

SYSTEMATIC REVIEW

Fenestrated and Branched Endografts for Post-Dissection Thoraco-Abdominal Aneurysms: Results of a National Multicentre Study and Literature Review[☆]

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WHAT THIS PAPER ADDS

Aortic dissection is progressive, with published data detailing aortic growth in 63% of patients submitted to endovascular repair at five years. The paravisceral aorta becomes aneurysmal due to retrograde false lumen perfusion from distal entry tears. Fenestrated and branched endografting (F/B-EVAR) has been proposed to treat chronic post-dissection thoraco-abdominal aneurysms (PD-TAAAs), by closing thoraco-abdominal aortic entry tears. This reduces false lumen pressure and may promote aortic remodelling during follow up. However, reported outcomes of such procedures are scarce. This study analysed the experience of four Italian academic centres in endovascular repair of PD-TAAAs by F/B-EVAR and details results available from the literature.

Objective: Fenestrated and branched endografting (F/B-EVAR) has been proposed as an endovascular solution for chronic post-dissection thoraco-abdominal aneurysms (PD-TAAAs). The aim of this study was to analyse the experience of four high volume centres nationwide and the current available literature.

Methods: Data on patients undergoing F/B-EVAR in four Italian academic centres between 2008 and 2019 were collected, and those from patients with PD-TAAAs were analysed retrospectively. Peri-operative morbidity and mortality were assessed as early outcomes. Survival, freedom from re-intervention (FFR), target visceral vessel (TVV) patency, and aortic remodelling were assessed as follow up outcomes. A MEDLINE search was performed for studies published from 2008 to 2020 reporting on F/B-EVAR in PD-TAAAs.

Results: Among 351 patients who underwent F/B-EVAR for TAAAs, 37 (11%) had PD-TAAAs (Crawford's extent I–III: 35% – 95%). Overall, 135 TVVs (from true lumen 120; false lumen seven; both true and false lumen eight) were accommodated by fenestrations (96% – 71%) and branches (39% – 29%). Technical success (TS) was achieved in 34 (92%) cases with three failures due to endoleaks (Ia: 1; Ic: 1; III: 1). There were no 30 day deaths. No cases of permanent spinal cord ischaemia (SCI) were recorded and six (16%) patients suffered from transient deficits. Renal function worsening (eGFR < 30% than baseline) and pulmonary complications were reported in two (5%) and four (11%) cases, respectively. From the Kaplan–Meier analysis, three year survival, FFR, and TVV patency were 81%, 66%, and 97%, respectively. Radiological imaging was available for 30 (81%) patients at 12 months with complete false lumen thrombosis in 26 (87%). Two hundred and fifty-six patients were reported in seven published papers with TS, 30 day mortality, and SCI ranging from 99% to 100%, 0 to 6%, and 0 to 16%, respectively. The mean follow up ranged from 12 to 26 months, with estimated two year survival between 81% and 90% and a re-intervention rate between 19% and 53%.

Conclusion: F/B-EVAR is effective to treat PD-TAAAs. A high re-intervention rate is necessary to complete the aneurysm exclusion and promote aortic remodelling successfully.

Keywords: Aortic dissection, Aortic remodelling, Fenestrated and branched endograft, Post-dissection thoraco-abdominal aneurysm, Thoraco-abdominal aneurysm

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INTRODUCTION

Acute aortic dissection, with extensive thoraco-abdominal aorta involvement, is a progressive disease with frequent late aneurysmal degeneration, regardless of the treatment received in the acute phase. Data from the International Registry of Acute Aortic Dissection show a mortality rate at five years of 16% in patients submitted to endovascular repair and in 29% of those under medical therapy.¹ Similarly, the five year re-interventions rate was 31% and 20% in patients managed by endovascular repair and medical treatment, respectively.¹ Finally, aortic growth was detected in 63% of patients submitted to endovascular repair and in 73% of those treated by medical therapy.¹ Dedicated techniques have been developed to minimise distal false lumen re-perfusion.^{2,3} However, the paravisceral and infrarenal aorta become aneurysmal in up to 55% of patients submitted to TEVAR for type B aortic dissection⁴ due to retrograde false lumen perfusion originating from multiple distal entry tears. Moreover, the rate of post-dissection TAAAs is likely to be under reported as a proportion of these patients could not be followed correctly or were referred for treatment in the past.

Fenestrated and branched endografting (F/B-EVAR) is an established technique to treat degenerative thoraco-abdominal aneurysms (TAAAs) with satisfactory early and midterm results.^{5–7} In the last decade, F/B-EVAR has been proposed as a treatment for chronic post-dissection thoraco-abdominal aneurysms (PD-TAAAs) as a result of its capacity to close all thoraco-abdominal aortic entry tears. This reduces false lumen pressure and may promote aortic remodelling during follow up.^{8–10} However, the outcome of these procedures has been reported only by few specialised high volume centres and a wider overview is lacking.

