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Two-Year Outcomes With Bentley BeGraft as Bridging Stent-Grafts for Reno-Visceral Target Vessels During Fenestrated Endovascular Aortic Repair

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Abstract

Introduction: The aim of this study was to present the short-term and 2-year outcomes after use of the Bentley BeGraft as bridging stent-graft (BSG) for reno-visceral target vessel (TV) during fenestrated endovascular aortic repair (FEVAR) from a contemporary multicentric experience. **Methods:** A retrospective review of all consecutive patients who underwent elective FEVAR at 7 institutions located in Italy from 2015 to 2021 was performed. The main outcomes of interest for this study were technical success and TV instability, defined in accordance with current reporting standards. Patients' survival was also assessed. **Results:** Overall, 81 patients received elective FEVAR during the study period. Mean age of patients was 78 years, and 89% were men. Most patients were treated for a juxta-pararenal abdominal aortic aneurysm (AAA) (68%), and 23% had already received an infrarenal aortic reconstruction. Most endografts had 3-vessel or 4-vessel design (27% and 55%, respectively), and a Cook endograft was used in 73% of cases. Overall, 266 Bentley BeGraft were implanted, of which 44 (16.5%) in the celiac trunk, 69 (26%) in the superior mesenteric artery, 79 (29.5%) in the right renal artery, and 74 (28%) in the left renal artery. Technical success was 94%, with 5 instances of technical failure that were recorded and required an additional intraoperative procedure. The early mortality rate was 4%, and acute kidney injury occurred in 14 cases with 1 requiring definitive hemodialysis. Survival at 6, 12, and 24 months in the overall cohort was 98.8%, 95.3%, and 83.4%, respectively. Freedom from TV instability at 6, 12, and 24 months in the overall cohort was 98.4%, 97.9%, and 97.2%, respectively. Events of TV instability included 3 cases of type 1C endoleak and 3 cases of type 3C endoleak, while no events of BSG fracture or thrombosis were noted. Five out of 6 cases of TV instability occurred in renal arteries, and they were all successfully treated by endovascular means. **Conclusions:** The data from this multicentric study show favorable short-term and 2-year outcomes of the Bentley BeGraft as BSG for reno-visceral TV during FEVAR, with low rates of TV-related endoleak and no stent occlusion up to 2 years.

Clinical Impact

The data from this multicentric study show satsfactory outcomes up to two years of follow-up for the Bentley BeGraft when used for brdiging reno-visceral vessels during fenestrated endovascular aortic repair. Further research will be needed to identify predictors of stent-related reinterventions and ascertain the long-term durability.

Keywords

aortic aneurysms, fenestrated endovascular repair, bridging stent-graft, mid-term outcomes

Introduction

Fenestrated endovascular aortic repair (FEVAR) is established for the treatment of complex abdominal aortic aneurysms (cAAAs)[1–4] and also in cases of failure from prior infrarenal surgery (whether open or endovascular),[5,6] with excellent short-term results and satisfactory mid-term durability. FEVAR procedures require bridging stent-grafts (BSGs) to connect the aortic stent-graft main body to reno-visceral target vessels (TVs), thereby maintaining antegrade flow through fenestrations and into vital organs. Despite the fact that FEVAR has been available more than 10 years, a dedicated BSG is still not available; indeed, all covered stents currently employed for this purpose are used off-label and are selected at the discretion of the user or based on local availability.[7,8] Nonetheless, TV instability (ie, complications that can occur related to the BSG such as occlusion, fracture, dislocation, and endoleaks) remains a major source of reinterventions during follow-up, which may not only be detrimental to patients' well-being but also affect the overall cost-effectiveness of treatment.[9] The BeGraft Peripheral Stent Graft (Bentley InnoMed GmbH, Hechingen) is a novel-generation balloon-expandable covered stent that has been previously evaluated in small single-center series demonstrating good results up to 2 years.[10,11] The aim of this study was to present the short-term and 2-year outcomes after use of the Bentley BeGraft as BSG for reno-visceral TV during FEVAR from a contemporary multicentric experience.

