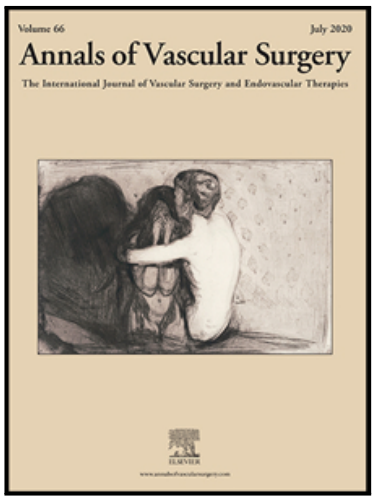

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PII: S0890-5096(21)00110-2
DOI: https://doi.org/10.1016/j.avsg.2020.12.047
Reference: AVSG 5578

To appear in: *Annals of Vascular Surgery*

Received date: September 26, 2020
Revised date: December 28, 2020
Accepted date: December 29, 2020

Please cite this article as: V. Makaloski , N. Tsilimparis , G. Panuccio , K. Spanos , T.R. Wyss , F. Rohlffs , E.S. Debus , T. Kölbel , Perioperative outcome of fenestrated and branched stent grafting after previous open or endovascular abdominal aortic repair, *Annals of Vascular Surgery* (2021), doi: https://doi.org/10.1016/j.avsg.2020.12.047

Perioperative outcome of fenestrated and branched stent grafting after previous open or endovascular abdominal aortic repair

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Word count: 2591

Abstract

Aim: To compare the perioperative outcome of patients treated with elective or urgent fenestrated and branched stent grafting (fbEVAR) for pararenal (pAAA) and thoraco-abdominal aortic aneurysm (TAAA) after previous open with previous endovascular abdominal aortic repair.

Methods: Single center retrospective analysis of all patients undergoing fbEVAR after previous open (post-open fbEVAR group) or endovascular abdominal aortic repair (post-endo fbEVAR group) between January 2015 and December 2017. Primary outcomes were technical success and in-hospital all-cause mortality.

Results: We identified 42 patients undergoing fbEVAR after previous open or endovascular abdominal aortic repair during this period. Twenty-one patients (post-open fbEVAR group) had previous open abdominal aortic repair, 13 with a bifurcated and eight with a tube graft. Of these, two patients presented with pAAA and 19 with TAAA. Twenty-one patients (post-endo fbEVAR group) had previous EVAR. Thirteen patients presented with pAAA, three of them with additional type Ia endoleak, two with stent-graft migration and two with previously failed fEVAR. Eight presented with TAAA. Median interval between previous repair and fbEVAR was 84 months (IQR 60-156) for the post-open fbEVAR group and 72 months (IQR 36-96) for the post-endo fbEVAR group (P=0.746). Eighteen patients (86%) had branched stent grafting in the post-open vs. eleven (52%) in the post-endo group (P<0.01). In two patients in the post-open group, three renal arteries were not catheterized due to severe ostial stenosis, resulting in technical success of 91% in the post-open and 100% in the post-endo fbEVAR group. Four patients (19%) in the post-open fbEVAR group died in hospital, two due to cerebral haemorrhage and two due to pneumonia, and none in the post-endo fbEVAR group (P=0.101). There were five non-stent-graft-related re-interventions, two (10%) in the post-open fbEVAR group and three (14%) in the post-endo fbEVAR group (P=0.844). After 12 months there were four events in the post-endo fbEVAR group: one renal artery stent

occluded, one renal artery stent required relining because of disconnection and two type II endoleaks were embolized with coils. There were no re-interventions in the post-open fbEVAR group during 12 months.

Conclusion: Fenestrated and branched repair after previous open or endovascular abdominal aortic repair appears safe with high technical success rate. There is no difference in the technical success and in-hospital all-cause mortality rates between fbEVAR after previous open or endovascular abdominal aortic repair.

