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Urgent endovascular repair of juxta/para-renal aneurysm by off-the-shelf multibranched endograft.

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ARTICLE HIGHLIGHTS

Type of Research.

Multicenter, observational study and retrospective.

Key Findings.

One hundred and ninety-seven urgent juxta/para-renal aneurysms were treated by off the shelf multibranched thoracoabdominal endograft in 23 European centers. The mean aortic coverage between the upper portion of the endograft and the lowest renal artery was about 150mm. Technical success , 30-day/in-hospital mortality and spinal cord ischemia were 92%, 11% and 6%, respectively. Estimated 3-year survival, freedom from target arteries instability and freedom from reinterventions were 58%, 72% and 77%, respectively. Risk factors for technical failure, spinal cord ischemia , 30-day/in-hospital and follow-up mortality were identified.

Take home Message.

Urgent repair of juxta/para-renal aneurysms by off the shelf multibranched thoracoabdominal endograft is feasible and effective with satisfactory technical success and 30-day/hospital mortality in high-risk patients. An extensive aortic coverage is necessary due to device-design, leading to a not negligible spinal cord ischemia rate, especially in case of aortic rupture or when adjunctive thoracic endografts are necessary. Predictors of technical failure , spinal cord ischemia and mortality were identified and should be considered for surgical indication and outcomes' optimization.

Table of Contents Summary.

Off the shelf multibranched thoracoabdominal endograft was adopted in 197 urgent juxta/para-renal aneurysms with 92% of technical success , 11% of 30-day/in-hospital mortality and 6% of permanent paraplegia. Estimated 3-year survival, freedom from target arteries instability and reinterventions were 58%, 72% and 77%, respectively.

ABSTRACT

Objective. To report outcomes of urgent juxta/para-renal aneurysms (J/P-AAAs) managed by off-the-shelf multibranched thoracoabdominal endografts (Cook, T-branch).

Methods. In this observational, multicenter, retrospective study, patients with J/P-AAAs treated by urgent endovascular repair by T-branch in 23 European aortic centers, from 2013 to 2023, were analyzed. Contained J/P-AAAs rupture, presence of related symptoms, and aneurysm diameter >70mm were considered as indication for urgent repair. Technical success (TS), spinal cord ischemia (SCI) and 30-day/hospital mortality were assessed as early outcomes. Survival, freedom from (FF) reinterventions and target arteries instability (TAI) were evaluated during follow-up.

Results. Overall, 197 patients [J-AAAs:64(33%), P-AAAs:95(48%), previous failed-EVAR 38(19%)] were analyzed. The mean age and aneurysm diameter was 75±8 years and 76±4 mm, respectively. The ASA score was 3 and 4 in 118(60%) and 79(40%) patients. Rupture, symptoms and diameter >70mm were present in 51(26%), 110(56%) and 53(27%) patients, respectively. An adjunctive proximal thoracic endograft was used in 28(14%) cases. The mean aortic coverage between the upper portion of the endograft and the lowest renal artery was 154±49mm. Single-stage repair and cerebral-spinal-fluid drainage were reported in 144(73%) and 53(27%) cases, respectively. TS was achieved in 182(92%) cases (rupture:84% vs no rupture:95%; P:.02). Failures consist of target artery loss (11-6%: renal artery - 9; celiac trunk - 2), type I-III endoleak (2-1%) and 24-h mortality (2-1%). Rupture was a risk-factor for technical failure (P:.02;OR:3.8;95%CI:1.1-12.1). Overall, 15(8%) patients had persistent SCI (rupture:14% vs no rupture:5%) with 11(6%) cases of paraplegia (rupture:10% vs no rupture:5%; P:.001). Rupture (P:.04;OR:3.1;95%CI:1.1-8.9) and adjunctive proximal thoracic endograft (P:.01;OR:4.1;95%CI:1.3-12.9) were risk-factors for SCI. Twenty-two (11%) patients died within 30-day or during a prolonged hospitalization. Previous failed-EVAR (P:.04;OR:3.6;95%CI:1.1-12.3), paraplegia (P:<.001;OR:9.9;95%CI:1.6-62.2), postoperative mesenteric complications (P:.03;OR:10.4;95%CI:1.2-93.3) as well as cardiac (P:.03;OR:8.2;95%CI:2.0-33.0) and respiratory (P:<.001;OR:10.1;95%CI:2.9-35.2) morbidities were associated with 30-day/hospital mortality. The mean follow-up was 19±5months. Estimated 3-year survival and FF-reinterventions was 58% and 77%, respectively. TAI occurred in 27(14%) patients (occlusion:15, endoleak:14) with an estimated 3-year FF-TAI of 72%.

Conclusions. Urgent repair of J/P-AAAs by T-branchis feasible and effective with satisfactory TS and 30-day/hospital mortality in high-risk patients. However, extensive aortic coverage is necessary, leading to a not negligible SCI rate, especially in case of aortic rupture or when adjunctive thoracic endografts are necessary. Previous failed-EVAR, postoperative mesenteric complications as well as cardiac and respiratory morbidities were associated with 30-day/hospital mortality and they should be subjected to more research for the purpose of improving outcomes.

INTRODUCTION.