Materials and Methods

Study Design and Data Sources

A retrospective review of all consecutive patients who underwent elective FEVAR at 7 institutions located in Italy from 2015 to 2021 was performed. Only cases with use of the Bentley BeGraft as BSG for reno-visceral TV were analyzed. One center was responsible for merging the data from each participating institution and assessing the quality of the imputed data, with audits performed as needed. All investigators had high experience with complex endovascular aortic repair (>10 years in practice and >50 FEVAR cases performed).

Device(s) Description and Surgical Practice

Two aortic endografts were used at participating centers, based on the platforms from Cook Medical and Terumo Aortic. The indications for repair were maximum aortic diameter >55 mm or rapid growth (>10 mm in 12 months) or prior EVAR failure (migration and/or type 1A endoleak), in accordance with current clinical practice guidelines.[12] The aortic endografts were planned according to each patient's anatomy and within the manufacturers' instructions-for-use. The Bentley BeGraft stent-grafts were used as BSG to connect fenestrations to TV (renal arteries and mesenteric arteries). The BeGraft stents are 0.035 compatible and built on a cobalt-chromium platform covered with a micro-porous expanded-PolyTetraFluoroEthilene (ePTFE) membrane that allows for 6F compatibility up to 8 mm; the ePTFE covering is fixed from the inside at both stent ends to reduce the risk of detachment of the graft material. All target arteries were analyzed on the preoperative computed tomography angiography (CTA) scan using a three-dimensional (3D) workstation to allow for analysis of the diameter of the target artery at the intended sealing zone and the distance from its origin to the first division branch. The seal zone was defined as the length of stent-graft in the TV with parallel vessel wall apposition and was planned to be ≥10 mm. Using both parameters, selection of size and length of the BSG was thereby performed accordingly. The BSGs were positioned so that at least one-third of the stent-graft protruded into the aortic lumen and the protruding segments were flared with 9 or 10 mm diameter (20 mm length) non-compliant balloon for the renal artery fenestrations, and a 10 or 12 mm diameter balloon (20 mm length) for the mesenteric stents. All patients received at least single antiplatelet therapy with low-dose acetylsalicylic acid or clopidogrel before and after the procedure. The choice to initiate dual antiplatelet therapy in the post-operative period was left to the treating physician's discretion unless otherwise required for concomitant medical comorbidity. Follow-up was performed according to each institution's local protocol but always included at least 1 CTA within the first month after the index procedure and 1 CTA within the first post-operative year. Alternatively, patients with severe renal disease were also evaluated by means of duplex ultrasound and basal computed tomography (CT).

Study Endpoints and Statistical Analysis

The main outcomes of interest for this study were technical success and TV instability, defined in accordance with

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Table 1. Baseline Characteristics of the Study Cohort.

Parameter	n	Frequency
Age, years	78±13.6	—
Sex, male	73	89.0%
Hypertension	79	96.3%
Hypercholesterolemia	48	58.5%
BMI, kg/m^2	26.4±3.6	—
Chronic obstructive pulmonary disease	33	40.2%
Coronary artery disease	25	30.5%
Chronic heart failure	8	9.8%
Baseline creatinine, mg/dL	0.9±0.3	—
Chronic kidney disease (stages III-IV)	10	12.2%
Diabetes mellitus	16	19.5%
Current smoking	24	29.3%
Type of aneurysm		
Short-neck	16	19.5%
Juxta-Pararenal	56	68.3%
Thoraco-abdominal	10	12.2%
Previous aortic procedure	19	23.2%

Abbreviation: BMI, body mass index.