The aim of this study was to analyse the experience of four Italian academic centres in the endovascular repair of PD-TAAAs by F/B-EVAR and to report the current results available in the literature.

METHODS

Study design and patient selection

This was a voluntary, observational, multicentre, and retrospective registry (Italian Multicentre Fenestrated Branched Endografting Study — IMFB Study).¹¹ From January 2008 to September 2019, data on all consecutive patients undergoing F/B-EVAR in four Italian academic centres were prospectively collected in local databases.¹¹ F/B-EVAR repair was proposed for patients at high risk of open repair if anatomically suitable.¹² In accordance with European General Data Protection Regulation (GDPR), all cases were de-identified with a coding number and clustered in a dedicated shared electronic database. Pre- and post-operative computed tomography angiograms were required for case enrolment. Data were monitored and validated by one study centre but there was no dedicated core lab.

Pre-operative, procedural, and post-operative data of patients with PD-TAAAs were extrapolated and analysed

retrospectively. All patients enrolled in the study provided written informed consent for the F/B-EVAR procedures and the use of their anonymous data for clinical studies. The study was approved by the local Institutional Review Boards (IMFB Study — 1376).

Endograft and procedure planning

A fenestrated and branched endograft platform manufactured by Cook Inc. (Bloomington, IN, USA) was used in all patients. Elective cases were treated with custom made devices as planned by the vascular surgeons performing the procedure. Splanchnic and renal artery revascularisation was usually achieved by fenestration or branch design dependent on the aortic lumen diameter at the level of the target visceral vessels (TVVs) and their origin from true or false lumen.^{9,11} Since 2012, off the shelf multibranch endografts (T branch) have been implanted in patients with acute TAAAs (symptomatic: pain, contained rupture, peripheral embolisation; or asymptomatic cases with a maximum diameter ≥ 80 mm) if anatomically suitable.¹³ Procedures, peri- and post-operative protocols have been accurately described in previous reports.^{7,11,14} Specifically, spinal cord ischaemia (SCI) prevention protocols, consisting of cerebral fluid spinal drainage (CSFD), early lower limb/pelvic re-perfusion, staged procedures whenever possible, high mean arterial pressure (> 80 mmHg) and haemoglobin > 10 mg/dL, were applied for Crawford extent I–III TAAAs or IV TAAAs with hypogastric artery occlusion or previous aortic repair.¹¹

If the left subclavian or the hypogastric arteries needed to be covered to achieve sufficient proximal and distal sealing in elective repairs, their patency was always guaranteed by surgical or endovascular means. Neurological deficits were classified according to the SVS reporting standard.¹²

Endpoints and definitions

Peri-operative morbidity and death were assessed as early outcomes. Survival, freedom from re-interventions (FFRs), TVV patency, and aortic remodelling were assessed as follow up outcomes. Pre-operative comorbidities, anatomical and aneurysm classification, operative risks, and post-operative complications were classified according to the SVS reporting standard.¹² Aortic remodelling was evaluated in terms of complete false lumen thrombosis and aneurysm shrinkage (≥ 5 mm). The status (patent, partial thrombosis, or complete thrombosis) of the false lumen was defined according to the SVS reporting standard on arterial and delayed phase computed tomography angiography (CTA).¹⁵

Statistical analysis

Continuous variables were reported as median and interquartile range (IQR) while categorical variables were expressed as frequencies. Survival, FFRs, and TVV patency were assessed by Kaplan–Meier analysis. Statistical analysis was performed with SPSS 25.0 for Windows (SPSS Inc, Chicago, IL, USA).

Literature research

An English language literature review was performed through PubMed and Embase/Scopus for any study reporting the outcomes of F/B-EVAR for PD-TAAAs published until December 2020. The research was conducted by two independent investigators (EG, RP). The keywords used for search purposes included “thoracoabdominal aneurysm” [All Fields] AND “chronic aortic dissection” [All Fields] AND “endograft” [All Fields] AND (“branched” [All Fields] OR “fenestrated” [All Fields]). The investigators independently reviewed the titles and abstracts of all citations to identify potentially relevant studies and to exclude duplicates; the full text of the corresponding publications was also examined to assess whether the study met the inclusion criteria and the references were analysed. The exclusion criteria were as follows: case reports; studies with no extractable dedicated data on PD-TAAAs, and multiple publications/overlapping series. Unpublished data or data reported only in abstracts were not included. The final inclusion of studies was based on agreement between the reviewers. Disagreements were resolved by discussion and consultation with a third author (GF) if necessary. The investigators used an extraction database to evaluate information on outcomes: study design, number of patients, early results, and follow up results.

RESULTS

Patient selection

Overall, 806 patients were treated for TAAAs between 2014 and 2019 in the four centres; 289 (36%) and 517 (64%) cases were managed by F/B-EVAR and open repair, respectively. One hundred and thirty-two (16%) cases were post-dissection TAAAs and among them 95 (72%) and 37 (28%) cases were managed by open repair and F/B-EVAR, respectively. The latter were analysed in the present study.