Fenestrated and branched endografting (F/B-EVAR) is an established endovascular solution to treat juxta/para-renal (J/P-AAAs) and thoracoabdominal aneurysms (TAAAs) with proven early/mid-term outcomes in high-risk patients, when anatomically feasibile.[1-5] These treatments are carried out by patient specific or off-the-shelf endografts, according to the clinical scenarios (elective vs urgent cases) and anatomical characteristics.[1-5]

Patient specific F/B-EVAR are routinely used to manage J/P-AAAs and TAAAs in elective situations, however manufacturing delays and anatomical limitations reduce their efficacy in urgent cases.[6,7] In 2012, the Cook Zenith T-branch (Cook Medical, Bloomington, IND, US) became the first off the shelf multi branched (OTS m-BEVAR) TAAA endograft commercially available in Europe, showing worldwide reproducible results in patients who cannot be timely managed by a custom-made solution.[8-10] Potential off-the-shelf FEVAR solutions (Cook Zenith P-Branch) have been investigated for J-AAAs in preliminary experiences, even if they are not yet commercially available in Europe or US.[11,12]

Physician modified endografts (PMEG) are another possible solution, however their use is limited by their discordance from IFU, longer operative time and necessity of highest level of expertise in their planning and preparation.[13]

If employed in urgent J/P-AAAs, OTS m-BEVAR endografts carry an enhanced risk of spinal cord ischemia (SCI), due to an extensive supra-celiac aortic coverage [14-16], possible intra-operative target arteries (TAs) loss - due to the narrow aortic lumen at the level of TAs - and diminished TAs follow-up patency - due to a lower long-term performance of renal branches vs fenestrations.[17-20] However, this strategy has not been investigated in an urgent setting.[9]

Aim of the present study is to report early/mid-term outcomes of urgent endovascular J/P-AAAs repair by Cook Zenith T-branch endograft in a multicenter European experience.

METHODS.

Study design, patient' selection.

This is an observational, multi-center, retrospective study performed without fundings from companies or other organizations. All patients undergoing urgent endovascular repair of J/P-AAAs by Cook Zenith T-branch in European aortic centers, from January 2013 to June 2023 were prospectively collected. Each patient signed a dedicated informed consent for the endovascular aortic repair and their anonymous data analysis for clinical studies. According with the European General Data Protection Regulation (GDPR), all cases were deidentified with a coding number and clustered in a shared electronic database. Anatomical, procedural, and post-operative data were retrospectively analyzed. Approval by Local Review Boards was not required due to the retrospective and anonymized nature of the study.

Inclusion / Exclusion criteria

Inclusion criteria were urgent endovascular repair by Cook Zenith T-branch in: J-AAAs, P-AAAs, proximal type I endoleak in previously failed EVAR or chimney (Ch-EVAR) without TAAA evolution above. For the present study, urgent endovascular repair was defined as the presence of symptoms (acute pain / peripheral embolization), contained aortic rupture and asymptomatic aneurysm with diameter > 70 mm.

Exclusion criteria were hemodynamic instability defined as loss of, or reduced level of consciousness or systolic blood pressure < 80 mmHg, according with the current ESVS guidelines for abdominal aortic - iliac aneurysm management.[21]

Endpoints and definitions

Technical success (TS), SCI and 30-day/in-hospital mortality were assessed as early endpoints. Survival, freedom from reinterventions (FFR) and TAs patency / instability (TAI) were evaluated as follow-up endpoints.

Preoperative comorbidities / cardiovascular risk-factors, anatomical and operative features as well as postoperative results were reported according to the current SVS-reporting standards of endovascular aortic repair of aneurysms involving the mesenteric and renal arteries.[1] Particularly, the definition of TS includes successful access to the arterial system, deployment of the aortic / iliac endografts, TVVs catheterization and placement of bridging stents with restoration and maintenance of flow in all intended target vessels, absence of type I or type III endoleaks at completion angiography and confirmed at 30-day radiological exams and patency of all aortic modular stent graft and intended side branch components.[1] Target artery instability was defined as any branch-related complication leading to aneurysm rupture, death, occlusion, component separation, or reintervention to maintain TAs patency or to treat TA-related component separation or endoleaks.[1] Reinterventions were defined as any procedure related to the aneurysm, device, TAs, or access occurring after the date of the index operation.

Statistical Analysis

Continuous data were reported as a mean and standard deviation (SD). Categorical data were expressed as frequency. Risk factors for TS, SCI and 30-day/in-hospital mortality were evaluated by uni- and multivariate analysis. Survival, FFR, FF TAI were estimated by Kaplan-Meier analysis. Risk factors for follow-up mortality were investigated by Cox Regression. P value was considered significant when < 0.05. Statistical analysis was performed by SPSS 28.0 (SPSS Inc., Chicago, IL, USA).

RESULTS.

Patient selection. Overall, 197 patients were enrolled in 23 European aortic centers (*Online Table I*). The mean age was 76 $\pm$ 7 years, the ASA score was 3 and 4 in 118 (60%) and 79 (40%)

patients, respectively. Demographics, cardio-vascular risk factors and preoperative comorbidities are summarized in *table I*. Rupture, symptoms, and diameter > 70 mm were present in 51 (26%), 110 (56%) and 53 (27%) patients, respectively.

Anatomical features, preoperative sizing and endograft planning.

Aortic pathologies were J-AAA, P-AAA and previous failed-EVAR in 64 (33%), 95 (48%) and 38 (19%) cases, respectively. In the latter group, 4 (2%) patients had a previous failed Ch-EVAR. The mean aneurysm diameter was 76 ± 4 mm. The mean proximal oversizing was 15% (range: 9 - 27%) and in 28 (14%) cases an adjunctive proximal thoracic endograft was necessary to achieve an effective proximal sealing. The mean aortic coverage between the upper portion of the endograft and the lowest renal artery was 154 ± 49 mm (isolated T-branch: 146 ± 34 mm; proximal TEVAR + T-branch: 199 ± 42). There were 750 TAs accommodated by branches:184 (25%) celiac trunks, 195 (26%) superior mesenteric arteries and 371 (49%) renal arteries. Twenty-seven (14%) patients had at least one preoperative hypogastric artery occlusion, which was bilateral in 4 (2%) cases. In 17 (9%) cases an iliac branch device was planned to manage concomitant iliac aneurysms maintaining the patency of the hypogastric artery. Anatomical and sizing / planning details are reported in detail in *table II*.

Procedure.

