies have evaluated covered and uncovered stents implanted during FEVAR[11]; however, there is currently a general consensus in favour of the liberal use of covered stents, which are associated with a 2.5% occlusion rate as compared to the occlusion rate of 10% for uncovered stents, as described by Mohabbat et al.[12]

The performance of the covered stents used in these complex endovascular repairs is critical as occlusion can lead to kidney loss or bowel ischaemia, which is often a fatal complication. The main graft may migrate or the native vessel may perform conformational change and kinking or disconnection of the stent may ensue. Target vessels patency rates at the 1-year follow-up of 92% to 98% have been reported in the literature.[13–16]

The following covered stents have been used as bridging stents during FEVAR: JOSTENT (Abbott Laboratories, Abbott Park, IL, USA), Advanta V12 (Atrium Medical, Hudson, NH, USA), Lifestream (Bard, Tempe, AZ, USA) and BeGraft (Bentley InnoMed, Hechingen, Germany).[17,18] Manufacturers have extended the indications for their current ranges of covered stents, rather than introduce dedicated products for the task. One example is the E-ventus BX balloon-expandable stent (Jotec, Hechingen, Germany). This stent graft comprises an ePTFE layer with a cobalt chromium stent. Stent graft diameters range from 5 to 10 mm and lengths from 18 to 58 mm, delivered via a low-profile (6/7F) delivery system. There are little published data regarding the performance of each device. To our knowledge, this is the first published analysis of medium-term performance of the Jotec E-ventus range of covered stents, deployed in complex endovascular repair including FEVAR and IBD.

Materials and Methods

This is a retrospective analysis of prospectively collected data for patients with juxta renal AAA or common iliac artery aneurysm conducted in Brighton and Sussex University hospitals between June 2015 and October 2017.

These patients received FEVAR using a custom-made Cook fenestrated endovascular device or a Cook iliac branch device (Cook Europe, Limerick, Ireland) with the adjunct use of a Jotec E-ventus BX stent graft as bridging stents between fenestration (or branch) to the target vessel, whether visceral or at the internal iliac artery, aiming at preserving normal antegrade flow to that specific branch.

Indications for treatment were abdominal aortic aneurysms 5.5 cm or above in diameter in unsuitable anatomy for standard EVAR and deemed to be a considerable risk for the open repair. Moreover, patients with aorto-iliac aneurysms with an iliac diameter above 20 mm (not suitable for the standard limb but suitable for a limb extension to the external iliac artery) and a suitable internal iliac artery landing zone for the iliac branch device and the bridging stent were also involved.

Patients' risk factors included ischaemic heart disease, hypertension, chronic obstructive pulmonary disease, chronic kidney disease, diabetes mellitus, transient ischaemic attack, cerebrovascular accident, hypercholesteremia, peripheral vascular disease, and smoking (**Table 1**).

The scoring system from the American Society of An-

Table 1 Risk Factors

Risk factors	No of patients (%)
IHD	14 (35%)
HTN	27 (60%)
COPD	6 (15%)
CKD	1 (2.5%)
DM	4 (10%)
TIA/CVA	2 (5%)
Hypercholesteremia	5 (12.5%)
PVD	5 (12.5%)
Smoking	11 (27.5%)

IHD: ischemic heart disease; HTN: hypertension; COPD: chronic obstructive pulmonary disease; CKD: chronic kidney disease; DM: diabetes mellitus; TIA: transient ischemic attack; CVA: cerebrovascular accident; PVD: peripheral vascular disease

aesthesiology (ASA) was used to stratify the risks associated with the intervention, with 12 patients scoring an ASA score of 2, 26 patients scoring a 3, and two patients scoring a 4.

Pre-operative preparation included clinical assessment and high-resolution spiral computed tomography (CT) scans. The CT images were reconstructed for analysis and measurements on a workstation (Syngo Via, Siemens Healthcare GmbH, Erlangen, Germany). Cardiac risk assessment included a myocardial perfusion scan, and a review by a consultant anaesthetist was also performed prior to the intervention.

Following the completed work-up, the patients were discussed in multidisciplinary meetings for the intervention method and reviewed later in the clinic to convey the decision, discuss the risks and benefits associated with the proposed intervention, and to obtain an informed consent for the procedure.

The follow-up protocol consisted of clinical assessment and a CT scan at four weeks followed by six monthly ultrasound scans in addition to yearly check-ups thereafter. If the scan shows endoleak, sac size expansion, or complications, the protocol is to repeat the computerised tomography angiogram.