Twenty nine (78%) patients were male and 30 (81%) had an ASA score ≥ 3 . The median age and aneurysm diameter were 66 (IQR 9) years and 65 (IQR 7) mm, respectively. Demographics, pre-operative comorbidities, and cardiovascular risk factors are summarised in [Table 1](#). Seven (19%) patients had a connective tissue disease. Procedures were performed in elective and urgent clinical settings in 31 (84%) and six (16%) cases, respectively.

Anatomical and endograft characteristics

The PD-TAAA was Crawford’s extent I–III and IV in 35 (95%) and two (5%) cases, respectively. Thirty-one (84%) patients had had previous open or endovascular aortic surgery ([Table 2](#)). The left subclavian and hypogastric (unilateral) arteries were pre-operatively occluded in two (5%) and three (8%) patients, respectively. Hostile iliac access was present in seven (19%) cases. Custom made and off the shelf endografts were employed in 33 (89%) and four (11%) cases, respectively. The level of proximal and distal endograft sealing is summarised in [Table 3](#). Overall, 135 TVVs (originating from true lumen 120; false

Table 1. Demographics, pre-operative comorbidities, and cardiovascular risk factors of 37 patients with chronic post-dissection thoraco-abdominal aneurysm treated with fenestrated and branched endograft and included in the national registry in Italy

| | Patients (n = 37) |
|---------------------------------------|-------------------|
| Male | 29 (78) |
| Hypertension | 36 (97) |
| Tobacco use | 20 (54) |
| Dyslipidaemia | 18 (49) |
| Diabetes | 10 (27) |
| BMI > 31 kg/m ² | 6 (16) |
| Chronic renal impairment | 10 (27) |
| Coronary artery disease | 17 (46) |
| Chronic obstructive pulmonary disease | 17 (46) |
| Peripheral artery occlusive disease | 16 (43) |
| ASA III | 21 (57) |
| ASA IV | 9 (24) |
| Aneurysm diameter – mm | 65 (7) |
| Age – y | 66 (9) |
| Weight – kg | 76 (16) |
| BMI – kg/m ² | 26 (4) |

Data are presented as n (%) or median (interquartile range). BMI = body mass index; ASA = American Society of Anaesthesiologists Score.

lumen seven; both true and false lumen eight) were accommodated by fenestrations (96% – 71%) and branches (39% – 29%). [Table 4](#) summarises the distribution of fenestrations and branches for each type of TVVs. In 15 (40%) cases a modified pre-loaded system was used for renal and superior mesenteric artery fenestrations. The F/B-EVAR device required at least one proximal thoracic endograft in 27 (73%) cases and distal abdominal endograft in 29 (78%) cases. The distal endograft configuration was tube, bifurcated, and aorto-uni-iliac in four (11%), 24 (65%), and one (3%) cases, respectively.

An inverted limb design was required in five (14%) cases to guarantee a bifurcated abdominal device for a short infrarenal aortic working length. A left carotid subclavian bypass and iliac branch device were planned in three (8%) and four (11%) cases, respectively. False lumen embolisation was performed in seven (19%) cases and selective inferior mesenteric artery embolisation in two (5%).

Table 2. Location of the previous aortic graft among 37 patients with chronic post-dissection thoraco-abdominal aneurysm and previous aortic repair who underwent fenestrated and branched endograft and were included in the national registry in Italy

| Aortic location of the previous graft | Patients (n = 37) |
|---------------------------------------|-------------------|
| Ascending | 19 (51) |
| Arch | 14 (38) |
| Descending | 15 (41) |
| Thoraco-abdominal | 2 (5) |
| Infrarenal | 5 (14) |
| Overall | 31 (83) |

Data are presented as n (%).

Table 3. Level of proximal and distal endograft sealing in 37 patients with chronic post-dissection thoraco-abdominal aneurysm after previous aortic arch repair who underwent fenestrated and branched endograft and were included in the national registry in Italy

| | Patients (n = 37) |
|------------------------------|-------------------|
| <i>Proximal sealing zone</i> | |
| 0 – 1 – 2 | 15 (41) |
| 3 | 9 (24) |
| 4 | 8 (22) |
| 5 | 3 (8) |
| 6 | 2 (5) |
| <i>Distal sealing zone</i> | |
| 9 | 9 (24) |
| 10 | 20 (54) |
| 11 | 8 (22) |

Data are presented as n (%). Zones were defined according to the Society for Vascular Surgery reporting standard.

