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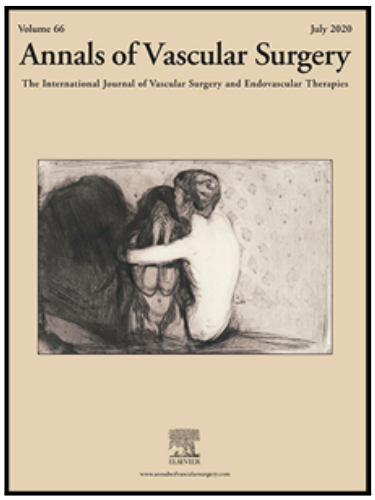

Efficacy and Safety of Jotec E-Ventus BX Stent Graft for Iliac Branch Device Procedure: A Retrospective Clinical Study

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RUNNING HEAD: Jotec E-Ventus BX Stent Graft for Iliac Branch Device Procedure

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ABSTRACT

Background: The endovascular aneurysm repair (EVAR) is a successful treatment for aorto-iliac aneurysms. The success of EVAR is enhanced by the use of devices that maintain the patency of targeted arteries namely the iliac branch device (IBD) With this study we aimed to evaluate the association between the use of Jotec E-ventus during EVAR with IBD and prognosis in patients with aorto-iliac aneurysms.

Methods: This is a retrospective, multicentric study enrolling patients referred to our Vascular Surgery Units from January 2015 to January 2020. All patients underwent EVAR with IBD using Jotec E-ventus as bridging stent. Primary endpoint was the

development of types I and III endoleaks. Secondary endpoint was the onset of device occlusion with loss of vascular patency.

Results: We studied 32 patients (mean age 71.7±4.5y). Of these, 25 patients were treated with standard EVAR procedure whereas 7 were treated with isolated IBD due to extension of disease involving iliac bifurcation. Median follow-up lasted 15[IQR11-27] months. During follow-up, incidence rates for endoleaks and occlusion were 3.98(95%CI 0.48-14.41) and 1.99(95%CI 0.05-11.12) per 100 pts/year.

Conclusion: Jotec E-ventus during EVAR is associated with a low rate of severe complications in a small cohort of patients with aorto-iliac aneurysms.

Keywords: aorto-iliac aneurysm; endoleaks; prognosis; Iliac Branch Device; endovascular treatment

Introduction

Aortic aneurysms (AA) represent a clinical condition associated with high risk of fatal complications such as rupture [1–4]. [4]. Moreover, the recent Global Burden of Disease report showed a striking 24% increase in mortality due to AA complication, from 2007 to 2017 [5].. Among the therapeutic strategies, which aimed to prevent the risk of complications, endovascular aneurysm repair (EVAR) has been widely used [6]. Notwithstanding, the EVAR encountered several troubles over time. Among them, the main trouble is to maintain the vascular branch patency [7]. The use of branch devices has allowed to warrant a similar perioperative risk as standard EVAR but with the great advantage of a greater patency rate over time and lower frequency of re-intervention [8]. With respect to aorto-iliac aneurysms, the branch devices called iliac branch device (IBD) have been used during EVAR procedures [9]. They allowed to preserve the blood flow to the hypogastric artery (HA), thus preventing the fearsome complication of

pelvic ischemia, up to the devasting ischemic colitis. The first results from the use of IBD are encouraging. Indeed, the complications after IBD use, namely the bridging stent occlusion, buttock claudication and the occurrence of endoleaks, were extremely low [10,11]. However, conflictual results have also been reported, suggesting the need of further studies showing in particular the medium and long-term follow-up of patients under-going IBD during EVAR [12]. Moreover, none of the bridging stents available in commerce is designed specifically to be used with IBD in EVAR procedures. The aim of our study is to evaluate the effectiveness of the new device Jotec E-ventus (Jotec, Hechingen, Germany) in preserving aortic collaterals during EVAR procedure. To this aim we assessed retrospectively the medium-term prognosis namely the occurrence of type I-III endoleaks and device occlusion in patients undergoing EVAR with the use of IBD and the Jotec E-ventus as last generation bridging stent.