All procedures were performed under general anesthesia. Single-stage repair and prophylactic cerebral-spinal-fluid drainage were reported in 144 (73%) and 53 (27%) cases, respectively. In the 53 (27%) cases managed by a multi-stage approach (symptomatic cases: 21; asymptomatic cases with aneurysm diameter > 70mm: 32), the mean inter-step time was 5 ± 1 days and in all cases the complete aneurysm exclusion was achieved in the same hospitalization. *Online table II* summarizes the different strategies of procedural staging. Femoral access was surgical, percutaneous or both surgical and percutaneous in 53 (27%), 137 (70%) and 7 (3%) cases, respectively. An axillary / brachial access was performed in 173 (90%) cases. Catheterization and stenting of TAs was performed by trans-axillary, trans-femoral or both trans-axillary and trans-femoral approach in 165 (84%), 24 (12%) and 8 (4%) cases, respectively. The partial deployment technique was adopted in 36 (18%) cases to allow the TAs cannulation when para-visceral aortic diameter was < 25 mm. *Online table III* summarizes types of bridging covered stents adopted in each TA. Relining by bare metal stents was performed in 89 / 750 (12%) TAs (celiac trunk: 23/184; superior mesenteric artery: 21/195; renal artery: 45/371) to correct compression of the covered stents (52-58%), acute angulation between covered stent and native TAs (32-36%) or a dissection (5-6%).

There were 38 renal/celiac arteries preoperatively occluded, and the respective branches of the T-branch were managed by cuff extension (balloon expandable covered stent) and plug.

Overall procedural and fluoroscopy time were 290 $\pm$ 117 and 80 $\pm$ 40 minutes, respectively. Iodinated contrast media volume and DAP was 192 $\pm$ 89 mL and 236 $\pm$ 92 Gy/cm^2, respectively.

Technical success was achieved in 182 (92%) cases (rupture: 84% vs no rupture: 95%; P:.02). Failures consist of 11(6%) TAs loss (renal artery: 9; celiac trunk: 2), 2(1%) type endoleaks (Ib:1; Ic from renal artery:1) and 2(1%) cases of 24-h mortality.

TAs patency at completion angiography was 99% (739/750). Both endoleaks were detected at the first postoperative CTA (before discharge:1, at 30-day:1) and were successfully managed (iliac branch device:1; renal artery relining: 1). Rupture was a risk-factor for technical failure (P:.02; OR:3.8; 95%CI:1.1-12.1). Procedural details and early outcomes were summarized in *table III.*

Overall, 15 (8%) patients had persistent SCI (rupture: 14% vs no rupture: 5%; P:.001) with 11 (6%) cases of paraplegia (rupture: 10% vs no rupture: 5%; P:.001). Rupture (P:.04; OR:3.1; 95%CI:1.1-8.9) and adjunctive proximal thoracic endograft (P:.01; OR:4.1; 95%CI:1.3-12.9) were independent risk-factors for SCI (*table IV*). The mean hospital stay was 13 ± 3 days (single-stage approach: 8 ± 3 days; multi-stage approach: 17 ± 4 days).

Twenty-two (11%) patients died within 30 days or during a prolonged hospitalization. Previous failed-EVAR (P:.04; OR:3.6; 95%CI:1.1-12.3), paraplegia (P:<.001; OR:9.9; 95%CI:1.6-62.2), postoperative mesenteric complications (P:.03;OR:10.4;95%CI:1.2-93.3) as well as cardiac (P:.03;OR:8.2;95%CI:2.0-33.0) and respiratory (P:<.001;OR:10.1;95%CI:2.9-35.2) morbidities were independent risk factor for 30-day/hospital mortality (*table V*).

Follow-up.

The mean follow-up was 19 ± 5 months. Twenty-seven (14%) patients needed at least one reintervention (within 30-day: 4; after 30-day: 24) with 4 (2%) cases requiring multiple reinterventions. Timing, cause, treatment, and results of each reintervention are summarized in *online table IV*. Estimated FFR was 91%, 84% and 77% at 1, 2 and 3 years, respectively (*figure 1a*).

TAI occurred in 27(14%) patients [within 30 days: 3 (11%); after 30 days: 24 (89%)] and in 8 (4%) cases more than 1 vessel was instable. There were 15 TA occlusions (renal arteries: 10, superior mesenteric artery: 3, celiac trunk: 2) and 20 TAs related endoleaks (renal arteries: 13; superior mesenteric artery: 3; celiac trunk: 4). Causes of the 35 TAIs are summarized in *online table V.* There was no difference in terms of patency between TAs with and without relining by bare metal stents (relining: 3/89 vs no relining: 12/661; P:.41).

Estimated FF-TAI (patients) was of 93%, 85% and 72% at 1, 2 and 3 years, respectively (*figure 1b*).

Overall, 60 (30%) patients died (within 30-day: 22, after 30-day: 38) with 2 (1%) cases of aortic - related mortality. Causes of mortality are summarized in *online table VI*. Estimated survival was 81%, 66% and 58% at 1, 2 and 3 years, respectively (*figure 1c*).

DISCUSSION.

In the present manuscript we report a series of 197 urgent J/P-AAAs treated in the last 11 years by T-branch in 23 European aortic centers.

Technical success, 30-day/hospital mortality and SCI were 92%, 11% and 8%, respectively with an estimated 3-year survival, FFR and FF TAI of 58%, 77% and 72%, respectively. These results can be considered satisfactory, especially if we consider that they were obtained in high-risk patients and urgent clinical setting.

