Early outcomes of t-Branch off-the-shelf multibranched stent graft for Pararenal and Thoraco-Abdominal Aortic Aneurysms: A Prospective, single centre study

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Abstract:

Objective: To investigate outcomes of the off-the shelf t-Branch device (Cook Medical, Bloomington, Ind) for the treatment of thoraco-abdominal and pararenal aortic aneurysms

Methods: All the data from the patients who underwent thoracoabdominal or pararenal aortic aneurysm repair were retrospectively collected in an electronic database and analyzed. Primary outcome was the technical success of the procedure while secondary outcomes were the mortality rate, all cause morbidity, primary branch patency, endoleak, aneurysm sac change, and access related complications after the index procedure. Follow up assessments were scheduled before discharge and at 30 days, six and 12 months after the index procedure.

Results: Between February 2022 and January 2024, 11 patients (mean age 73.4±10.7 years; 10 men; [90%]) underwent endovascular repair using the off-the shelf t-Branch endograft. Most of the patients were treated electively (9/11;81%) while 2 (19%) were emergent cases; The technical success was 100%. In the early period (<30 days), one patient (9%) experienced immediate spinal cord ischemia (grade 3) that has not been restored. During follow-up, one patient had thrombosis in both renal arteries and the flow has been restored with percutaneous angioplasty. The primary branch patency was 95%. No other major events have been reported. Shrinkage of the aneurysm's sac has been detected in 2 patients (18%).

Conclusion: The off-the shelf t-Branch device yielded high technical success with good early and midterm outcomes for the treatment of TAAA and PAAs.

Keywords: Endovascular aortic repair, multibranched stent graft, Off the self, aortic aneurysm, pararenal aortic aneurysm, thoracoabdominal aortic aneurysm

INTRODUCTION

Endovascular repair of thoraco-abdominal (TAAA) and pararenal aortic aneurysms (PAAs) has achieved remarkable success over the last decade, offering low peri-operative morbidity and mortality, especially in patients unfit for open surgical repair.[1,2] Custom-made devices have played a primary role in this success, with manufactures working side by side with the physicians to design grafts tailored to the patient's anatomy, allowing optimal alignment between graft and target vessels.[3]

However, the manufacturing time, which can take up to three months represents the "Achilles heel" of these devices, limiting their applicability in emergency cases.[4] More specifically, patients with large in diameter aneurysms, symptomatic or ruptured cannot resist for this delay and necessitate alternative solutions. In this context, other alternatives such parallel aortic grafts have been proposed, yet gutter endoleak and compromise of the sealing zone remain serious concerns of this technique.[5,6]

The t-Branch (Cook Medical, Bloomington, Ind) introduced in 2009, represents an off-the shelf stent graft that includes four branches for visceral target vessel. This endograft yields encouraging results comparable with those of custom-made devices, and constitutes an appealing option, especially in emergency situations.[7,8]

The aim of this study is to report the early and midterm outcomes of the t-Branch off the shelf device for TAAA and PAAA at a single centre.

MATERIAL AND METHODS

Data from patients with thoracoabdominal aortic aneurysms and pararenal aortic aneurysms who were treated with t-Branch graft at our institution from February 2022 to January 2024 were retrospectively collected and analyzed. All the patients provided written informed consent for clinical research. Owing to the retrospective analysis of the anonymized data,

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the requirement for approval by the local ethics committee was waived.

Treatment indications were elective or symptomatic TAAA or pararenal aortic aneurysms. Patients who had previously undergone endovascular aortic aneurysm repair (EVAR) and subsequently experienced aortic dilatation were also included. The criteria for elective treatment included a maximum aortic diameter of ≥55 mm or rapid growth of an aneurysm (≥10 mm during 12 months). Symptomatic cases were defined as the presence of aneurysm-related pain, peripheral embolization, or contained rupture.

Follow-up

All the patients were followed-up clinically and with computed tomography angiography scan at 1, 6 and 12 months and annually thereafter. In cases where there was a suspicion of endoleak or branch vessel malperfusion, a digital substraction angiography was performed for further evaluation.