Materials and Methods

Study Design and Procedures

This is a cross-sectional multicentric clinical study examining, retrospectively, 32 consecutive patients referred to two Vascular Surgery Units from January 1st 2015, to January 1st, 2020. The cohort was originally built to collect information about the efficacy and safety of the Jotec E-ventus device. The study was approved by the Ethics Committee Napoli 3 SUD, Italy, (protocol code 0164934, date of approval 2018/11/15) and all the patients gave written informed consent. Inclusion criteria were patients with age > 18 years, indication for surgical repair of aorto-iliac aneurysms. Indications for endovascular repairs were defined as follow: unilateral or bilateral aorto-iliac or iliac aneurysm, iliac/femoral access vessel morphology compatible with the implantation procedure and the 18 F delivery system, a non-aneurysmal common iliac

artery landing area in case of iliac artery aneurysm ≥ 20 mm, diameter of the common iliac artery in the proximal landing area: 12-17 mm, non-aneurysmal external and internal iliac artery segment distal to the aneurysm ≥ 15 mm, diameter of the external iliac artery in the distal landing area: 8-13 mm, angle between external iliac artery and internal iliac artery ≤ 50°, thrombus free iliac lumen in the area of iliac bifurcation to open the side branch and to implant covered stent ≥ 18 mm, sufficiently open internal iliac artery ostium. We also included unilateral or bilateral common iliac aneurysm diameter ≥ 25 mm, unsuitable distal sealing site within the common iliac artery (CIA) for traditional EVAR, availability of the patient for appropriate follow up.. Patients with a life ex-pectancy <6 months, advanced liver or heart disease were excluded. All patients included in the present study underwent to EVAR with the additional use of Jotec E-ventus stent graft as bridging stents between branch to the HA as target vessel, aiming at preserving normal antegrade flow to that specific branch. In the same morning of the operative procedure, study investigators collected the medical history including history of Chronic Kidney Disease (CKD), major cardiovascular disease (CVD among myocardial infarction, stroke and heart failure), dyslipidemia, hypertension, smoking habit and main laboratory parameters.. We adopted a customized pre-operative planning based on contrast enhanced CT (with strata <= 1mm) performed for each patient to determine the diameters and lengths of the stent grafts. No specification was made for the type of peripheral stent graft and, after an amendment to the study protocol, to the type of abdominal stent graft to be used. During follow-up, patients were evaluated by clinical assessment, radiograms, CT scan at 1 month to evaluate integrity and correct location of grafts and ultrasound exams and clinical examination every six months thereafter. Ultrasound controls have been planned if the

CT scan at 1 months reported no complications. Conversely, CT was repeated 3 months thereafter if the scan at 1 month was positive. . The primary study endpoint was the risk for endoleaks development. Secondary endpoints were target vessel patency, secondary intervention, procedure-related complications and death.

Statistical Analysis

Continuous variables were reported as either mean ± standard deviation (SD) or median and interquartile range [IQR] based on their distribution. Categorical variables were reported as percentage (%). Incidence rates for the study endpoints were computed as number of events/person-time and 95% confidence interval (CI) was calculated assuming a Poisson distribution. Data were analyzed using STATA version 14 (Stata Corp. College Station, TX, USA).

Results

Baseline Characteristics

We studied 32 patients, more frequently of male gender (31 males versus 1 female). The mean age was 71.7 (SD 4.5) years. The cohort was characterized by high frequencies of hypertension, dyslipidemia and active smoking habit, which were 76.5%, 59.4% and 62.5% respectively. A high cardiovascular (CV) risk profile was also testified by the high frequency of previous CVD (31.3% of patients reported a myocardial infarction). Baseline demographic and laboratory characteristics are reported in Table 1.

In the overall cohort, we performed EVAR procedures with the IBD to preserve the unilateral HA in 31 patients whereas bilateral intervention was necessary in 1 patient. The aorto-iliac aneurysms were treated with a standard EVAR procedure without use of fenestration, T-Branching or CHIMNEY technique, since these aneurysms did not