Procedure

PD-TAAA exclusion was staged in 27 (73%) cases (two [18% – 67%] and three [9% – 33%] steps) with a median time between the first and last procedure of 107 (IQR 40) days. The staging modalities are summarised in Table 5. To reduce the re-perfusion of false lumen from the distal back entry tear, a candy plug was deployed in the false lumen during the thoracic stage in three (8%) cases. For the F/B-EVAR step, procedures were performed under general and local anaesthesia in 26 (70%) and 11 (30%) cases, respectively. The femoral access was bilateral or unilateral in 34 (92%) and three (8%) cases, respectively. Among the 71 femoral accesses, 36 (51%) were percutaneous. An axillary or brachial access was performed in 22 (60%) cases, of which nine were percutaneous. The median procedure and fluoroscopy times of the F/B-EVAR procedures were 288 (IQR 60) and 177 (IQR 30) minutes, respectively, with a median iodinated contrast volume of 241 (IQR 40) mL. Technical success (TS) (first + second step) was achieved in 34 (92%) cases; technical failures were determined by three cases of endoleaks detected on the post-operative CTA: one type Ia, one type Ic, and one type III. The type Ic and III endoleaks were successfully managed by endograft relining during the same recovery. The patient with the type Ia endoleak refused an endovascular arch repair and was alive after six months. In six (16%) cases a type II endoleak was detected on the post-operative imaging.

Table 4. Target visceral vessel accommodation in 37 patients with chronic post-dissection thoraco-abdominal aneurysm who underwent fenestrated and branched endografts and were included in the national registry in Italy

| | Fenestration | Branch | Overall |
|----------------------------|--------------|--------|---------|
| Coeliac artery | 23 | 10 | 33 |
| Superior mesenteric artery | 23 | 13 | 46 |
| Renal arteries | 50 | 16 | 66 |
| Overall TVVs | 96 | 39 | 135 |

Data are presented as n.

Table 5. Mode of staged approach for chronic post-dissection thoraco-abdominal aneurysm in 37 patients with previous aortic arch repair who underwent fenestrated and branched endografting and were included in the national registry in Italy

| | Patients (n = 37) |
|--|-------------------|
| <i>PD-TAAAs</i> | |
| Single stage repair | 10 (27) |
| Multistaged repair | 27 (73) |
| <i>Staging modality</i> | |
| 1st step: TEVAR; 2nd step: FEVAR | 16 (59) |
| 1st step: TEVAR; 2nd step: FEVAR; 3rd step: iliac limb | 9 (33) |
| 1st step: TEVAR + FEVAR; 2nd step: iliac limb | 1 (4) |
| 1st step: TEVAR + FEVAR; 2nd step: TASP branch | 1 (4) |

Data are presented as n (%). PD-TAAAs = post-dissection thoraco-abdominal aortic aneurysm; TASP branch = temporary aneurysm sac perfusion branch.

Early results

Six (16%) patients (Crawford's extent II: 4; III: 2) suffered post-operative SCI but there were no permanent paraplegia cases. According to Tarlov's neurological scale, there were five cases of grade 4 and one of grade 3. Staging approach and CSFD were adopted in four and three of these six cases, respectively. There were no cardiac or cerebrovascular complications; two (5%) patients suffered worsened post-operative renal function with no cases requiring dialysis. Pulmonary complications were reported in four (11%) cases. There were no 30 day or in hospital deaths.