current reporting standards (composite end point of any branch-related complication leading to aneurysm rupture, death, occlusion, component separation, or reintervention to maintain branch patency or to treat a branch-related component separation or endoleaks).[13] Patients' survival was also assessed, and causes of death were obtained by medical records search, review of death certificates when available, or by phone interview with the patient's general practitioner. Patients were excluded from the analysis if complete data were not available for the in-hospital phase and did not have at least 1 post-operative CTA available within the first year of follow-up (if patients survived ≥30 days from the index FEVAR intervention). A patient was considered lost to follow-up when available clinical data were older than 2 years, but death could not be confirmed. All data were evaluated for normality with quantile-quantile plots. Continuous variables are expressed with either mean or median values, with corresponding SD or interquartile range (IQR). Categorical variables are presented as absolute numbers with a percentage. Univariable analyses were carried out with either Student's *T* test or Mann-Whitney *U* test for continuous variables, and χ^2 test or Fisher's exact test for categorical variables. Time-dependent outcomes were reported using Kaplan-Meier curves; differences were determined by the log-rank test. Per-specified subgroup analysis was carried out by repeating life-table estimations of TV instability in the following scenarios: (1) renal arteries versus mesenteric arteries; and (2) small arteries (<6 mm) versus large arteries (6 mm or more); Cook endograft versus Terumo endograft. Statistical analysis and graphing were performed with SPSS Statistical Software.

Results

Study Cohort and Baseline Characteristics

Overall, 81 patients received elective FEVAR during the study period. Mean age of patients was 78 years and 89% were men (Table 1). Mean body mass index in the study cohort was 26 kg/m^2, and 12% had severe chronic kidney disease defined as eGFR <30 mL/min/m^2. Most patients were treated for a juxta-pararenal AAA (68%), and 23% had already received an infrarenal aortic reconstruction.

Procedural Details and Peri-operative Results

All the procedures were performed under general anesthesia, and the mean operative time was 317 minutes (Table 2). Most endografts had 3-vessel or 4-vessel design (27% and 55%, respectively) and a Cook endograft was used in 73% of cases. Overall, 266 Bentley BeGraft were implanted, of which 44 (16.5%) in the celiac trunk, 69 (26%) in the superior mesenteric artery, 79 (29.5%) in the right renal artery, and 74 (28%) in the left renal artery. Technical success was 94%, with 5 instances of technical failure that were noted and required an additional intraoperative procedure (Table 3). In 4 of these cases, the left renal artery was subsequently bridged from an upper arm access; only in 1 case it was not feasible to advance a sheath through the encroaching bare metal stents of a previously placed infrarenal endograft, and the fenestration was left unstented owing to good apposition to the inner aortic wall. Other intraoperative complications included 1 case of kidney hematoma that required intraprocedural embolization and 1 case of iliac dissection that required intraprocedural relining. The early post-operative mortality rate was 4% (1 acute pancreatitis, 1 acute cardiac ischemic event, and 1 pulmonary infection with septic shock), and acute kidney injury occurred in 14 cases with 1 requiring definitive hemodialysis. At discharge, 43% of patients were placed on dual antiplatelet therapy.

Follow-up Outcomes and Subgroup Analyses

Survival at 6, 12, and 24 months in the overall cohort was 98.8%, 95.3%, and 83.4%, respectively (Figure 1). There were no instances of aneurysm-related mortality or need for endograft explantation throughout the entire follow-up period. Freedom from TV instability at 6, 12, and 24 months in the overall cohort was 98.4%, 97.9%, and 97.2%, respectively (Figure 2). Subgroup analyses of freedom from TV instability were performed as previously described. Freedom from TV instability of renal artery versus visceral artery at 6, 12, and 24 months was 97.2% versus 100%, 97.2% versus 98.8%, and 95.9% versus 97.2%, respectively (p=0.19; Figure 3). Freedom from TV instability with Cook graft versus Anaconda graft at 6, 12,

Table 2. Procedural and Postoperative Data.

Parameters	n	Frequency
General anesthesia	82	100%
Prophylactic cerebrospinal fluid drainage	8	9.8%
Procedures time, minutes±SD	317.6±117.7	
Contrast medium, mL±SD	173.8±60.8	
Fluoroscopy time, minutes±SD	97.8±39.8	
Percutaneous femoral access		
Unilateral	5	6.1%
Bilateral	27	32.9%
Endograft design		
1 fen	3	3.7%
2 fen	12	14.6%
3 fen	22	26.8%
4 fen	45	54.9%
Access scallop	19	23.2%
Pre-loaded guidewire	6	7.3%
Type of aortic endograft		
Cook	60	73.2%
Anaconda	22	26.8%
Technical success	77	93.9%
ICU, days	1 (range: 0–58)	
Spinal cord ischemia		
Transient	1	1.2%
Definitive	1	1.2%
Acute kidney injury		
Transient	13	15.9%
Definitive dialysis	1	1.2%
Early reintervention	15	18.3%
Early mortality	3	3.7%
Dual antiplatelet therapy	35	42.7%
Anticoagulant therapy	4	4.9%

Abbreviation: ICU, intensive care unit.