involve the renal arteries emergency. The most used device was the E-Iliac Jotec device (Jotec, Hechingen, Germany) (22 procedures), instead the ZBIS Cook device (Cook Medical, Bloomington, IN, US) was used in 11 procedures, with a total of 33 branching of internal iliac artery. In all the successful IBD procedures the bridging stent was E-ventus. Thirty-three target common iliac arteries presented a mean diameter of 38.8±9.41 mm, and in case of a concomitant aortic aneurysm, the mean axial aortic transverse diameter was 50.23±10.79 mm. Seven cases of 32 (22%) were characterized by an extension of disease of a previous EVAR procedure with type IB endoleak. In nine of ten bilateral aorto-iliac aneurysms the contralateral hypo-gastric artery to the IBD was embolized (5 cases with detachable coils, 2 cases with Amplatzer Vascular Plug and 2 cases with standard coils). In all the de novo aorto-iliac aneurysms treated an aortic bifurcated stent graft was deployed after the IBD. The aortic body largely used was Jotec E-Tegra (Jotec, Hechingen, Germany, n=16; 64%); other stent grafts included Cook Zenith (Cook Inc., Bloomington, IN, USA, n=5; 20%), Endologix AFX (Endologix, Inc., Irvine, CA, USA, n=3; Medtronic Endurant (Medtronic Vascular, Santa Rosa, CA, USA, n=1; 4%). Femoral access was performed mostly under spinal anesthesia (87.5%) with a surgical cut-down of the common femoral artery (84.4%) but in two cases the access was achieved one side surgically and one side percutaneously. In four selected patients (12.5%) the procedure was performed under local anesthesia with a bilateral percutaneous access with previous insertion of two Proglide for each side according to the Perclose technique [13]. Three E-ventus bridging stents (9.4%) were introduced via an axillary access performed under local anesthesia due to the presence of a bifurcated aortic graft already implanted or the impossibility to release from the contralateral due to short target common iliac artery. Overall, 35 Jotec E-ventus BX

stents were used. Mean diameter of the stents used was 9.4±0.7 mm whereas mean length was 51.9±8.8 mm.

Periprocedural and Medium-Term Outcomes

Technical success was 91% and it was defined as perioperative absence of proximal or distal type I endoleak and of type III endoleak with IBD or E-ventus disconnection and also as complete release of branch limb in the HA. No case of perioperative or 30 days mortality occurred. There was no cases of cardiac and cerebral adverse events or pelvic ischemia, also there was no local complications about the surgical or percutaneous ac-cesses. No patient was converted to open surgery. Median study follow-up was 15 [IQR 11-27] months. During follow-up, we observed 2 primary endpoints and 1 secondary endpoint. The incidence rate for endoleaks was 3.98 (95% CI 0.48-14.41) per 100 pts/year whereas incidence rate for occlusions was 1.99 (95% CI 0.05-11.12) per 100 pts/year (Figure 1) . In particular, we reported one case of E-ventus occlusion due to an aneurismatic disease of the hypogastric artery, noticed during the long-term follow-up. We have no cases of endoleak involving the branch device and the E-ventus graft. The IB endoleak was about the E-Iliac branch device distally and it was treated with an extension leg landing in the external artery, instead the III type endoleak concerned the connection between the main body of E-Tegra endoprosthesis and the E-iliac branch device, treated with a relining.

Discussion

The EVAR and IBD are well demonstrated techniques used to exclude AAs and to preserve at the same time the patency of important arteries; indeed, the occlusion of the HA may cause buttock claudication, colic ischemia or even perineal necrosis,

erectile dysfunction, and, very rarely, spinal cord ischemia. A long-term follow-up study showed that EVAR decreased by about three folds the long-term mortality risk when compared to standard open repair of AAs [14]. Such as striking difference has been attributed to the perioperative complications which occur immediately after the open repair. Conversely, the success of IBD-EVAR has been principally related to the efficacy of bridging stent used. Appropriate techniques and technologies would indeed allow to reduce the risk for endoleaks, occlusions and thus re-interventions [15–17]. With the present dual-center study we showed that the use of the Jotec E-ventus device warranted a very low rate of complications over a follow-up longer than 1 year. In fact, among 32 patients for whom the Jotec E-ventus has been adopted, the incidence rate of endoleaks was lower than 5% while the device occlusion was observed in only 1 patient. These findings lead to consider that technical success attainable with the use of this type of device is higher than 90%. Another original point of our study is the homogeneity of target vessel. Previous results are principally confused by the inclusion of disparate interventions namely those involving abdominal AA or thoraco-abdominal AA [18,19]. Spear and Colleagues assessed the patency rate at 1 year from intervention among 39 patients treated with fenestrated endografts with bridging stents and found an excellent performance of the BeGraft stent graft, being associated to a 98% patency rate at 1 year. In this study rate of endoleaks was of 2.6%, close to what we observed in our patients [18]. In another study involving abdominal AA only, patency rate of branched stent graft was about 96% at 1 year and decreased to about 89% after 4 years follow-up [19]. Considered together, the 1-year patency rate was about 97 to 99% with the use of branched device [20]. It is remarkable that patents included in our study have similar demographic characteristics