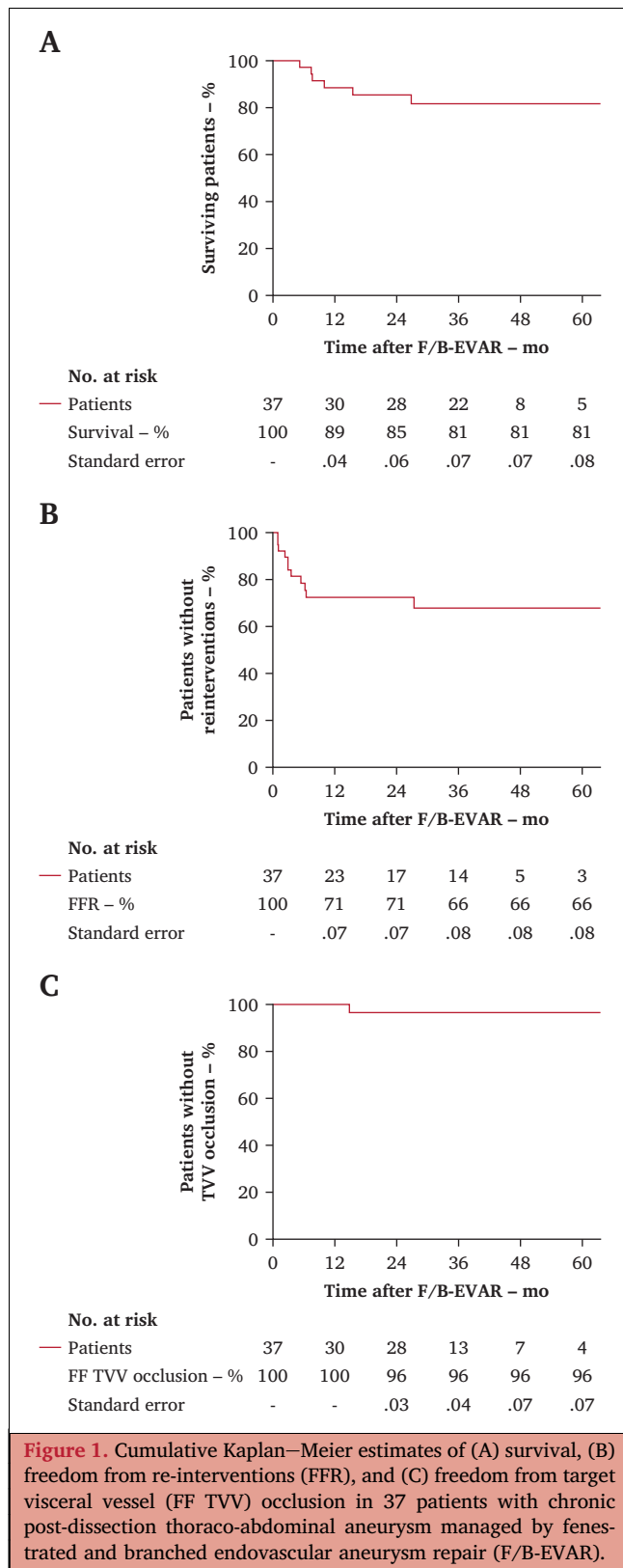
Follow up results

The median follow up was 32 (IQR 14) months. Seven (19%) patients died during follow up, none from aneurysm related causes. Causes of death were pneumonia with respiratory failure – two cases, sepsis with multi-organ failure – two, cardiac failure – one, cancer – one, and old age – one. Survival was 81% at 36 months (Fig. 1A). Overall, 12 (32%) patients required at least one re-intervention, with five (14%) needing multiple re-interventions; re-intervention was performed to seal endoleaks in 10/12 (83%) cases. Supplementary Table S1 summarises all the re-interventions, their timing, and indications. Estimated FFR was 66% at 36 months (Fig. 1B), with 97% primary TVV patency at 36 months (Fig. 1C).

Regarding aortic remodelling, 30 (81%) patients had a radiological follow up at 12 months; among these, complete false lumen thrombosis was reported in 26 (87%) cases. Aneurysm shrinkage was detected in 22/30 (73%) cases.

Literature review

Figure 2 shows the study selection process. Among 20 screened records,^{8–10,16–32} seven studies were considered eligible for the present review (Supplementary Table S2). They were published between 2013 and 2020 (cases enrolled between 2005 and 2019).^{17,21,23–25,30,32} Three



papers were reported by North American^{17,25,30} and four by European centres,^{21,23,24,32} respectively. Five were single centre^{17,21,24,25,32} and two multicentre experiences.^{23,30} Five were observational^{17,21,23,24,32} and two comparative studies between degenerative TAAAs and PD-TAAAs.^{25,30} The first experience was reported by Kitagawa *et al.*,¹⁷

while the largest one was published by Oikonomou *et al.*²³ (71 cases from two German centres). Spear *et al.*²¹ reported an experience of 40 patients (43 procedures), who underwent FB-EVAR for aortic arch (19) and TAAA (24) dissection. Similarly, Kuzniar *et al.*³³ reported 26 patients who underwent arch (13) and TAAA repairs. Kitagawa *et al.*¹⁷ reported 30 patients comparing results of extensive vs. focal aortic dissection near visceral vessel origin. Overall, 256 cases were reported.^{17,21,23–25,30,32}

Pre-operative anatomical and endograft details, early and follow up results are summarised in dedicated tables (Supplementary Tables S3 and S4).

The majority of patients were treated for Crawford's extent I–II–III TAAAs (80% – 100%).^{17,21,23–25,20,32} Procedures were frequently performed in elective clinical settings with custom made FB-EVAR endografts. Urgent repairs were performed in from 0 to 15% of cases, and an off the shelf multibranched device was adopted in only a small percentage of cases (0 – 15%).^{17,21,23–25,20,32} The mean number of TVVs/patient ranged between 3.4 and 3.7 and they were more frequently accommodated by fenestrations (52% – 79%).^{17,21,23–25,20,32} In only one experience reported by Werlin *et al.*,²⁵ were TVVs accommodated only by branch design. A multistaging approach was proposed to reduce the risk of post-operative SCI from 40% to 83% of cases.^{17,21,23–25,20,32}

TS was achieved between 89% and 100% of cases, 30 day death occurred between 0 and 6% and SCI between 0 and 16%, with a permanent paraplegia rate from 0 to 5%.^{17,21,23–25,20,32} Post-operative acute kidney injuries occurred in between 0 and 25%, requiring haemodialysis in 0–5% of cases.^{17,21,23–25,20,32} Thirty day re-interventions occurred from 0 to 14% of cases.^{17,21,23–25,20,32}