Table 3. Details of Bridging Stent-Grafts.

	n	Vessel diameter, mm±SD	Stent length, mm±SD	Stent diameter, mm±SD	Additional procedure, n (%)
CT	44	7.6±1.6	31.9±7.8	8.1±0.9	1[a] (2.3%)
SMA	69	7.7±1.1	35.5±6.5	8.1±1.4	—
R-RA	79	6.2±1.1	30.6 ±6.7	6.4±0.6	2[b] (3.8%)
L-RA	74	6.1±0.9	30.1±5.9	6.5±0.6	2[c] (2.7%)

Abbreviation: CT, computed tomography; RA, Renal Artery; SMA, Superior Mesenteric Artery.
[a]One angioplasty for ostial stenosis.
[b]One reflaring and 1 relining.
[c]One angioplasty for ostial stenosis and 1 reflaring.

and 24 months was 99.4% versus 95.9%, 98.7% versus 95.9%, and 97.7% versus 95.9%, respectively (p=0.22; Figure 4). Freedom from TV instability of larger artery (6 mm or more) versus smaller artery (<6 mm) at 6, 12, and 24 months was 98.1% versus 100%, 97.5% versus 100%, and 96.5% versus 100%, respectively (p=0.29; Figure 5). Events of TV instability (6 events, 2.2%) included 3 cases of type 1C endoleak and 3 cases of type 3C endoleak, while no events of BSG fracture or thrombosis were noted (Table 4). All but one case of TV instability occurred in renal arteries, and they were all successfully treated by endovascular means.

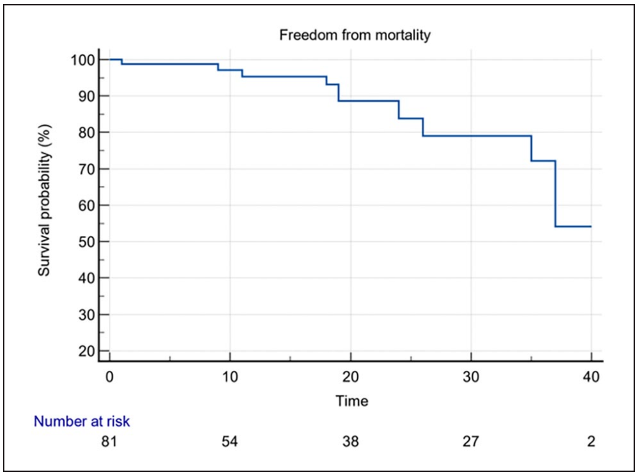

Figure 1. Survival at 6, 12, and 24 months was 98.8%, 95.3%, and 83.4% respectively (SE 0.053; 95% confidence interval, 0.025–0.127).

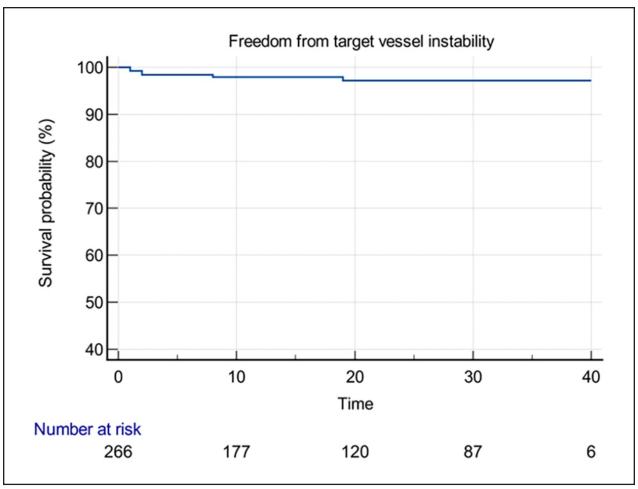

Figure 2. Freedom from target vessel instability at 6, 12, and 24 months was 98.4%, 97.9%, and 97.2%, respectively (SE 0.032; 95% confidence interval, 0.019–0.098).