Introduction

Despite significant improvement of stent-graft technology over the past 25 years, increased numbers of re-intervention after EVARs can be expected over time, due to natural aortic disease progression and use outside of instructions for use.[1] Open surgical repair after failed EVAR is a high-risk treatment with increased morbidity and mortality, especially in an emergency setting.[2,3] Endovascular repair with fenestrated and branched stent-grafts (fbEVAR) after failed EVAR is potentially less invasive by using healthy suprarenal sealing zones but is technically demanding with a reported lower technical success rate compared with primary fbEVAR.[4-7]

Progressive aneurysmal degeneration of the aorta after previous open abdominal aortic repair can lead to aneurysmal dilatation proximal to the previous repair as para- or suprarenal aneurysm. Re-do open aortic surgery in this usually elderly population with significant co-morbidities is challenging with a high risk for complications and prolonged intensive care unit (ICU) and hospital stay.[8,9] Alternatively, the use of fbEVAR after previous open repair may be a less morbid option with low morbidity and high technical success rates.[10-13]

The aim of this study is to compare the perioperative outcome of patients treated with elective or urgent fbEVAR for pararenal (pAAA) and thoraco-abdominal aortic aneurysm (TAAA) after previous open with previous endovascular abdominal aortic repair in a single tertiary institution.

Methods

This is a single center cohort study of all patients undergoing fbEVAR with the use of off-the-shelf, custom-made and surgeon-modified fenestrated or branched stent-grafts for pAAA and TAAA. Indications included aneurysmal progression after previous open or endovascular abdominal aortic repair, type Ia endoleak with or without stent-graft migration after previous EVAR between January 2015 and December 2017. Patients with connective tissue disease were excluded from the study. Written informed consent for the anonymous data use for scientific purposes was obtained in all cases. Since this is a retrospective analysis, no approval from the institutional review board was obtained.

Patients were divided in two groups: after previous open abdominal aortic repair (post-open fbEVAR) and after previous endovascular abdominal aortic repair (post-endo fbEVAR). Primary outcomes were technical success defined as successful delivery and deployment of the fenestrated/branch graft without type I and III endoleak, catheterization and preservation of the planned target vessels and in-hospital all-cause mortality. Secondary outcomes were major adverse events, including any complication, perioperative myocardial infarction, sepsis, respiratory failure, neurological deterioration/stroke, postoperative acute kidney injury, spinal cord injury (SCI), ICU and hospital stay and stent-graft related and non-stent-graft related re-interventions. The major adverse events were stratified by categories and adapted according to previously accepted standards.[14] In-hospital clinical outcomes for all patients were extracted from hospital records.

Elective repair was generally indicated in aneurysm size diameter of ≥55mm for pAAA and ≥60mm for all types of TAAA, including post-dissection aneurysm and in failed EVARs with type Ia endoleak independent of aneurysm size, with or without stent-graft migration. Immediate repair was undertaken in patients with ruptured aneurysm. Patients with back- and/or thoracic pain without other identifiable cause were considered as symptomatic and treated urgently usually within 24 hours. Prophylactic spinal fluid drainage was placed

immediately before the endovascular repair and left in place for at least 48 hours postoperatively in cases of high risk for SCI according to our standardized protocol for spinal injury prevention as previously published.[15]

Staged treatment was performed in elective cases with high risk for SCI by either separating proximal TEVAR and fbEVAR into two procedures or with temporary aneurysm sac perfusion by leaving a branch or the contralateral iliac component uncompleted for at least 5 days.

Hypertension was defined as a baseline blood pressure > 140/90 mmHg and/or the intake of one or more antihypertensive drugs. Hyperlipidemia was defined as abnormal cholesterol or triglycerides blood level and/or the intake of lipid-lowering drugs. Chronic kidney disease was defined as reduction of kidney function (GFR <60 ml/min) according to the KDIGO 2017 Clinical Practice Guideline.[16] Postoperative acute kidney injury was defined according to the KDIGO 2012 Clinical Practice Guideline.[17] Postoperative stroke was defined according to the updated definition of stroke for the 21st century.[18] Peripheral artery disease was defined as a positive history of lower limbs surgical or endovascular revascularization and/or clinical symptoms such as claudication, rest pain or foot ulcers and/or abnormal ankle/brachial index (ABI) and duplex scan findings. The preoperative physical status was rated according to the American society of anesthesiologists (ASA) classification.[19] Target vessel was defined as an aortic side-branch that was attached by either a fenestration or a branch using a covered stent. Vessels treated with scallop were not considered as target vessel.