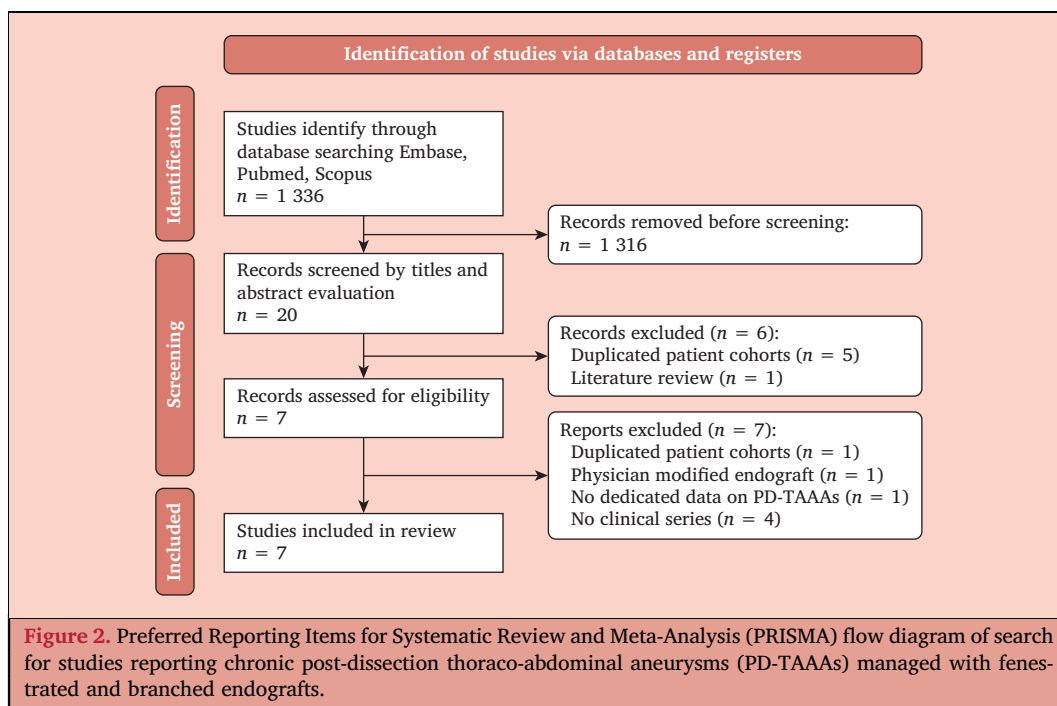
The median follow up was reported between 12 and 26 months,^{17,21,23–25,20,32} with survival ranging from 84% to 90% at 24 months, with aortic related death reported between 0 and 11%.^{17,21,23–25,20,32} TVV patency was estimated between 95% and 100% at two years.^{17,21,23–25,20,32} Overall, the endoleak rate was reported between 16% and 76%.^{17,21,23–25,20,32} Overall, re-interventions occurred in between 19% and 53% of patients, with an estimated FFR at two years between 48% and 63% of patients.^{17,21,23–25,20,32}

Only two studies reported information about the complete false lumen thrombosis at one year: Law *et al.*²⁴ 92% and Oikonomou *et al.*²³ 85%. Overall aneurysm shrinkage was reported in between 80% and 95% of cases.^{17,21,23–25,20,32}

DISCUSSION

This study analyses early/midterm outcomes of PD-TAAAs submitted to F/B-EVAR in four Italian academic centres, in the light of the data of the series published between 2013 and 2020.

In the present authors' experience, PD-TAAAs represent approximately 10% of all TAAAs managed by F/B-EVAR and can be treated satisfactorily with TS, and 30 day mortality, and post-operative renal function worsening rates of 92%, 0%, and 5%, respectively. Post-operative SCI remains a complication (16%); however, no cases of permanent



paraplegia occurred in this series. These results remained consistent at a median follow up of 32 months with estimated three year survival, TVV patency and FFR of 81%, 97%, and 66%, respectively.

Open repair of PD-TAAAs is usually more complex than that of degenerative TAAAs, and leads to notable post-operative mortality and morbidity rates.^{33,34} In a recent experience, Latz *et al.*³⁴ showed a higher peri-operative mortality rate (12% vs. 6%; $p = .034$), post-operative stroke (8% vs. 2%; $p = .010$), re-interventions (24% vs. 14%; $p = .030$), and longer hospitalisation (median 18 vs. 14 days; $p = .020$) in PD-TAAAs compared with degenerative TAAAs. PD-TAAAs were independently associated with both peri-operative death and major adverse events.

Following satisfactory results of F/B-EVAR in degenerative TAAAs repair,^{5–7} some pioneering centres proposed approaching PD-TAAAs with this technology to reduce the peri-operative complications of open repair in high risk patients.^{8–10} In these situations, F/B-EVAR could be considered as the last and most effective stage in PD-TAAA endovascular management, because it excludes the multiple distal entry tears in the paravisceral and infrarenal aorta, promotes false lumen thrombosis, and stimulates subsequent aortic remodelling. These cases require technically demanding and time consuming procedures due to the anatomical peculiarities and therefore all these aspects should be accurately discussed in the pre-operative endograft planning, procedural steps, and follow up protocols.