Discussion

This multicenter retrospective study reports favorable 2-year outcomes of more than 250 Bentley BeGraft stent-grafts used as BSG during FEVAR, which compares extremely well to prior series with this device.[10,11,14] Indeed, all stent-grafts currently used during FEVAR have not been specifically developed for this application, and experts agree there is a need to focus on BSG technology to reduce TV-related issues that remain a significant source for secondary reinterventions.[1,2] In the literature, 2-year TV patency rates after complex EVAR procedures may range from 92% to 98%, but it is not easy to analyze the evidence as a mix of interventions, anatomies, and devices are reported.[4,7] In a prior study, the Bentley

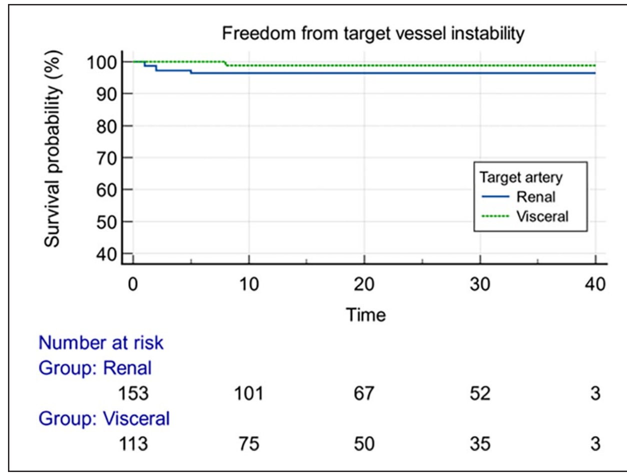

Figure 3. Freedom from target vessel instability of renal artery versus visceral artery at 6, 12, and 24 months was 97.2% versus 100%, 97.2% versus 98.8%, and 95.9% versus 97.2%, respectively (p=0.19) (SE 0.011; 95% confidence interval, 0.006–0.051).

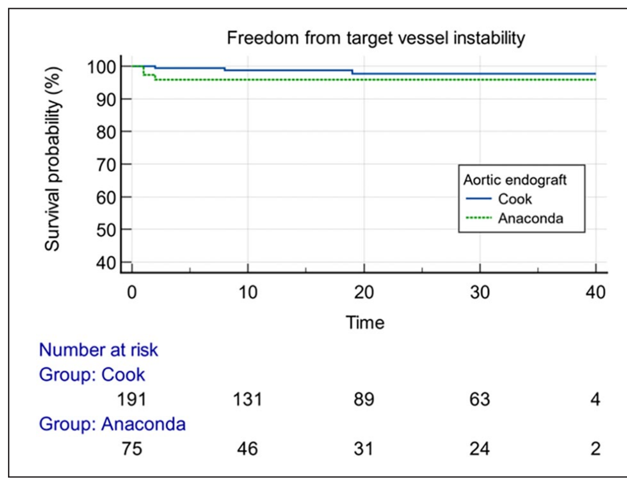

Figure 4. Freedom from target vessel instability with Cook graft versus Anaconda graft at 6, 12, and 24 months was 99.4% versus 95.9%, 98.7% versus 95.9%, and 97.7% versus 95.9%, respectively (p=0.22) (SE 0.011; 95% confidence interval, 0.008–0.046).

BeGraft was associated with a 2% renal occlusion rate, while in our experience, no instances of occlusions were detected.[10] Furthermore, no instances of the low-profile graft fabric tears were observed despite the stents were effectively flared with larger balloons at the level of the fenestrations, as per the standard practice of FEVAR procedures.