The end results were target vessel patency, secondary intervention, procedure-related complications, and death.

Aneurysm-related mortality was defined as all deaths occurring within 30 days from the procedure as well as late deaths associated with stent graft complications, while non-aneurysm-related mortality would be death due to any other cause.

Results

Forty patients (37 males and three females) were treated with 82 stents for branch preservation. The mean age was 75, and the mean time for follow-up was 18 months. We successfully deployed 82 stents of planned 84 branch vessel preservation with a technical success of 97.6%. We performed 32 FEVAR procedures using Jotec E-ventus BX stents for branches in single fenestration in four patients, two fenestrations in eight patients, and three fenestrations in 18 patients. Furthermore, we performed EVAR procedures with the IBD to preserve the unilateral internal iliac artery (IIA) in eight patients. Nineteen stents were performed for the superior mesenteric artery (SMA) with a mean diameter of 8 mm, two for the coeliac trunk with a mean diameter of 9 mm, 25 stents for the right renal artery with mean diameter of 7 mm, 28 stents for the left renal artery with a mean diameter of 7 mm, and eight stents for the internal iliac arteries with a mean diameter of 10 mm.

Perioperative mortality (30-days mortality) was reported as nil. Complications in the first 30 days included four patients with groin complications and one needed a pseudoaneurysm thrombin injection. One patient developed a deep venous thrombosis after 10 days. One patient developed a right iliac limb occlusion and had a femoral–femoral crossover. One patient developed a temporary spinal cord ischaemia. He improved with the insertion of a spinal drain and cerebro-spinal fluid drainage to improve spinal cord perfusion, and his neurological deficits improved. Two patients had an early stent occlusion and failed the intervention to re-line (**Table 2**).

The early blocked renal stents had kinks and thrombosis, and the first patient had an anastomotic juxta-renal aneurysm after open repair of the AAA with the single left renal artery. The renal artery was 4.3 mm and was coming out at an angulated angle. The second patient had a small diameter right renal artery (4.2 mm) with a short main stem and was angulated starting from the aorta.

Table 2 Complications

Complications	No of patients (%)
Failure to cannulate/deploy	2 (2.4%)
Endoleak Type III	1 (from IIA, resolved by further ballooning) (1.2%)
Thrombosis/kink	4 (1 thrombosis, 3 occlusion) (4.8%)
Bowel ischaemia	0
Buttock ischaemia	0
Renal functions derangement	7 (1 needed permanent dialysis) (8.5%)
Others	1 DVT
	1 Right iliac limb occlusion (had fem–fem bypass)
	4 Groin complications
	1 Spinal cord ischaemia (No permanent damage)
	5 Type II endoleak

IIA: internal iliac artery; DVT: deep venous thrombosis; fem–fem: femoral–femoral

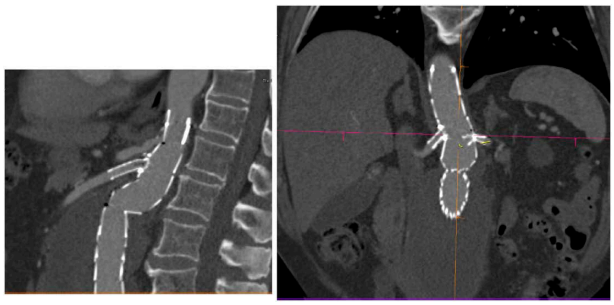

Fig. 1 Patent SMA and renals in a 2 year follow-up CTA after the FEVAR with bridging Jotec E-Ventus stents.
SMA: superior mesenteric artery; CTA: computerised tomography angiogram; FEVAR: fenestrated endovascular aortic repair

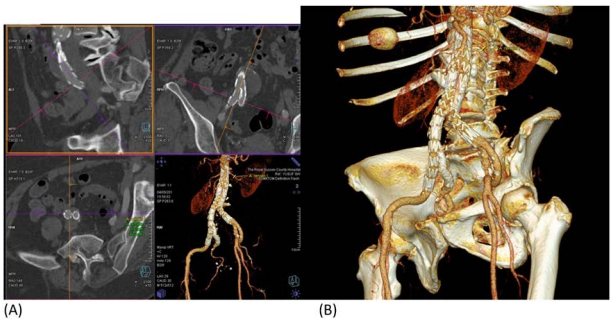

Fig. 2 The patent right iliac branch device with the Jotec E-Ventus bridging stent in a 1 year follow-up CTA (**A**: reconstruction cuts, **B**: 3D image).
CTA: computerised tomography angiogram; 3D: 3 dimensions