As reported by the SVS practice guidelines on the care of patients with abdominal aortic aneurysm, perioperative mortality of open repair procedures can be predicted according to preoperative patient's and procedural characteristics.[22] For example, a patient ≥ 75 years old, with aneurysm diameter ≥ 65 mm, preoperative CRF, severe COPD and need of suprarenal aortic cross clamping, has a predictive score of 11, corresponding to a prohibitive perioperative mortality of 31%.[22]

This risk increases further in urgent situations. Mortality after open repair of urgent complex aortic aneurysm can be as high as 32%.[21,23] Comparative studies between open and endovascular repair of ruptured complex AAAs are rare and possibly influenced by patient's heterogeneity. In a propensity score analysis from the American College of Surgeons, open repair had a 1.75-fold higher risk of perioperative mortality compared with cases managed by endovascular technique.[21,24] Moreover, open repair was associated with higher pulmonary complications, bowel ischemia, and longer ICU stays.[21,24]

A clear definition of urgent complex aneurysm repair is of paramount importance to obtain homogeneous data for further comparisons/analysis. According to our inclusion criteria, 3 different clinical situations are considered as urgent J/PAAAs: those with rupture (26%), those with symptoms (56%) and those larger than 70 mm in diameter (27%). Each of these scenarios carries different risks, complications and outcomes and should be considered separately as summarized in table 3. Ruptures and symptomatic J/PAAAs have worse clinical outcomes compared with asymptomatic large aneurysms. The latter should be considered as 'relatively' urgent cases, due to the risk of acute aortic events occurring in the lead time of the device customization. Different clinical experiences have reported a mean waiting time $\geq$ 3 months, with aneurysm rupture occurring in up to 3% of cases, with an aortic diameter $\geq$ 70 mm an independent predictor of this risk.[6,7] Ruptures have the worst technical and clinical outcomes even if cases with hemodynamic instability are excluded; probably these cases had not an ideal anatomical situation, associated with a high fragility of patients.

F/B-EVAR by patient specific device should be the first endovascular strategy for elective complex aneurysms according to the current ESVS guidelines,[21] but in urgent cases other different OTS endovascular solutions should be adopted for a prompt repair.

Parallel graft technique and standard abdominal endograft plus endoanchors have been proposed for urgent JAAAs with specific anatomical characteristics and lack of other solutions.[21] Recently, we have demonstrated that they have an anatomical feasibility in 37% and 27% of cases if performed inside IFU by CE mark materials.[25] Cherfan et al reported an experience of 58 complex aneurysms managed in urgent and elective situations by chimney and periscope techniques. [26] Fourteen (24%) cases developed endoleak, 11 (19%) required reinterventions for an endoleak while 10 (17%) for compression / occlusion of the parallel graft.[26] According with these data, the authors concluded that chimneys/periscopes lead to poor outcomes, due to their low technical success, high morbidity/mortality and reintervention rates.

Physician modified endografts (PMEG) have been widely reported by US surgeons in the last decades and it is now gaining popularity in Europe as well. In urgent or even elective cases with complex aortic aneurysms, fenestrations or branches are customized over a standard thoracic endograft by the surgical team right before its deployment. Recently, Gouveia and Melo performed a systematic review and meta-analysis on the PMEG's outcomes.[13] Overall, 282 urgent cases showed a 30-day mortality, SCI and major adverse events of 10%, 4% and 25%, respectively with 19% of reintervention rate at mid-term follow-up.[13] This technique is attractive, however, the quality of available data is presently still low, and results should be validated in larger and prospective studies. Several issues should be considered in this context. One or two hours are necessary to customize the graft, and this is not always possible in urgent/emergent situations. A dedicated learning curve is necessary even for surgeons with high experience in F/B-EVAR procedures andlong-term results need to be validated, especially in terms of endograft integrity and component disconnection. Finally, possible legal controversies may arise due to the uncontrolled endograft modification in countries where other validated OTS solutions are commercially available.

The pivot branch (p-Branch) manufactured by Cook was proposed as potential OTS fenestrated solution in JAAAs and showed an anatomical feasibility of 70% in JAAAs managed by custom-made FEVAR and about 50% in ruptured JAAAs.[11,27] It is provided by a proximal OTS component incorporating a scallop for the celiac trunk, a fenestration for the superior mesenteric artery and 2 pivot fenestrations for the renal arteries. Differently from a device with outer branches, an OTS endograft with fenestrations may be more difficult to adapt in urgent cases and the mismatch between the renal arteries take offs and the appropriate fenestrations was the most common reason of unfeasibility.[11,27] Faber et al reported a prospective multicenter experience with 76 cases managed in both urgent (11) and elective (65) situations[28]. Technical success was 96% with no cases of 30-day mortality. The mean follow-up was 25 months with 26 (34%) patients requiring reinterventions, 2 (3%) cases of bowel ischemia and 8 (11%) renal artery occlusions[28]. Sveisson et al reported a single center experience including 23 patients with a mean follow-up of 45 months.[29] Technical success was 92% and the estimated 5-year survival and TA patency was 76% and 91%, respectively.[29] The conclusions of both experiences suggest that OTS FEVAR with p-Branch device may be safe and effective in anatomically selected JAAAs with acceptable early follow-up outcomes, being a reasonable option in cases where a custom-made solution is not available.[28,29] Despite these encouraging preliminary data, only few experiences have been reported and this platform is not commercially available in Europe yet.

Since 2012, the Cook T-branch was the first commercially available OTS m-BEVAR with an anatomical feasibility reported in up to 80% of TAAAs managed by custom-made F/B-EVAR.[8-10] It is a safe and effective solutions for elective and urgent TAAAs repair with worldwide early and mid-term reproducible results published in the last 10 years.[8-10] Recently, in a multicenter collection of 100 endovascular repairs of ruptured TAAAs, 88 cases were managed by T branch with satisfactory results in terms of TS (88%), 30-day/hospital mortality (24%) and paraplegia (8%).[30]

This device was designed to repair TAAAs and no robust data are available for J/P-AAAs. However, OTS m-BEVAR technology has dramatically increased in the last decades, and it may be proposed as an effective solution in the urgent repair of J/P-AAAs due to the lack of dedicated devices in this setting.