In elective cases custom-made fbEVAR stent-grafts (Cook Medical, Bloomington IN, USA) were individually planned. For urgent cases with pAAA surgeon-modified fenestrated and for urgent cases with TAAA the Zentih® t-branch, an off-the-shelf multibranched stent-graft (Cook Medical, Bloomington IN, USA) were used.[20] Surgeon-modified stent-grafts were

modified using off-the-shelf stent-graft components. The fenestrations were performed on a back-table, while the patient was prepared for the procedure.[21]

Categorical data were reported as counts and percentages and compared between groups through Chi-square test and Fisher tests, while continuous data were reported as median and interquartile range and compared through Mann-Whitney U test. A P-value ≤0.05 was considered significant in all tests. SPSS for Macintosh (version 22.0.0.0; IBM corp., Armonk, NY) was used for statistical analysis.

Results

207 patients (149 male, 72%) with mean age of 73 ± 8 years had elective or urgent fbEVAR for pAAA (n=96; 46%) or TAAA (n=111; 54%) between January 2015 and December 2017. Of those, 165 patients (80%) had primary fbEVAR. Twenty-one patients (10%) had previous open abdominal aortic repair, 13 with a bifurcated and eight with a tube graft. Two patients presented with pAAA and 19 with TAAA. (Table 1) Twenty-one patients (10%) had previous endovascular abdominal aortic repair. Thirteen patients presented with newly developed pAAA: three of them with additional type Ia endoleak, two with stent-graft migration and two with previously failed FEVAR. Eight presented with newly developed TAAA. Median interval between previous open abdominal aortic repair and post-open fbEVAR was 84 months (IQR 60-156) and between index endovascular procedure and post-endo fbEVAR was 72 months (IQR 36-96)(P=0.746).

In the post-open fbEVAR group 19 patients (19/21, 90%) were treated for TAAA, whereas eight patients had TAAA in the post-endo fbEVAR group (8/21, 31%) (P<0.01). Detailed distribution of aneurysm morphology is listed in Table 1. There were no females in the post-endo fbEVAR group compared with two female patients (10%) in the post-open fbEVAR group (P<0.01).

Eighteen patients (86%) had branched stent grafting in the post-open vs. eleven (52%) in the post-endo group (P<0.01). There was no significant difference between the groups regarding the clinical presentation. (Table 2)

A total number of 162 vessel (38 celiac trunks, 41 superior mesenteric arteries and 83 renal arteries) were intended to treat in both groups. Of those 159 (98%) were successfully catheterized and stented with bridging stents. In two patients in the post-open group, three renal arteries were not catheterized due to severe ostial stenosis and their branches were occluded with vascular plugs. (Table 2) The patient in whom both renal arteries could not be

catheterized presented with ruptured TAAA and was already on dialysis at admission. The other one had postoperative acute kidney injury stage 1 and required no dialysis postoperatively. No target vessel was lost because of inability to catheterize due to mechanical problem from previous open or endovascular repair. Initial technical success of 91% (19/21) and 100% (21/21) was achieved in the post-open and post-endo fbEVAR group, respectively (P=0.200). Total number of target vessels was similar between the groups: 3.8 ± 0.6 (median 4.0) for the post-open fbEVAR group and 3.8 ± 0.4 (median 4.0) for the post-endo fbEVAR group (P=0.254). No difference was observed between the numbers of fenestrations used. (Table 2)

Total operating time was longer but statistically not significant in the post-open (473 ± 152 minutes) vs. post-endo (406 ± 134 minutes) fbEVAR group (P=.011). There was no difference between the groups in fluoroscopy time and dose area product (DAP). (Table 2) Increased amount of contrast medium was used in the post-open group 179 ± 88 vs. 111 ± 56 in the post-endo group (P=.232).