Endovascular technique

Computed Tomography angiography was performed in every patient before the endovascular procedure. All post-CT angiography images were transferred to a dedicated software workstation (Osirix MD (Pixmeo SARL, Geneva) or_3mensio Vascular Workstation (Pie Medical Imaging, BV, Maastricht, the Netherlands) to obtain preoperative measurements. All interventions were performed in a conventional for open repair operational theatre, equipped with a digital mobile C-arm (BV Pulsera, Koninklijke Phillips N.V., up to December 2022 and Ziehm Imaging GmbH, since January 2023).

Each patient was placed in the supine position. Both groins were prepared and draped. All the procedures were performed with the patient under general anesthesia. A broad-spectrum antibiotic was administered, a femoral artery cutdown or a percutaneous approach was performed in both groins, and the patient received 100U/kg units of heparin with a target activated clotting time of >250 seconds. The technique of the t-Branch implantation has been described before.[9] For catheterization of the branch vessels, the left axillary artery was the most common. Our strategy for reducing the cerebrovascular events was the insertion of a 12x45cm Flexor Check-Flo introducer (Cook Medical, Bloomington, Ind) and through it an Arrow sheath 8x90cm (Teleflex Medical Europe Ltd) to join the branches. Each branch with its corresponding artery was catheterized, wire and stented with balloon expandable Be-Graft [Bentley, Innomed GmbH, Germany], or VBX [W. L. Gore & Associates]) covered stents. In cases of severely angulated or tortuous visceral arteries (commonly the renal arteries) or long distances between the visceral branch and the target vessel ostium, relining of the bridging stents was performed with balloon-expandable or self- expanding stents.

Definitions and outcomes

The primary objective of the present study was technical success. Secondary objective was to assess the early (<30days) and late mortality rate, all cause morbidity, primary branch patency, endoleak, aneurysm sac change, and access related complications after the index procedure.

Technical success was defined as successfully completed treatment with exclusion of the aneurysm without type I or type III endoleak (EL), target vessel (TV) occlusion or injury, conversion to open repair, or intraoperative mortality. Morbidity was defined as a severe adverse event such as spinal cord ischemia, stroke, myocardial infraction, respiratory decline, mesenteric ischemia, and any unplanned reintervention.[10] Spinal cord ischemia (SCI) was defined any new neurological deficit of the lower limbs that leads to paraplegia (complete inability to move the lower limbs) or paraparesis (lower limb weakness; required assistance to stand or to walk) after the index procedure. Its appearance could be immediate (up to the first 12 hours postoperatively) or late (after 12 hours postoperatively) while further could be subdivided in temporary or permanent.[11] The TAAA classification by Crawford was presented by Safi in revised version.[12] PAAs were defined as aneurysms, degenerative in aetiology, that had no sufficient length of normal aorta between the upper extent of the aneurysm and the renal arteries to allow a conventional EVAR or necessitating suprarenal aortic clamping for open repair. They are further classified into 3 types; short neck infrarenal (<10 and >4mm infrarenal neck), juxtarenal (0-4 mm infrarenal neck) and suprarenal which involve at least one renal artery sparing the orifice of the superior mesenteric artery.[10]

Data analysis

Continuous data were reported as mean ± standard deviation (SD) and median (range) respectively. Categorical data were expressed as absolute numbers and percentage prevalence in the study cohort. P value was considered significant when it was <.05. Statistical analysis was performed by SPSS 26.0 for Windows software (IBM Corp, Armonk, NY).

RESULTS

Patient characteristics

Between February 2022 and January 2024, 11 patients (mean age 73.4±10.7 years; 10 men; [90%]) underwent endovascular repair using t-Branch endograft. Most of the patients were treated electively (9/11;81%) while 2 (19%) were emergent cases; Patient characteristics are illustrated in Table 1. The American Society of Anaesthesiologists classification for assessment of the patients' status was class II (8;73%), III (3;27%) (Table 2). The aneurysm classification was pararenal aortic aneurysms in 8 (73%) patients, Crawford extend type II in 2 (18%) patients (figure 1) and one (9%) patient who had undergone EVAR a few years ago and presented with a type Ia endoleak. The mean maximum aneurysm diameter was 73.7±15.8mm.