Obviously, it cannot be considered a common solution because only 197 cases were collected in 23 high-volume aortic centers over a 11-year period. Despite the overall satisfactory results, a series of concerns should be analysed, for this solution.

First, there is an extensive proximal aortic coverage with a higher number of segmentary arteries sacrificed in comparison with patient specific endograft or open repair, with a theorical increase of SCI.[14-16] This is a critical issue especially in J/P-AAAs treated by custom-made FEVAR, where the incidence of SCI is less than 1%.[4,5] However, the adjunctive risk of SCI may be balanced by the urgent setting of repair, where a lifesaving procedure is quickly required.

In our series the mean aortic coverage between the lowest renal artery and the top of the endograft was 154 mm, with a paraplegia rate of 6% (10% in ruptured cases vs 5% in not ruptured). Due to the extensive aortic coverage, all these patients should be considered at high-risk of SCI and all the preventive medical, anesthesiologic and surgical measures should be adopted if possible. Possibly, by increasing the number of cases treated by multi - staged approach (adopted in only 27%) and prophylactic CSF drainage (adopted in only 27%), SCI may be reduced. These cannot be safely adopted in rupture cases but in anatomical and clinical selected patients (symptomatic or large asymptomatic) they may be safe adjuncts in the prevention of SCI.The aneurysm rupture and adjunctive proximal thoracic endograft were independent risk factors for SCI. The first one impacts on 26% of our population and it may be related to the hemodynamic instability and low hemoglobin values. Unfortunately, these data are not available for all rupture cases, due to the retrospective study design, and they were not considered in the uni-multivariable analysis as potential risk factors for SCI. The second one occurred in 27% of cases and it is likely associated with the longer aortic coverage (mean adjunctive aortic coverage of 5 cm in comparison with isolated T-branch). The adjunctive proximal thoracic endograft was necessary due to the standard proximal diameter (34mm) of the T-branch which may need a wider - tapered thoracic endograft to achieve an effective proximal oversizing (15-20%) in some instances. This endograft limitation should be corrected in further developments with the availability of different designs in terms of proximal diameter (34 - 38 mm) and numbers of proximal sealing stents (1-3). Ferreira et al proposed an easy and rapid physician modified technique to reduce the aortic coverage, by cutting the first proximal sealing stent and creating a large fenestration in the posterior segment of the second sealing stent (fenestration for intercostal artery).[31] However, it is important to underline that in the first proximal stent there are the active fixation barbs and leaving a T-Branch without active fixation is not desirable as it may result in its caudal migration and crushing of the bridging stents. The second concern is the risk of periprocedural TAs loss due to the narrow para-visceral aorta which would not allow the complete opening of the external branches or determine the compression of the bridging stent-grafts with possible early occlusion. Recently, Ferrer et al reported that the use of T-branch in cases of complex aneurysms with narrow para-visceral aorta can lead to results comparable with cases with para-visceral aortic lumen > 25 mm in terms of TS and mid-term clinical outcomes.[32]

In our series the mean aortic diameter at the level of the SMA and renal arteries was 32 and 30 mm, respectively and 22% of cases had an aortic diameter < 30 mm at the level of the renal arteries. In these cases, an important trick to guarantee the safe TAs cannulation / stenting is the partial deployment technique, adopted in 18% of cases in our cohort, and reported for the first time by Simonte et al and Timaran et al.[33,34] According with this technique, a partial endograft deployment (unsheathing the graft up to the outer branches origins and opening the proximal stent of the graft) is useful to save space and guarantee an easy cannulation of TAs from above to below with the distal part of the endograft still closed. The theoretical negative aspect of this technique consists of a prolonged pelvic / lower limb ischemia which may be an adjunctive risk factor for SCI. Overall, TAs patency at completion angiography was excellent (99%) with only 11 TAs (renal arteries: 9; celiac trunks: 2) lost among 750.

The incidence of TAs occlusion within 30-day was low (patients:1%; TAs: 0.4%) and it is possibly the consequence of an aggressive approach in relining bridging stent-graft by bare metal stent in case of any diagnostic doubts of compression (12% of TAs) as well as the intraoperative quality control by cone-beam CT or IVUS and the potential protective role of dual antiplatelet therapy in the first 6 postoperative months.

TAs patency and instability should be evaluated also during follow-up since outer branches, especially those for renal artery, have poorer clinical outcomes than fenestrations.[17-20] In these cases, we are accommodating with outer branches some renal arteries that should be managed by fenestrations in an elective setting. However, the rate of late renal artery events was not high and was comparable with cases managed by custom-made device.[2-5]

The choice of a correct bridging stent-graft plays a crucial role to obtain the effective aneurysm exclusion and durable TAs patency after F/B-EVAR. Even if new generation of covered stents were available in the last years, the absence of dedicated devices remains one of the main critical issues of this technology. In the present experience we report the use of balloon-expandable, self-expandable and combination of balloon and self-expandable in 59%, 29% and 12% of TAs, respectively (online table III). We did not analyze the outcomes of each single type/brand of covered stent because the different subgroups would be too heterogeneous due to the long study period, important manufacturing innovations and different physicians' preferences in 23 centers. Moreover, considering the number of TAI events (27/197 patients) and the different types of covered stents, we did not perform the analysis of potential risk factor for TAI because of a poor statistical significance.

Estimated 3-year freedom from TAIs and reinterventions were 72% and 77%, respectively. An important proportion of reinterventions (about 15%) occurs within 30 postoperative days, and it may be probably related to the urgent setting of the repair. In emergent cases, these procedures are focused to fix promptly the acute situation, optimizing technical details with early reinterventions.