Four patients (19%) after post-open fbEVAR died in-hospital and none after post-endo fbEVAR (P=0.101). Two patients died due to cerebral haemorrhage, one on 2nd and one on 23rd day after symptomatic type IV TAAA and ruptured type I TAAA repair, and two patients died due to pneumonia on 14th and 15th day after elective PAA and ruptured PAA, respectively. The comparison of the elective cases only in both groups showed no difference between the mortality rates (one in the post-open vs. none in the post-endo group, P=.275)

A significantly higher rate of postoperative myocardial infarction 3/21 (14%) was found in the post-open fbEVAR group and none in the post-endo fbEVAR group (P<0.01). All three patients had ST elevation myocardial infarction and a history for previous cardiac coronary artery disease. None required coronary re-intervention and all were discharged home. Stage 1 postoperative acute kidney injury was observed in four patients (19%) in the

post-open vs. two (10%) in the post-endo group (P=507). Six patients, all receiving branched EVAR suffered SCI postoperatively: five (three in the post-open and two in the post-endo group) had transient paraparesis and recovered prior to discharge, and one remained paraplegic. The latter had stroke as well and was the same patient on previous dialysis with no connected renal arteries dying after cerebral haemorrhage.

No patient required a stent-graft related re-intervention. There was no difference between the number of non-stent-graft-related re-interventions between the groups [two (10%) in the post-open group and three (14%) in the post-endo group, P=0.844]. One common femoral artery bleeding and one brachial artery pseudoaneurysm in the post-open group required surgical revision. One retroperitoneal hematoma and two infections in the groin required surgical revision in the post-endo group. (Table 3) Both groups had similar ICU (8 ± 7 in the post-open group and 6 ± 5 in the post-endo group, P=0.126) and hospital stay (16 ± 9 in the post-open group and 13 ± 11 in the post-endo group, P=0.655), respectively.

After 12 months there were four events in the post-endo fbEVAR group: one renal artery stent occluded, one renal artery stent required relining because of disconnection and two type II endoleaks were embolized with coils. There were no re-interventions in the post-open fbEVAR group during 12 months postoperatively.

Discussion

We identified a cohort of 42 patients undergoing fbEVAR after previous open or endovascular aortic repair at a single center over three years. This is one of the largest single-center studies including elective and urgent cases as well as extended pathologies (i.e. thoraco-abdominal aneurysms).[22] Complex fenestrated and branched stent grafting after previous open and endovascular abdominal aortic repair is feasible with high technical success rates and acceptable in-hospital mortality.

Without reaching statistical significance, there was a higher in-hospital mortality rate in the post-open fbEVAR group (19%) compared with the post-endo group (0%). The post-open fbEVAR group had higher percentage of patients undergoing branched repair for TAAA (19/21, 90%) and higher percentage of symptomatic/ruptured aneurysm (8/21, 38%) compared with the post-endo group. Higher in-hospital mortality rates could be expected in patients with urgent clinical presentation, increased repair complexity and extension of aneurysmatic disease.[23] Of the four deaths in our series three had urgent clinical presentation and underwent branched repair, two of them for TAAA. All in-hospital deaths were non-aortic related. Additional comparison of the elective cases in both groups revealed no differences in mortality between the groups.

A recent Swedish study on fbEVAR after previous infrarenal repair included 43 patients from two centres over a period of 14 years. After a median follow-up of 33 months, they reported a 30-day mortality of 0% and a 1-year mortality of 5%. Similar to our results, a median time of 59 months between the initial repair and the fbEVAR was observed. The authors concluded that fbEVAR is a valid alternative to open surgery after previous infrarenal repair.[13]