According to the literature data, PD-TAAAs usually occur at a younger age compared with degenerative ones and are frequently associated with connective tissue disorders.^{25,30,32} Both of these features are present in the study cohort, where the median age was 66 years and 19% of cases had connective tissue disorders. This should be considered, especially when planning long term follow up protocols.

Patients with PD-TAAAs could have a chronic dissection of aortic arch or supra-aortic branches or a previous aortic surgical or endovascular repair.^{17,21,23–25,20,32} In the present series, 84% of cases had been previously submitted to aortic procedures and 35% had a previous aortic arch repair. The latter may increase the technical difficulty of arterial access from above, for example in case of previous supra-aortic trunk debranching and acute angle re-implantations or frozen elephant trunk. Right subclavian access³⁵ or a brachial femoral through and through technique could be considered as technical adjuncts to improve the stability of TVV cannulations and stenting from above. Moreover, cannulation of caudally directed branches can be safely and effectively performed by a transfemoral approach with steerable introducers.^{36,37}

The aortic dissection usually extends to the paravisceral aorta and iliac arteries and can be associated with challenging management of both TVVs and hypogastric arteries. Specifically, TVVs may originate from the true lumen, the false lumen, or both. The true lumen is usually narrow and an issue for endograft sizing, design (fenestration vs. branches) and difficult TVV cannulation in a restricted space. Another important aspect to evaluate is the false lumen reperfusion caused by back flow from intercostal or lumbar, inferior mesenteric, or hypogastric arteries, which can lead to continued false lumen pressurisation and failure of aortic remodelling. For this reason, adjunctive planned intra-operative procedures, such as primary false lumen coiling or a first therapeutic stage with TEVAR plus candy plug technique,³⁸ should be considered to reduce the rate of persistent type II endoleak and pressurisation of the false lumen. In the present series, three (8%) patients received a candy plug during the first thoracic stage and seven (19%) false lumen coiling during the F/B-EVAR repair.

Due to all these anatomical peculiarities, endograft planning should be discussed in detail. As reported in the

literature review, in the majority of cases custom made endografts are used, in line with the present experience (custom made: 69% vs. off the shelf: 31%). The endograft is usually planned with a proximal portion consisting of two or more sealing stents sized according to the proximal healthy aortic diameter (oversizing about 15% – 20%) and a second portion tapering at the level of TVV origin (diameter 18 – 22 mm), to guarantee space for the TVV cannulations.^{10,21,23,24} In this segment, the endograft diameter is usually evaluated according to the length of the main axis of elliptic shape of the true lumen, the so called French croissant rule.^{10,21,23,25} Due to the narrow true lumen space, TVVs are mostly accommodated by fenestrations, as in the present series, with 71% of 135 TVVs. Fenestrations are usually planned for TVVs that originate from the true lumen or for vessels originating from false lumen with a clear tear at their level.^{10,21,23,24} For vessels originating from the false lumen without an entry tear at this level, a branch revascularisation could be planned by a branch located above an entry tear, to connect the endograft deployed in the true lumen with the TVVs that originate from the false lumen.^{10,21,23,24} It is clear that in these cases, a long bridging stent graft should be used, creating a risk of late TVV instability. A third option consists of creating a new tear at the level of the TVV origin before customisation of the F/B-EVAR endograft.^{10,21,23,24} Another helpful adjunct to overcome the problem of the narrow true lumen, for both ipsi- and contralateral access, is to use the modified pre-loaded system for renal arteries.^{39,40}

The sizing of TVV bridging stents requires particular attention. These patients usually have large TVV diameters and the distance between fenestrations or branches and the native vessels may be longer than cases with degenerative pathology.^{10,21,23,24} Both these aspects may increase the risk of TVV instability and could lead to a higher incidence of re-interventions. For these reasons, particular attention could be required in the sizing of TVV diameter, length, overlap, and follow up, to detect and manage possible problems in a timely manner. In the case of iliac artery aneurysmal evolution or dissection at this level, an iliac branch device can be implanted to maintain hypogastric artery patency, closing the last distal entry tear of dissection and preventing the risk of paraplegia.^{10,23,25,26}

In the literature, the incidence of SCI in PD-TAAAs ranges between 0 and 16%, with permanent paraplegia reported in up to 5%.^{17,21,23–25,30,32} The risk of this catastrophic complication is not negligible because most patients have Crawford extent II–III TAAAs, have had previous aortic surgery, and have involvement of the left subclavian and/or hypogastric arteries.^{17,21,23–25,30} A dedicated SCI prevention protocol should be used to reduce as far as possible the incidence of SCI.