Out of 32 reinterventions, there were 4 (13%) femoral / iliac access related events. One of the main theorical limitations of T-branch is the presence of challenging access, because it has a delivery system requiring up to 8.5mm (24Fr outer diameter) [8,9]. Previous studies have demonstrated that hostile iliac access are associated with technical demanding F/B-EVAR procedures carrying need for adjunctive intra-operative maneuvers and increased mortality during follow-up[35,36]. Bertoglio et al. reported that 18-22% of TAAAs should be theoretical excluded from off the shelf BEVAR for iliac access ineligibility [37]. The availability of BEVAR with low-profile platform as off the shelf device may be an effective tool to manage urgent complex aneurysm in presence of hostile femoral/iliac access, ensuring a safe and rapid life-saving repair and reducing risks of complications. Ramanan et al in 2016 reported low-profile custom made BEVAR with similar configuration of T-branch in elective J/PAAAs or TAAAs, reducing the incidence of surgical/endo conduit and access artery injury [38]. However, this is a preliminary experience with limited follow-up and results should be analyzed during a longer timeframe especially regarding low-profile/fabric integrity and target arteries patency.Finally, a dedicated consideration should be reserved on the follow-up survival because about 60% of patients are alive at 3 years. This value should be considered acceptable considering the patient's age at the time of repair, preoperative risk-factors, and the urgent setting of procedures. Moreover, several predictors of mortality were identified (table VI), and they should be taken in account during the decision-making process.

The present study has several limitations. It is a retrospective, multicenter experience, reporting < 200 cases, managed in 23 centers in a 10-year period. The median number of cases per center and year is limited and the operator learning curve cannot be considered. Moreover, in the study period important improvements of the ancillary materials were achieved. The multicenter design may influence the study's outcomes because different techniques, and perioperative patient's managements - for example SCI prevention protocols - were used in each center. The retrospective study design and the limited number of cases did not allow a specific analysis of each protocol. The small sample size and short term follow up limit the power of the study's conclusions. The urgent definition includes ruptured aneurysms, symptomatic cases as well as asymptomatic patients with large aneurysms. Obviously, these are three different clinical scenarios, with different risks and outcomes. For these reason the study's outcomes should be separately considered for each of the three clinical scenarios even if it reduces the power of the statistical evaluation.

Moreover, the time and entity of pre / post-operative hypotension as well as hemoglobin levels in case of aneurysm rupture were not available for the analysis. Finally, it is a single brand experience and nowadays there are alternative OTS platforms with different endograft designs, proximal diameter, and number of sealing stents. All these factors may play a crucial role in the risk of SCI and should be considered.

CONCLUSION.

Urgent repair of J/P-AAAs by T-branch is feasible and effective with satisfactory TS and 30-day/hospital mortality in high-risk patients. However, a more extensive aortic coverage is necessary, leading to a not negligible SCI rate, especially in aortic rupture or when adjunctive thoracic endografts are necessary. Predictors of TS, SCI and mortality were identified, and they should be considered for surgical indication and outcomes' optimization.

Conflict of interest

E Gallitto, G Faggioli, M Austermann, N Tsilimparis, G Melissano, G Simonte, A Katsargyris, K Oikonomou, K Mani, L Mendes Pedro, and M Gargiulo are proctors for Cook Medical and received travel, educational grants or speaker's fees.

T Kölbel, N Dias and S Haulon are consultants for Cook Medical and they have intellectual property with Cook Medical and received speaking fees, and research, travel, and educational grants.

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Table I. Demographics, cardio-vascular risk factors and preoperative comorbidities.

	N	%
Male	165	84
Octogenarians	58	30
Hypertension	174	88
Smoking	77	39
Dyslipidemia	100	51
Diabetes	27	13
Chronic obstructive pulmonary disease	72	37
Coronary artery disease	87	44
Peripheral arterial occlusive disease	33	17
Atrial fibrillation	41	21
Oral anticoagulant therapy	81	41
Cerebrovascular disease *	27	14
BMI > 31	34	17
Chronic kidney disease	59	30
Dialysis	6	3
Previous laparotomy	49	25
Previous aortic repair	72	37
Previous endovascular aortic repair	50	69
Previous surgical aortic repair	26	36
ASA score $\leq$ 3	118	60
ASA score $\geq$ 4	79	40
	Mean	**Standard Deviation**
Age (years)	75	8
Aneurysm diameter (mm)	77	18
Creatine (mg/dL)	1.3	0.4

BMI: body mass index; *History of stroke or transitory ischemic attack; BMI: Body Mass Index; ASA: American Anesthesiologist Score.

Table II. Preoperative anatomical, sizing and planning details.

Aortic lesion	N	%
Juxta-renal AAAs	64	33
Para-renal AAAs	95	48
Proximal type I endoleak in previous failed EVAR	34	17
Previous failed Ch-EVAR	4	2
Overall	197	100
Clinical setting	**N**	**%**
Rupture	51	26
Symptoms	110	56
Aneurysm Diameter > 70mm	53	27
Aortic coverage	**Mean**	**Standard deviation**
From the lowest renal artery to bottom of the endograft (mm)	154	49
From superior mesenteric artery to bottom of the endograft (mm)	134	48
Target arteries	**N**	**%**
Celiac trunk	184	25
Superior mesenteric artery	195	26
Renal arteries	371	49
Overall	750	100
Aortic diameter at the level of	**Mean**	**Standard deviation**
Celiac trunk origin (mm)	32	10
Superior mesenteric artery origin (mm)	32	13
Left renal artery origin (mm)	30	17
Right renal artery origin (mm)	30	18
Hypogastric artery status	**N**	**%**
Bilateral patency	170	86
Unilateral patency	23	12
Bilateral occlusion	4	2
Endograft details	**N**	**%**
Adjunctive thoracic endograft	28	14
Extra branches respect to preoperative target arteries*	38 / 788	5
Aortic bi iliac abdominal endograft	176	89
Tube distal abdominal endograft	20	10
Aortic uni iliac endograft	1	1
Iliac branch device	17	9

Ch-EVAR: Chimney

*: there were 38 renal or celiac arteries preoperative occluded. The respective 38 branches of the T-branch were managed by cuff extension and plug.