The presence of previous endovascular material in the iliac arteries and in the pararenal aorta makes post-endo fbEVAR technically more demanding. Varying rates of technical success were reported. [4-6,10,22,24-27] Wang et al recently reported a 100% technical

success rate in six patients after fenestrated EVAR for previously failed EVAR and in six after previous open repair.[24] Similar to our experience, Wang et al. did not find a difference between the technical success rates after post-open or post-endo fbEVAR, respectively. Katsargyris et al.[5] and Martin et al.[22] reported a high technical success rate of 92% for fEVAR as salvage of prior EVAR, but experienced difficult iliac and renal artery access in some patients, resulting in dislodgement of the first stent-graft or difficult catheterization of the renal arteries. Falkensammer et al. reported significantly lower primary technical success rates (58%) in 12 patients receiving fenestrated EVAR for failed EVAR.[4] We did not identify technical difficulties of renal artery completion due to the presence of stent-grafts in the pararenal aorta or stent-graft passage through iliac stent-grafts. (Figure 1) We found a similar number of target vessel and similar rates of technical success in both groups. In total 98% (159/162) of all target vessel were successfully catheterized and bridging covered stents were placed. Severe ostial stenosis was the reason for technical failure in two patients and not a mechanical component after previous open or endovascular repair.

Although statistically not significant, we found longer operating and fluoroscopy time, as well increased use of contrast medium in the post-open group. Identical findings were previously reported.[4,6,22,24] In the post-endo group, previously implanted endovascular material can reduce the visibility of the new stent-grafts and influence the image quality. Consequently, higher image quality with increased radiation exposure may be used. In the post-open group, there was no interference with the old implanted material, but the number of complex branched EVAR for TAAA was higher resulting in more complex procedures with longer operating and fluoroscopy times as well as increased contrast medium use.

The post-open group had higher rates of any complication compared with the post-endo group, but this group had more emergency cases and branched repair. Therefore, the post-open group had a slightly longer ICU and hospital stay. There was no difference between the groups in the early re-intervention rate, but the post-endo group had higher re-intervention

rate during first 12 months, one of them related to renal bridging stent dislocation and two required coiling of type II endoleak. One renal artery stent occluded during 12 months postoperatively in the post-endo group after previous fenestrated repair.

Limitation

Limitations of the current study are the retrospective nature of the study and the limited number of patients in the post-open and post-endo group and the use of various devices and techniques for different aortic pathologies, thus potentially influencing patient's outcome. By including both, emergent and elective cases and also relatively simple pararenal as well as highly complex thoracoabdominal cases in varying percentages among groups there is a potential bias in the data analysis.

Conclusion

Fenestrated and branched repair after previous open or endovascular abdominal aortic repair appears safe and technically feasible. There is no difference in the technical success and in-hospital all-cause mortality rates between fbEVAR after previous open or endovascular abdominal aortic repair. Further studies need to assess the long-term results of these promising techniques.

Study design: VM, TK

Data collection: VM

Data analysis: VM, TK

Writing: VM, TRW, TK

Critical revision: NT, GP, KS, FR, ESD

Overall responsibility: VM

Conflict of interest: NT is Proctor for Cook Medical and has received Travel grants.
TK has Intellectual Property with Cook Medical.

Funding: none

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Table 1. Baseline characteristics fbEVAR

Characteristic	Post-open (21 patients)	Post-endo (21 patients)	P
Age, years	75 ± 6	74 ± 7	.157
Female	2 (10%)	0	<.01
Coronary artery disease	13 (62%)	10 (48%)	.336
Hypertension	15 (71%)	16 (76%)	.734
Hyperlipidaemia	7 (33%)	6 (29%)	.432
Smoking	8 (38%)	7 (33%)	.886
COPD	6 (29%)	3 (14%)	.530
Diabetes	3 (14%)	4 (19%)	.507
Chronic kidney disease*	9 (43%)	9 (43%)	.844
Peripheral artery disease	5 (24%)	2 (10%)	.470
ASA class			.639
2	1 (5%)	1 (5%)	
3	11 (52%)	15 (71%)	
4	8 (38%)	5 (24%)	
5	1 (5%)	0	
Type of aneurysm			<.01
pararenal	2 (10%)	11 (52%)	
suprarenal	0	2 (10%)	
type I TAAA	3 (14%)	0	
type II TAAA	3 (14%)	2 (10%)	
type III TAAA	1 (5%)	1 (5%)	
type IV TAAA	9 (43%)	4 (19%)	
type V TAAA	3 (14%)	1 (5%)	
Post-dissections aneurysm	2 (10%)	0	.305
Max. aneurysm diameter	68 ± 17	71 ± 21	.026

fbEVAR fenestrated or branched endovascular aortic repair; COPD chronic obstructive pulmonary disease; *mild loss (or more) of kidney function (GFR <60 ml/min) according

to the KDIGO 2017 chronic kidney disease Clinical Practice Guidelines; ASA American society of anaesthesiology; TAAA thoraco-abdominal aortic aneurysm