Procedure details

The median operation time was 240 minutes (range, 180-310) while the mean fluoroscopy time was 72 minutes (range, 51-271) (Table 2). Two patients suffered from Crawford type II TAAA, and they underwent a staged procedure at 6 weeks and

Table 1: Demographics, comorbidities, and pre-operative aneurysm features of 11 patients with thoraco-abdominal or pararenal abdominal aortic aneurysm included in the study

Characteristic	Patients (n)
Demographics	n/(SD)
Age (years)	73.4 ± 10.7
Male (sex)	10 (90%)
Comorbidities	
Hypertension	11
CAD	2
Hyperlipidaemia	9
Chronic kidney disease	2
COPD	1
Smoking	11
Diabetes	6
Stroke	1
PCI	2
ASA score	
1	0
2	8
3	3
Aneurysm Features	
Pararenal	8
Extent II TAAA	2
Failed previous EVAR	1
Type of presentation	
Elective	9
Emergent	2
Maximum aneurysm diameter (mm)	73.7 ± 15.8
Diameter of renovisceral artery (mm)	
Celiac Trunk	8.1 ± 0.7
SMA	7.8 ± 0.5
Left renal artery	6.0 ± 0.7
Right renal artery	5.6 ± 0.6
Length of renovisceral artery (cm)	
Celiac Trunk	2.7 ± 0.6
SMA	3.0 ± 0.8
Left renal artery	2.5 ± 0.9
Right renal artery	3.3 ± 1.6

Data are presented as mean ± standard deviation (SD) or as n (%).
CAD: coronary artery disease; **COPD:** chronic obstructive pulmonary disease; **PCI:** percutaneous coronary intervention; **ASA** =American Society of Anesthesiologists; **EVAR:** Endovascular aortic repair; **TAAA:** Thoracoabdominal aortic aneurysm

Table 2: Procedural details in 11 patients with thoraco-abdominal or pararenal abdominal aortic aneurysm

Characteristic	Patients (n)
CSF drainage	0 (0)
Operation time (min)	240 minutes (range, 180-310)
Fluoroscopy time (min)	72 minutes (range, 51-271)
Contrast volume (ml)	160 (60-210)
ICU stay (days)	0 (0)
Renovisceral arteries	44
Balloon expandable covered stents (Begraft/Bentley)	44
Self-expandable bare metal stent (Lifestent, Bard)	4
Relining	4

Data are presented as median (range), and as n (%). **ICU**= intensive care unit; **ASA** =American Society of Anesthesiologists **CSF=** Cerebrospinal fluid Drainage