It is well known that renal arteries are associated with a higher rate of secondary interventions as compared with visceral arteries.[15,16] This is probably linked to several contributing factors: the kidneys undergo a considerable amount of displacement in response to respiratory motion,

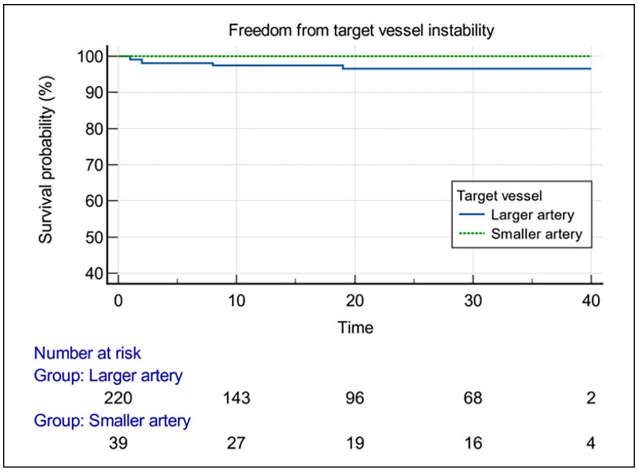

Figure 5. Freedom from target vessel instability of smaller artery (<6 mm) versus larger artery (6 mm or more) at 6, 12, and 24 months was 98.1% versus 100%, 97.5% versus 100%, and 96.5% versus 100%, respectively (p=0.29) (SE 0.012; 95% confidence interval, 0.005–0.032).

the renal arteries typically have a smaller diameter and may have more tortuous anatomy, and the renal parenchyma has higher resistance to end-organ perfusion.[17–19] Despite this, the overall occlusion rate at 2 years in our experience was 0%. However, also in this study, all secondary procedures (but one) were required to treat renal artery issues, namely endoleaks. Indeed, prior evidence has shown that TV-related endoleak at discharge may occur in 1 of 10 patients treated by complex endovascular aortic repair. Of these, two-thirds may resolve spontaneously, especially those affecting directional branches and more extensive repairs with a larger number of TV included have a higher risk for TV-related endoleaks. While the actual mechanism(s) beyond this observation remain difficult to ascertain, it may have resulted from underestimation of the renal artery diameter or insufficient flaring of the BSG. There is also evidence that an optimal geometrical conformation between the BSG and the main body of the aortic endograft at the level of TV is warranted to improve the mid-term outcomes of FEVAR.[9,19] Considering the number of TV, it is reasonable to assume that the risk of endoleak for an individual target artery may be higher in patients with more incorporated vessels. However, one should not compromise on the number of TVs incorporated, if this may result in a suboptimal proximal sealing zone. Previous studies have shown that use of supraceliac sealing zones with 4-vessel incorporation can result in lower rates of type IA endoleaks, which are technically challenging to treat in patients with fenestrated stent-grafts.[20,21] Of note, all the endoleaks in this experience were successfully treated by endovascular means without any requirements for surgical conversion nor any instances of aortic-related death in the whole cohort.

Renal impairment is a major concern after FEVAR, especially in patients with already existing chronic kidney disease, as shown by recent evidence.[22] Therefore, close imaging and laboratory follow-up remains crucial to detect complications promptly and treat them effectively. This is especially true in those patients who may be at higher risk for such complications, such as those with smaller renal arteries or those with non-horizontal geometry.[17,19] Some experts have also suggested that use of dual antiplatelet therapy may be beneficial to improve primary patency rates in smaller and/or angulated TV, but it remains a matter for future research.[23] When discovered, renal artery occlusions should be treated as soon as possible primarily by endovascular means and may be effective in restoring (at least partly) renal function even after 24 hours from the index event.[15] The systematic adoption of on-table cone-beam CT at the end of the procedure, which offers a 3D imaging assessment that is more accurate than a 2D completion angiogram, has been shown to be effective in detecting BSG issues that can be fixed during the same procedure, thus limiting the need for secondary interventions during follow-up.[24–26]