Concerning the literature review, use of F/B-EVAR technology for PD-TAAAs has been reported in the last decade with only a few dedicated papers, reporting 256 cases.^{17,21,23–25,30,32} Results are satisfactory in terms of TS (93% – 100%), 30 day mortality (0 – 6%) and SCI (0 – 16%).^{17,21,23–25,30,32} Midterm outcomes (mean or median follow up range: 12 –

26 months) show two year survival rate of 81% – 90% and TVV patency of 95% – 100%, respectively.^{17,21,23–25,30,32} These results can be considered acceptable and comparable with results of degenerative TAAAs.^{5–7}

One of the critical issues is the high rate of late re-interventions. The rate of re-interventions ranges between 19% and 53%,^{17,21,23–25,30,32} and it is higher than degenerative TAAA cases.^{5–7} This aspect underlines the crucial importance of a strict and dedicated follow up to promptly detect any defect and correct it. In the present authors' experience, the rate of re-intervention was 32%, in line with previous literature reports.^{17,21,23–25,30,32} The causes of re-interventions are heterogeneous and seem to be associated with high back flow in the false lumen or TVV instability. Both these aspects could be ameliorated by adjunctive planning and procedural manoeuvres as reported above. Finally, literature cases with reported radiological follow up demonstrated that there is an excellent rate of complete false lumen thrombosis with aortic remodelling.^{17,21,23–25,30,32} In the present series, 81% of cases completed radiological follow up at one year, with a satisfactory complete false lumen thrombosis rate (87%) and aneurysm shrinkage (73%).

The present study has several limitations. It is a retrospective analysis of a small cohort of patients collected in a multicentre registry. The clinical follow up is limited and complete radiological evaluation of aortic remodelling was available for only 81% of cases at one year and without a dedicated core lab. Due to the study's characteristics (retrospective and multicentre) some important data, such as the overall iodinated contrast volume and radiation dose, are not available or validated. However, the literature review suggests that these cases are infrequent with no long term data available. These are particular cases reported in centres with high experience, and the learning curve is a key point in planning and execution of these challenging cases. However, the small sample size and the multicentre nature does not allow for a subanalysis at the moment. Finally, cases included in the registry were performed over a long time period (2014 – 2019) and technical evolution occurred over these years (graft design, steerable sheath, indwelling catheters and wires), which was not considered in the analysis.

Conclusion

F/B-EVAR can be performed successfully to treat patients with PD-TAAAs. A high rate of re-interventions is necessary, however, to complete aneurysm exclusion and aortic remodelling effectively. Intra-operative preventive endoleak strategies and strict follow up protocol should be adopted to guarantee clinical success during follow up.

CONFLICT OF INTEREST

L.B., G.F., E.G., M.G., G.M. are clinical proctors for Cook Zenith fenestrated endograft.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2022.06.019>.

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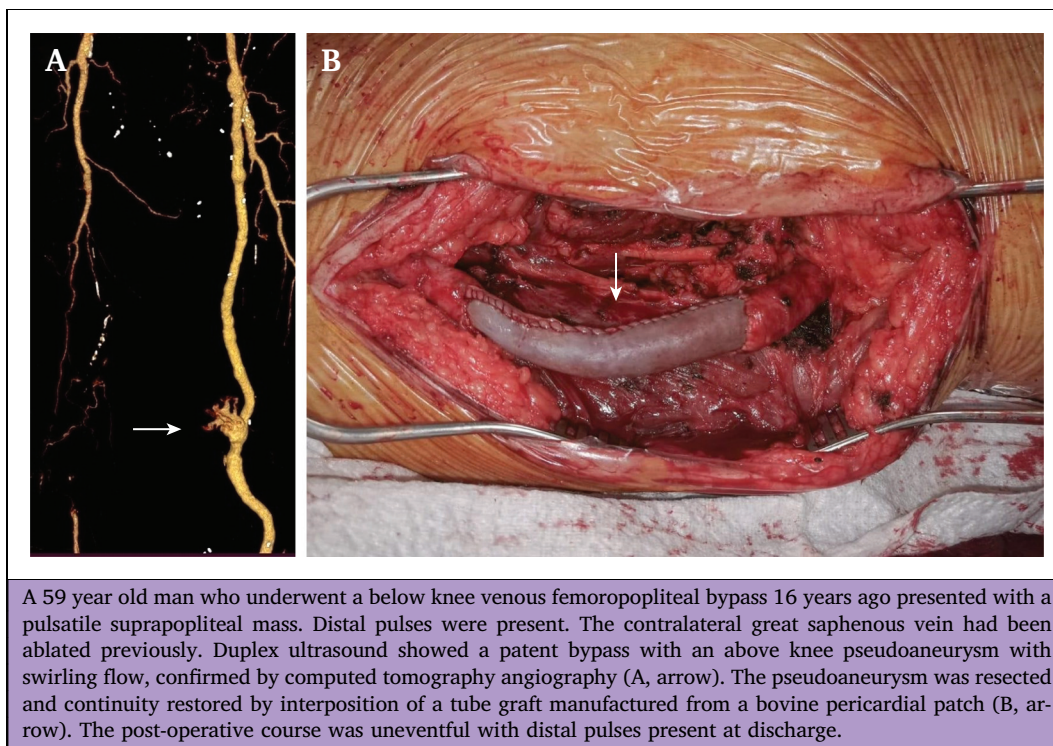
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The Bovine Pericardium — Salvage Option for a Late Complication

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