Table III. Procedural details and early outcomes.

Steps of repair	N	%
Single	144	73
Multi	53	27
CSF-drainage	53	27
Femoral access		
Percutaneous	137	70
Surgical	53	27
Both percutaneous and surgical	7	3
Axillary access		
Overall	173	100
Left	117	68
Right	56	32
Surgical	144	83
Percutaneous	29	17
Target arteries cannulation		
Trans-axillary	165	84
Trans-femoral	24	12
Both trans-femoral and axillary failure of cannulation from below with rescue maneuvers from above	8	4
Partial deployment	36	18
	Mean	**Standard deviation**
Overall procedural time (min)	290	117
Fluoroscopy time (min)	80	40
DAP (mGy/cm^2)	235722	92379
Iodinated contrast media (mL)	192	89
	N	**%**
Technical Success	182	92
Technical Failure	15	8
Target Visceral Vessels loss	11	
Renal: 9; Celiac trunk: 2		
Endoleaks I - III	2	
Intraoperative / 24 h death	2	

	Mean	Standard deviation
Intensive care unit (days)	4	2
Postoperative hospitalization (days)	13	3
30-day / In-hospital outcomes	**N**	**%**
Overall SCI	21	11
Permanent SCI	15	8
Permanent Paraplegia	12	6
Cardiac morbidity	18	9
Respiratory morbidity	28	14
Acute kidney injury	44	22
New onset of Dialysis	5	2
Mesenteric complication	8	4
Stroke*	2	1
Major adverse evets	69	35
Reintervention within 30-day	4	2
30-day / In-hospital mortality	22	11

	Overall N - %	Ruptured aneurysm (51) N - %	No ruptured aneurysm (146) N - %	P
Technical Success	182 - 92	43 - 84	139 - 95	.02
Overall SCI	21 - 11	11 - 22	10 - 7	.006
Permanent Paraplegia	12 - 6	5 - 10	7 - 5	.36
30-day / In-hospital mortality	22 - 11	8 - 16	14 - 10	.30

CSF: cerebral spinal fluid;
Stroke*: hemorrhagic-1 (upper extremity access for target arteries cannulations); ischemic-1 (trans-femoral access for target arteries cannulations)

Table IV. Independent risk factors for spinal cord ischemia at uni and multivariable analysis.

	Univariate	Multivariate		
	P	P	OR	95% CI
Preoperative factors				
Male	.23	-	-	-
Symptomatic aneurysm	.36	-	-	-
Ruptured aneurysm	.007	.04	3.3	1.1 - 8.9
Aortic diameter > 7 cm	.06	-	-	-
Hypertension	1	-	-	-
Smoke	.75	-	-	-
Previous smoker	1	-	-	-
Dyslipidemia	.65	-	-	-
Diabetes	1	-	-	-
Chronic obstructive pulmonary disease	.82	-	-	-
Coronary artery disease	.49	-	-	-
Peripheral arterial occlusive disease	.05	.13	2.5	.73 - 8.8
Atrial fibrillation	.58	-	-	-
Oral anticoagulant therapy	.25	-	-	-
Carotid artery stenosis > 70%	.40	-	-	-
History of stroke / AIT	.75	-	-	-
BMI > 31	.33	-	-	-
Chronic Kidney Disease	.62	-	-	-
Dialysis	.13	-	-	-
ASA 3	.40	-	-	-
ASA 4	.36	-	-	-
Juxta-renal aortic aneurysm	.81	-	-	-
Para-renal aortic aneurysm	.11	-	-	-
Endoleak IA in previous EVAR	.13	-	-	-
Previous failed Ch-EVAR	1	-	-	-
Both hypogastric arteries patent	.32	-	-	-
One hypogastric artery patent	.48	-	-	-
No hypogastric artery patent	1	-	-	-
Procedural factors				
Adjunctive proximal TEVAR	.04	.01	4.1	1.3 - 12.9
Multiple stages procedure	1	-	-	-
Aorto-bisiliac endograft	.68	-	-	-
Tube endograft	.45	-	-	-
Aorto-uniliac endograft	1	-	-	-
Iliac Branch Devices	.1	-	-	-
Partial deployment	1	-	-	-
Trans-femoral TAs cannulation	.48	-	-	-
Trans-axillary TAs cannulation	.21	-	-	-
Intraoperative TVVs loss	.29	-	-	-
Cerebral-spinal fluid drainage	.19	-	-	-
Technical Success	.67	-	-	-
Postoperative factors				
Major adverse events	.003	.33	1.8	.53 - 6.2
Stroke	.20	-	-	-
Cardiac morbidity	.42	-	-	-
Respiratory morbidity	.01	.73	1.28	.30 - 5.4
Dialysis	.01	.65	.60	.09 - 4.4
Mesenteric complications	.04	.60	1.95	.02 - 13.8
30-day / Hospital mortality	.003	.30	2.2	.50 - 10.1

OR: odd ratio; CI: confidential interval; BMI: body mass index; BMI: Body Mass Index; ASA: American Anesthesiologist Score.

Table V. Independent risk factors for 30-day / Hospital mortality at uni and multivariable analysis.