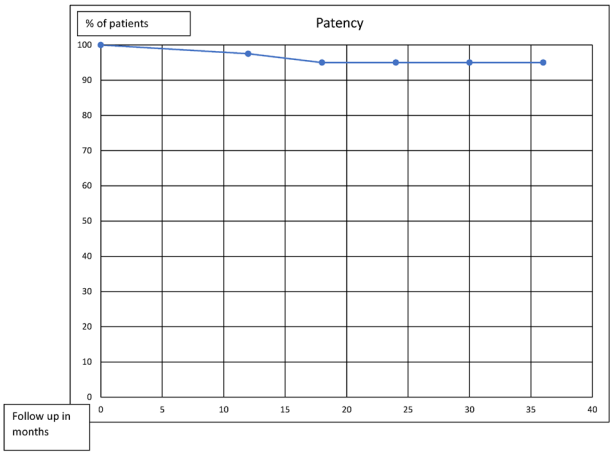

Fig. 3 Kaplan–Meier analysis curve for target vessel patency.

Late complications included further two renal stents occlusions due to kink. One needed re-intervention for a declined kidney function which was done successfully as day case under local anaesthesia, and the other one was managed conservatively as there was no significant deterioration of renal function.

Follow-up was maintained for 36 patients until April 2018. One patient died of a non-aortic-related cause. The patency rate was 97.5%, 95.1% and 95.1% at 12, 24 and 36 months, respectively (**Figs. 1, 2** and **3**).

Discussion

The FEVAR and IBD are recognised techniques for successful exclusion of aneurysms with a complex anatomy to achieve preservation of target branches. Success and durability of the FEVAR and IBD are closely linked to the effectiveness of the bridging stent.

Oderich et al. advocate the need to focus on bridging stent technology to reduce occlusions, Type III endoleaks, and reintervention rates.[19] In the literature, 1-year target vessel patency rates after complex endovascular repairs range from 92% to 98% and around 97% to 100% with IBD.[13,16,19,20] The single-centre prospective study series report 1-year outcomes of 101 BeGraft stent grafts used as bridging stents during FEVAR as a 98% patency rate.[21] Analysing the literature is difficult as a mix of complex abdominal AAA and thoraco-abdominal aneurysm are reported.[21]

There is a 2.4% early renal occlusion rate observed in this study, which is similar to the multicentre study on the F/BEVAR 2.3% occlusion rate published by Martin-Gonzalez et al.[22] In the literature, renal arteries are associated with a higher rate of secondary interventions, compared to visceral arteries.[18] In this study, secondary interventions for renal artery were needed in three patients (3.6%), and only one was successful. A total of seven patients (8.5%) experienced a renal functions derangement. One patient (1.2%) needed permanent dialysis and another one (1.2%) needed temporary dialysis. These results are comparable with those of a recent study on the F/BEVAR with a 5% rate of post-operative dialysis. Following FEVAR, Martin-Gonzalez et al. reported that 37% of patients experience a decrease in the estimated glomerular filtration rate .[22,23]

Type III endoleaks, described by Mastracci et al. as endoleaks from bridging stent disconnection to the fenestration or disconnection between two bridging stents, are reported to be the major cause of re-intervention following complex endovascular repair.[18]

In this study, 1.2% of the Type III endoleak was reported in the iliac branch device and bridging stent to IIA, which resolved by further ballooning. In this study, the patency of target vessels with E-ventus stent grafts correspond with these rates with 1-year 97.5% and 3-year 95.1% patency rates. This study shows three years of follow-ups for the bridging stent graft which was used with reasonable technical success rates of the E-ventus BX stent as the bridging stent. This study also showed low mortality and morbidity risks associated with considerable benefits on the mid-term outcome.

Conclusion

This series show that Jotec E-ventus BX stent grafts can be used as a bridging stent with comparable technical success, mid-term patency (up to three years), and a reasonable post-operative and late complications rate. Long-term follow-ups are still needed to confirm this favourable outcome.

Disclosure Statement

Nothing to disclose.

Author Contributions

Study conception: SWY, TS, KES, AR
Data collection: TS, IA
Analysis: TS
Investigation: TS, SWY, KES, AR
Writing: TS, IA, AR
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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