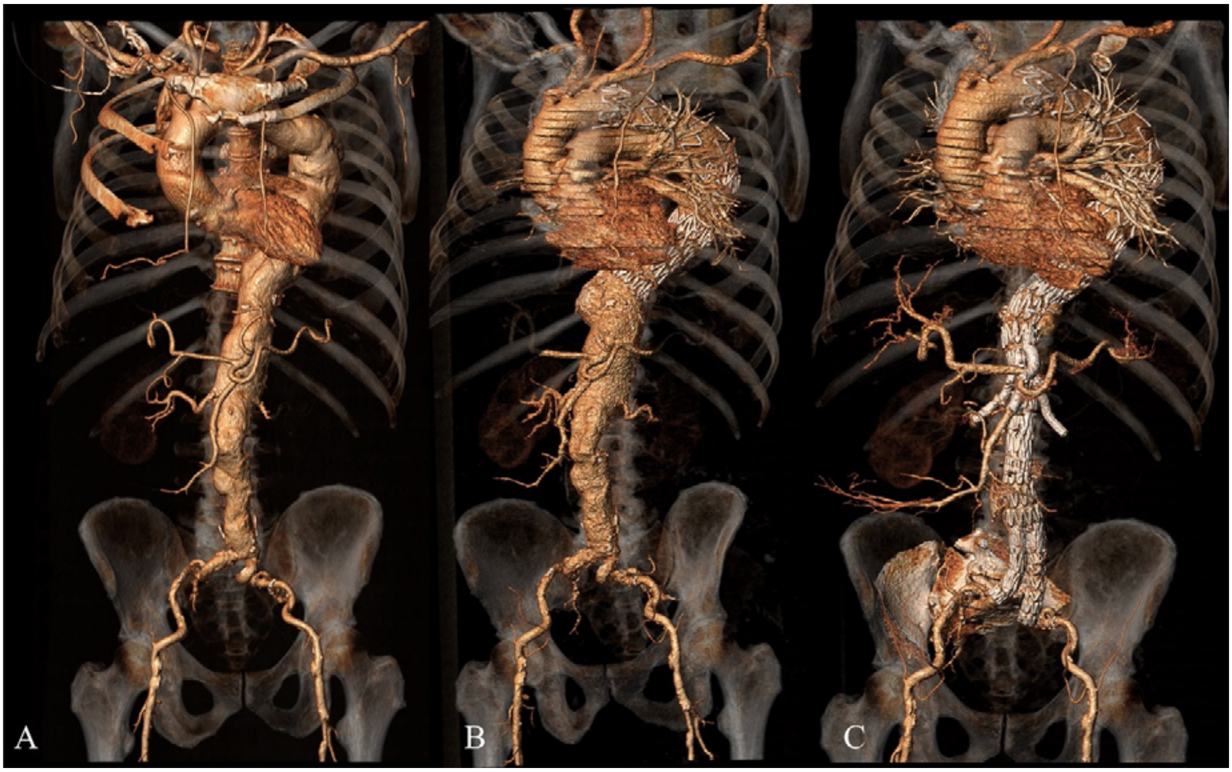

Figure 1. a) Preoperative 3-D reconstruction b) First stage (TEVAR) c) Second stage (off-the shelf multibranched stent graft

4 months respectively. One of them, had history of stroke with left hemiplegia few years ago and he decided after the first Thoracic endovascular aortic repair (TEVAR) procedure to postpone the second stage. A total of 44 renovisceral arteries were reconstructed with overall 48 visceral stents. Due to the abrupt upward angulation of 4 renal arteries, relining has been performed using self-expandable bare metal stent (Table 2).

30-day Outcomes

The technical success was achieved in all 11 patients (100%). No death occurred during this period. One patient (9%) with TAAA Crawford type II, experienced spinal cord ischemia within 24 hours of the index procedure's second stage. Cerebrospinal fluid drainage was immediately implemented in this patient and strict monitoring was maintained including measurement of median arterial pressure (MAP≥80mmHg), drainage of cerebrospinal fluid, the haemoglobin level ≥8 g/dl, and strict hydration. Despite these efforts, the patient was discharged after 7 days without any neurological improvement. Two (18%) patients experienced a slight deterioration of renal function which resolved by discharge. There were no other severe complications such as respiratory failure, myocardial infarction, stroke, mesenteric ischemia, or the need for re-intervention within 30 days post-operatively. Three (27%) patients developed groin haematoma without bleeding. Table 3 reports the 30-day outcomes of the 11 enrolled patients.

Outcomes beyond 30-day postoperatively

The median follow-up period was 6 months (range, 1-22 months). There were no deaths in this period. One patient suddenly appeared pulmonary oedema due to deterioration of the kidney function. He underwent immediately in haemodialysis and in CTA scan that revealed thrombosis of both renal arteries. He underwent in percutaneous transluminal angioplasty in both renal arteries and relining with self-expandable stenting with successful restoration of the arterial flow. Slowly, the patient was weaned from the dialysis, and remained asymptomatic up to date. The primary branch patency was 95%. During the follow up period, 4 type II endoleak were detected with stable aneurysm sac and remained in surveillance. No other type of endoleak has been detected. Nine (82%) patients presented stable aneurysm sac and two patients (18%) shrinkage. No dilatation of aneurysm sac has been detected (Table 3).

DISCUSSION

In the present study we report the early and mid-term results of the t-Branch for TAAAs and PAAs in both elective and emergent situations. The technical success rate was high, with no mortality events. The main reason of these acceptable outcomes was that the patients had been treated within the instructions for use for t-Branch stent graft. Another factor was that most of the patients (81%) were operated on in elective situations rather than emergently. Cases in emergent situations and outside the instructions for use might be more technically demanding, requiring longer operation and fluoroscopy times. Silingardi et al[13] attempted to compare the elective and emergent/urgent treatment for patients with TAAAs. Their findings indicated a higher mortality rate and adverse events rate in emergent/urgent situations as well as longer

Table 3: 30-day and one year outcomes of the enrolled 11 patients with thoraco-abdominal or pararenal abdominal aortic aneurysm