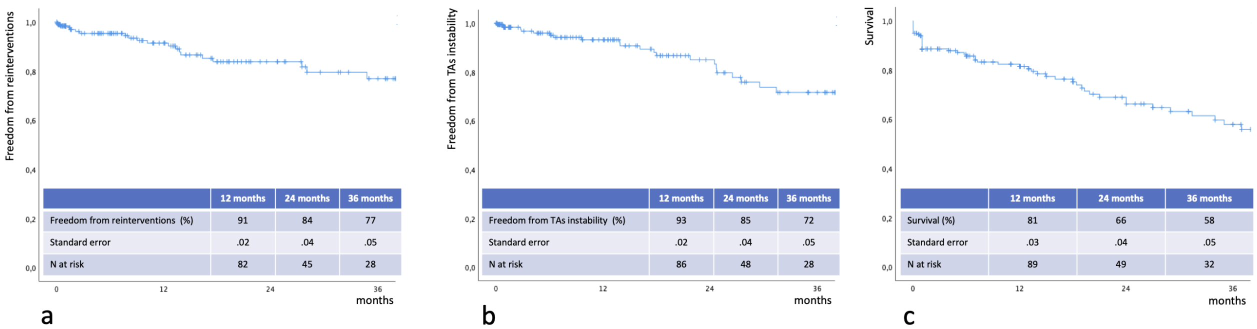
	Univariate	Multivariate		
	P	P	OR	95% CI
Preoperative factors				
Male	.48	-	-	-
Symptomatic aneurysm	.17	-	-	-
Ruptured aneurysm	.30	-	-	-
Aortic Diameter > 7 cm	.64	-	-	-
Hypertension	.30	-	-	-
Smoke	.56	-	-	-
Previous Smoker	.25	-	-	-
Dyslipidemia	.82	-	-	-
Diabetes	1	-	-	-
Chronic obstructive pulmonary disease	.24	-	-	-
Coronary arteries disease	.17	-	-	-
Peripheral arteries occlusive disease	.22	-	-	-
Atrial fibrillation	.41	-	-	-
Oral anticoagulant therapy	.25	-	-	-
Carotid Artery Stenosis > 70%	.70	-	-	-
History Stroke / TIA	.51	-	-	-
BMI > 31	1	-	-	-
Chronic kidney disease	.046	.40	1.73	.47 - 6.29
Dialysis	.14	-	-	-
ASA 4	.006	.07	3.1	.89 - 11.1
Juxta-renal	.81	-	-	-
Para-renal	.43	-	-	-
EL1A in previous failed EVAR	.03	.04	3.6	1.1 - 12.3
Previous failed Ch-EVAR	1	-	-	-
Both hypogastric arteries patent	.74	-	-	-
One hypogastric artery patent	.14	-	-	-
No hypogastric artery patent	.07	-	-	-
Procedural factors				
Adjunctive proximal TEVAR	.33	-	-	-
Multiple stages procedure	1	-	-	-
Aortic bis iliac endograft	.70	-	-	-
Tube endograft	.47	-	-	-
Aortic mono iliac endograft	1	-	-	-
Iliac branch device	.41	-	-	-
Partial deployment	.38	-	-	-
Trans-femoral TAs cannulation	1	-	-	-
Trans-axillary TAs cannulation	.54	-	-	-
Intraoperative TAs loss	.09	-	-	-
Cerebral spinal fluid drainage	.45	-	-	-
Technical success	.016	.25	.34	.025 - 3.41
Postoperative factors				
Postoperative MAEs	< .001	.40	1.8	.41 - 8.3
Stroke	.21	-	-	-
SCI	.003	.06	3.6	0.7 - 12.1
Permanent paraplegia	< .001	.001	9.9	1.6 - 62.2
Cardiac morbidity	.001	.03	8.2	2.0 - 33.0
Respiratory morbidity	< .001	< .001	10.1	2.9 - 35.0
Acute kidney injury	.11	-	-	-
Dialysis	.02	.30	.02	.01 - 3.7
Mesenteric complications	.006	.03	10.4	1.2 - 93.3
Redo at 30 days	.06	-	-	-

OR: odd ratio; CI: confidential interval; BMI: body mass index; BMI: Body Mass Index; EL1a: proximal type I endoleak; ASA: American Anesthesiologist Score.

Table VI. Independent risk factors for follow-up mortality at the Cox Regression.

	Univariate			Multivariate		
	P	HR	95% CI	P	HR	95% CI
Preoperative factors						
Preoperative chronic kidney disease	.001	2.4	1.4 - 4.2	.006	2.5	1.3 - 4.6
EL1A in previous failed EVAR	<. 001	3.1	1.7 - 5.4	< . 001	3.3	1.7 - 6.3
Preoperative bilateral hypogastric occlusion	.01	3.8	1.3 - 10.8	.008	4.5	1.5 - 13.7
Postoperative factors						
Paraplegia	<.001	5.1	2.2 - 11.6	.01	3.4	1.3 - 8.8
Postoperative cardiac morbidity	<.001	3.5	1.7 - 7.1	.18	1.9	0.7 - 4.4
Postoperative respiratory morbidity	<.001	5.0	2.8 - 9.1	.04	2.3	1.1 - 5.0
Postoperative dialysis	< .001	4.6	1.9 - 11.1	.35	0.5	0.14 - 2.2
Postoperative mesenteric events	.002	4.3	1.6 - 11.0	.006	4.2	1.5 - 11.6

HR: hazard ratio; CI: confidential interval; EL1a: proximal type I endoleak



	12 months	24 months	36 months
Freedom from reinterventions (%)	91	84	77
Standard error	.02	.04	.05
N at risk	82	45	28

	12 months	24 months	36 months
Freedom from TAs instability (%)	93	85	72
Standard error	.02	.04	.05
N at risk	86	48	28

	12 months	24 months	36 months
Survival (%)	81	66	58
Standard error	.03	.04	.05
N at risk	89	49	32

Figure legend.

Fig.1. A. Estimated freedom from reinterventions during follow-up by Kaplan Meier. **B** Estimated freedom from target artery instability during follow-up by Kaplan Meier. TAs: target arteries. **C** Estimated Survival during follow-up by Kaplan Meier.