and comorbidities (frequency of smoking habit, hypertension, diabetes) as the previous reports [18–20]. Hence, we can expand and confirm these positive results of previous studies to the peculiar setting of patients with aorto-iliac aneurysms. In this setting, Pratesi et al., enrolling patients treated with EVAR procedures and IBD found a technical success (98.7% over a median follow-up of 20 months) similar to what we reported, with the substantial difference of the device and bridging stent adopted [10]. Another advantage of the branched devise is the ease of implantation and their ability to restore the blood flow very quickly [21]. A recent observational, multicenter analysis of the PLIANT cohort evaluated the efficacy and safety of E-liac Stent Graft in the treatment of common iliac artery aneurysms [22]. Among the bridging stent used, the 74% was represented by the Jotec E-ventus, 21% by Advanta V12 Covered stent and a minority portion by Life-Stream Balloon Expandable Vascular Covered Stent and BeGraft stent. Authors found that the E-liac Stent Graft has an excellent performance when appropriately used and is associated with a very high (up to 90%) clinical success during 1-year follow-up. In fact, none of the treated patients developed endoleaks in the PLIANT study and only two patients underwent reintervention. As compared with the PLIANT study, our analysis provided, for the first time, evidences about the efficacy and safety of E-ventus graft in a cohort with longer follow-up. In fact, more than half of our patients were followed-up for more than 1 year after procedure. Moreover, this is the first study showing positive results with the use of Jotec E-ventus even with cook devices. Similarly, low frequency of reinterventions has been reported in other studies [23,24]. A bit higher frequency of reinterventions was only found in an exceptional study which enrolled patients undergoing the treatment of hypogastric artery aneurysms with IBD [25]. Nevertheless, although the IBD was used for a different

scope namely the exclusion of hypogastric artery aneurysms, authors judged as acceptable their results. The present study has strength and limitations. As strength, we evaluated for the first time the use of Jotec E-ventus device in patients with aorto-iliac aneurysms in a generous number of patients. Moreover, this is one the first studies showing a multicenter, time-to-event data around the IBD and E-liac Stent Graft use. As limitations, albeit being a dual-center cohort, the small sample size limits the generalizability of our findings. Moreover, the low event rate did not allow us to evaluate the adjusted risk factors for the primary and secondary endpoints. Nevertheless, this latter concept could be interpreted in a positive fashion since this means that a very low rate of complications was observed with this technique.

Conclusions

In conclusion, the Jotec E-ventus stent graft was found to be effective and safety when used as a bridging stent. This is true in term of technical success, mid-term patency and a post-operative complications rate. Further and hopefully larger studies are needed to give more insights about the risk factors forecasting complications in patients undergoing EVAR with IBD.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee Napoli 3 SUD, Italy, protocol code 0164934 date of approval 2018/11/15.

Conflicts of Interest: The authors declare no conflict of interest.

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Table 1. Clinical and laboratory features of patients at basal study visit.

Risk factors	**Overall (n = 32)**
Age, years	71.7 ± 4.5
Male gender, %	96.8
Hypertension, %	76.5
Active smokers, %	62.5
Dyslipidemia, %	59.4
Diabetes, %	9.4

Chronic Kidney Disease, %	9.4
Major Cardiovascular Disease, %	31.3
Glycemia, mg/dL	95.1 ± 8.2
Serum creatinine, mg/dL	1.18 ± 0.38
Uric acid, mg/dL	5.2 ± 1.1
Hemoglobin, g/dL	14.5 ± 2.3
Total cholesterol, mg/dL	184 (112-269)
Iliac arteries diameter, mm	38.8 ± 9.41
Aortic aneurysm diameter, mm	52 ± 8

Figure legend

Figure 1. Incidence rates for endoleaks and occlusion in our study population. Vertical bars represent 95% confidence intervals computed by assuming a Poisson distribution.