The Bentley BeGraft offers the main advantages of lower profiles available (6 Fr for most stent diameters may represent a significant technical benefit) and because of the 8, 9, and 10 mm diameters with 27 mm lengths, it is well suited to the superior mesenteric artery and celiac trunk. Several in vitro studies have been undertaken to study the biomechanical properties of current BSG.[14] In these studies, the Bentley BeGraft has showed no stent fractures or alteration in the ePTFE coverage on flaring, and similar pull-out forces and resistance to dislocation of the device at 150% of the stent diameter to the Advanta (V12/iCast) device. Other studies have also quantified the geometry and respiratory-induced deformations in abdominal branch vessels after FEVAR using the Bentley BeGraft, showing that it allowed for celiac trunk and renal artery bending similar to that in the native preoperative state; therefore, these findings suggest that the use of this device with FEVAR may closely mimic the native arterial branch geometry and vessel conformability caused by relatively aggressive respiratory motion.[9,18] All the above biomechanical characteristics may translate into excellent durability of the BSG, at least at mid-term, as evidenced by this study.

Irrespective of the devices used as BSG, careful attention should be focused on the protocol of post-operative antithrombotic therapy. The optimal post-operative antithrombotic regimen after complex EVAR procedures is still debated, and no level 1 evidence is available from the current literature. In our analysis, no stent-graft thrombosis was observed, despite only 43% of patients receiving DAPT. Indeed, dual antiplatelet therapy (DAPT) may be considered useful, according to the advantages that are known from cardiologic procedures, but caution should be used in aortic procedures because of the potential risk for bleeding

Table 4. Details of Target Vessel Instability After Mean Follow-up 19.8 Months (±13.2).

Patient	TV	Vessel diameter, mm	Intraoperative adjunct procedure	Type of stent-graft	Proximal flaring diameter, mm	Type of complication	Type of aortic endograft	Type of reintervention	Time from FEVAR, months
N_1	R-RA	6.5	NO	6×28	9	TIcEL	Cook	Relining	19
N_2	SMA	9.9	NO	10×37	12	TIIIcEL	Cook	Angioplasty	8
N_3	L-RA	6.1	NO	6×37	8	TIIIcEL	Anaconda	Relining	1
N_4	L-RA	5.9	NO	6×27	9	TIcEL	Anaconda	Relining	4
N_5	R-RA	6.1	NO	6×27	8	TIIIcEL	Cook	Angioplasty	1
N_6	L-RA	6.1	NO	6×27	9	TIcEL	Anaconda	Relining	2

Abbreviations: FEVAR, fenestrated endovascular aortic repair; TV, target vessel.

complications. In a recent international Delphi consensus study, a panel of experts suggested the use of DAPT only in selected cases, such as small and tortuous vessels or in case of multiple stents.[23] Furthermore, the recent introduction of new combination of drugs (such as Aspirin plus low-dose Rivaroxaban) as medical treatment following peripheral endovascular procedures may open newer scenarios and further research is warranted on this delicate topic.

Study Limitations

The present study has several inherent limitations, and our findings must be interpreted within their context. We performed a retrospective review with a limited sample size which prevented further regression analyses to identify independent associations with the outcomes of interest. However, the study cohort was comparably larger to the few studies already published with the same device. Although the median follow-up was close to 2 years and life-tables estimates were valid up to 3 years, longer follow-up is needed to assess the long-term and durability of the Bentley BeGraft in the reno-visceral position. Furthermore, owing to different practice patterns endorsed at participating institutions, we could not ascertain the reasons beyond the choice to place different FEVAR platforms in each individual patient. Nonetheless, the real-world nature of our study can strengthen the external validity of our findings. Last, as commonplace for retrospective studies, there was no external core-lab adjudication of imaging findings, which were assessed by treating physicians at each participating institution.

Conclusions

The data from this multicentric study show favorable short-term and 2-year outcomes of the Bentley BeGraft as BSG for reno-visceral TV during FEVAR, with low rates of TV-related endoleak and no stent occlusion up to 2 years. Most endoleaks occurred in renal arteries, thereby highlighting the potential need for stricter imaging surveillance to allow early detection of problems and timely reintervention, preventing potentially major adverse events. Future studies are needed to ascertain predictors of complications and assess the long-term durability.

Declaration of Conflicting Interests

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