Table 2. Perioperative characteristics

Characteristic	Post-open (21 patients)	Post-endo (21 patients)	P
Clinical presentation			.832
elective	13 (62%)	16 (76%)	
symptomatic	5 (24%)	3 (14%)	
ruptured	3 (14%)	2 (10%)	
Types of grafts used			<.01
fenestrated	3 (14%)	10 (48%)	
branched	14 (67%)	11 (52%)	
combined	4 (19%)	0	
Number of fenestrations			.195
1	1 (5%)	0	
2	1 (5%)	0	
3	3 (14%)	2 (10%)	
4	2 (10%)	8 (38%)	
Planned target vessel			
Celiac trunk	19/19 (100%)	19/19 (100%)	.548
Superior mesenteric artery	20/20 (100%)	21/21 (100%)	1.00
Right renal artery	21/23 (91%)	19/19 (100%)	<.01
Left renal artery	19/20 (95%)	21/21 (100%)	.014
Technical success	19 (91%)	21 (100%)	.200
Operation time, minutes	473 ± 152	406 ± 134	.011
Contrast medium, ml	179 ± 88	111 ± 56	.232
DAP, Gy/cm^2	222 ± 284	224 ± 211	.016
Fluoroscopy time, minutes	81 ± 41	69 ± 32	.386
Spinal fluid drainage	13 (62%)	14 (67%)	.351

DAP dose area product; percentages may not total 100 due to rounding

Table 3. Postoperative outcome

	Post-open (21 patients)	Post-endo (21 patients)	P
Any complication	13 (62%)	8 (38%)	.135
SIRS/sepsis	3 (14%)	2 (10%)	.358
Myocardial infarction	3 (14%)	0	<.01
Respiratory problems	2 (10%)	2 (10%)	.099
Stroke	1 (5%)	0	.076
Postoperative acute kidney injury*			.507
stage 1	4 (19%)	2 (10%)	
stage 2	0	0	
stage 3	1 (5%)	0	
Spinal cord injury			.883
transient paraparesis	3 (14%)	2 (10%)	
paraplegia	1 (5%)	0	
Re-intervention			.844
Stent-graft related	0	0	
Not related to stent-graft	2 (10%)	3 (14%)	
Access complications	1 (5%)	0	.458
Bleeding			.146
Requiring re-intervention	1 (5%)	1 (5%)	
Treated conservatively	2 (10%)	0	
Wound healing problems			.366
Requiring re-intervention	0	2 (10%)	
Treated conservatively	0	0	

ICU stay	8 ± 7	6 ± 5	.126
Hospital stay	16 ± 9	13 ± 11	.655
In-hospital all-cause mortality	4 (19%)	0	.101

SIRS systemic inflammatory response syndrome; *according to the KDIGO 2012 acute kidney injury Clinical Practice Guidelines; ICU intensive care unit; percentages may not total 100 due to rounding

Figure legend

Figure 1: 74y-old male with a type 1A endoleak and aneurysm growth after EVAR with iliac side-branch 3 years before. A: Multiplanar reconstruction (MPR) demonstrating Type 1A endoleak B: Axial image demonstrating enlargement of aneurysm diameter to 8.1cm. C: Digital subtraction angiography (DSA) before partial deployment of a 4-fenestrated EVAR stent-graft demonstrating potential challenge of catheterizing the right renal artery (RRA) and achieving graft-wall apposition at the left renal artery. D: selective angiography before catheterizing the RRA crossing the proximal bare stent of the previous EVAR device. E: selective angiography after deployment of a bridging covered stent in the RRA. F: final angiography demonstrating unimpeded flow to all 4 reno-visceral arteries and absence of a Type 1A endoleak. G: 3D reconstruction of preoperative CT-angiography. H: 3D reconstruction of postoperative CT-angiography.