Outcome	0-30 days	>30 days
Clinical outcomes	n/(%)	**n/(%)**
Patients (n)	11	11
Technical success	15 (100)	-
Mortality	0 (0)	0 (0)
Spinal cord ishemia		
Grade 0	10 (90%)	10 (90%)
Grade 1	0 (0)	0 (0)
Grade 2 (paraparesis)	0 (0)	0 (0)
Grade 3 (paraplegia)	1 (10%)	0 (0)
Renal function decline	2 (18%)	0 (0)
Dialysis	0 (0)	1(10%)
Respiratory failure	0 (0)	0 (0)
Myocardial infraction	0 (0)	0 (0)
Stroke	0 (0)	0 (0)
Mesenteric ischemia	0 (0)	0 (0)
Access related complcations		
Hematoma	3 (27%)	0 (0)
Pseudoaneurysm	0 (0)	0 (0)
Arteriovenous fistula	0 (0)	0 (0)
Thrombosis or dissection	0 (0)	0 (0)
Reintervention	0 (0)	1(10%)
Imaging outcomes		
Patients (n)	11(100%)	11(100%)
Primary branch patency	100%	90%
Endoleak		
Type I	0 (0)	0 (0)
Type II	0 (0)	4 (36%)
Type III	0 (0)	0 (0)
Aneurysm Diameter change		
Stabilisation	-	9 (82%)
Shrinkage	-	2 (18%)
Increase	-	0 (0)

Data are presented as n (%)

operation and fluoroscopy times compared with the elective group. Unfortunately, in the present study we cannot confirm these findings due to the lack of a robust sample in elective and emergent situations.

Regarding the postoperative morbidities, spinal cord ischemia represents the most dreadful event. In open surgical repair the rate of permanent neurological deficit ranges from 3% to 8%.[14,15] In a recent systematic review and meta-analysis on endovascular treatment with the t-Branch device, the rate of SCI was 12.2% (range, 4.1%-23.2%), with the rate of permanent paraplegia ranging from 0% to 8.7%.[16] In our series, one Crawford type II patient (9%) experienced immediate paraplegia. A possible explanation might be the prolonged coverage of the aorta within a short timeframe between the two stages. During preoperative planning and discussion of the case, we agreed to leave a side branch or an iliac extension open and complete the repair a few days later. However, intraoperatively, the patient had a heavily calcified aorta and presented hemodynamic instability despite continuous anesthesiological support. Consequently, we decided to complete the repair and to evaluate him upon awakening. Another weak point contributing to this result, is the avoidance of using CSF drains. The role of spinal drainage in preventing SCI is debatable today. Recent studies have demonstrated that although the incidence of SCI after F/B-EVAR with selective spinal drainage was low, major spinal drainage-related complications may exceed the SCI rate and undermine the benefits of using spinal drainage.[11]

The primary branch patency in the present study was also high (95%). Only one case of bilateral thrombosis of the renal arteries have been reported. This rate is similar to other recent publications in the literature which, range from 96% to 99%.[16] One possible explanation of this failure might be the emergent nature of the case and the severely upward angulated renal arteries. Unfortunately, we did not perform the relining technique and the use of balloon expandable covered stent graft, which, is less flexible, led to this unforeseen event. However, a successful reintervention has been performed using PTA and relining, achieving patency of both renal arteries. The present reintervention rate (5%) was comparable to the previously reported data of 14% to 36%.[13,17]

Last but not least, access related complications (27%) were noted in the present study. One possible explanation might be that we selected the cut-down for femoral arteries exposure instead of percutaneous technique. This situation was exacerbated after the administration of iv Heparin intraoperatively to achieve an ACT value >250 sec. Unfortunately, there is lack of standardization regarding the strategy of heparin administration in these procedures. Initially, due to the lack of experience, we attempted to maintain an ACT > 250sec throughout the entire procedure. However, this strategy was later revised, and now we aim to maintain an ACT≥200sec during the catheterization of the last branch. This adjustment significantly reduced the appearance of hematomas in subsequent operations.

The present study presents some limitations. Firstly, it was conducted at a single centre with limited sample size. A larger number of patients, both in elective and emergent/urgent situations, is needed to compare the performance of the technique in these scenarios. Secondly, it is retrospective in nature and has a short follow-up period. A longer follow-up timeframe is needed to better understand the requirements of the t-Branch device and the technique. Thirdly, these outcomes were influenced by the management and the decisions of three different physicians. Unfortunately, there was not a single master orchestrating the procedure, as might be happen in high-volume centres.

CONCLUSION

The off the shelf t-Branch endograft was designed to address difficult anatomies and situations either for TAAAs or PAAs. The high technical success and the good early and midterm outcomes of the t-Branch in this study support continued clinical investigation.

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