

Outcomes and evolution of fenestrated-branched EVAR: a 10-year single-centre learning curve analysis

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ABSTRACT

INTRODUCTION: Fenestrated and branched endovascular aneurysm repair (f/bEVAR) represents an advanced technique for treating aortic aneurysms that extend to or involve visceral and renal vessels. This technically demanding procedure requires specialised skills and has a steep learning curve. This study aimed to analyse a single-centre 10-year experience with F/BEVAR, focusing on the learning curve effect.

METHODS: A retrospective analysis was conducted on all f/bEVAR cases performed between 2016 and the present day. Patients without follow-up were excluded. Cases were stratified by study period quartile to account for unequal case distribution over the years. Primary outcomes included technical success (defined as successful incorporation of target vessels), 30-day mortality, major adverse events (MAE), and one-year reintervention rates. Procedural characteristics and outcomes were compared across quartiles.

RESULTS: A total of 53 cases were included, with a median age of 71 years, and 49 (92.5%) of the patients were male. Six (11.3%) were symptomatic aneurysms, and one patient presented with a ruptured aneurysm. Twenty-one (39.6%) cases had thoracoabdominal aneurysms, followed by juxta-renal (19 cases, 35.8%). Five patients (9.4%) had a history of aortic dissection. Six patients (11.3%) underwent arch procedures. Most cases (44 cases, 83%) had 4 target vessels incorporated. Thirty-day mortality was 11.3%, and 30-day MAE was 13.2%. When analysing by temporal quartile, the 4th study quartile demonstrated higher proportions of arch procedures, higher numbers of vessels incorporated, increased use of femoral-only access, higher implementation of fusion imaging, and lower 30-day mortality and MAE rates. A proctor was present in 34% of cases, primarily in the first 2 study quartiles.

CONCLUSION: This 10-year experience with f/bEVAR demonstrates a significant learning curve effect. These findings highlight the importance of specialised training, proctorship in early experience, and the value of cumulative institutional expertise in managing complex aortic pathologies with f/bEVAR.

Keywords: Endovascular aneurysm repair; Aortic aneurysm; Learning Curve



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INTRODUCTION

Complex endovascular aortic repair (EVAR) has been widely used in the treatment of aortic aneurysms involving visceral branches. Multiple techniques have been developed, including fenestrated endovascular aortic repair (fEVAR) and branched endovascular aortic repair (bEVAR). Since the first implant in the 1990s, postoperative outcomes have improved with the growth of worldwide experience, and the advantages of this technique have been shown when compared with open repair.[2] These procedures are more demanding than conventional EVAR, due to the use of tailored stent grafts for each visceral vessel incorporated and the necessary planning and endovascular skills needed. As with any new procedure, a learning curve is associated with the technique. This learning curve is not defined by a single parameter but is composed by patient selection, team performance, ability to adapt to unexpected events, and duration of repair. (3) Learning curve analysis has been reported for EVAR, but more rarely for complex EVAR. In high-volume centres, it has been reported that there is increased complexity with lower mortality and major adverse events (MAE) over time. [3]

The objective of this study was to assess the learning curve of f/bEVAR in a single institution and to assess trends in complexity and outcome variables.

METHODS

A retrospective analysis was conducted on all f/bEVAR cases performed between January 2016 and January 2025. Patients without follow-up were excluded. Demographics, clinical characteristics, maximum aneurysm diameter, intraoperative data and outcomes were reviewed from clinical records. Thoracoabdominal aneurysms were classified according to the Safi classification.⁽⁴⁾

Figure 1. Number of f/bEVAR procedures performed over time

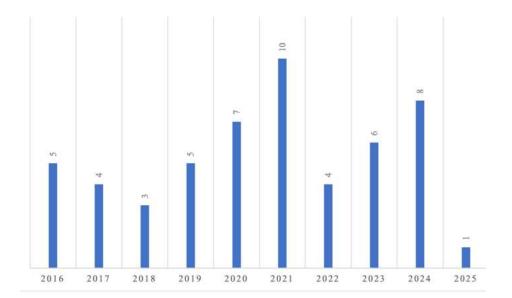
Procedures were performed either in the operating room using a mobile C-arm (Ziehm Vision FD) or in the angiographic suite using a ceiling-mounted arm (either Philips Azurion 5 M12 or Canon Alphenix).

Primary outcomes included technical success (defined as successful incorporation of target vessels), 30-day mortality, 30-day major adverse events (MAE), and one-year reintervention rates. MAE were defined as the occurrence of any 30-day deaths, myocardial infarction, respiratory failure requiring prolonged (>24 h from anticipated) mechanical ventilation or reintubation, renal function decline resulting in >50% reduction in baseline eGFR or new-onset dialysis, bowel ischemia requiring surgical resection or not resolving with medical therapy, major stroke or grade 3 paraplegia. (4)

Cases were stratified by study quartile to account for unequal case distribution between years. Procedural characteristics and outcomes were compared across quartiles. All patients enrolled in the study signed a dedicated informed consent. This manuscript was composed according to STROBE guidelines. Statistical analysis was performed using IBM SPSS Statistics for macOS, version 29 (IBM Corp., Armonk, N.Y., USA). Continuous variables are presented as mean and standard deviation (SD). Categorical variables are presented as numbers with percentages. Baseline differences were assessed using the chi-square test or the t- test, when appropriate. All tests were 2-sided and used a type I error rate of 0.05.

RESULTS

A total of 53 cases were included, with a mean age of 69.9 \pm 7.7 years and 49 (92.5%) male patients. The distribution of procedures over time is depicted in <u>Figure 1</u>. Six (11.3%) were symptomatic aneurysms, and one patient presented with a ruptured aneurysm. Twenty-one (39.6%) cases had thoracoabdominal aneurysms, followed by juxta-renal (19 cases, 35.8%). Five patients (9.4%) had a history of aortic dissection. Demographic variables are presented in <u>Table 1</u>.



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Table 1. Number of f/bEVAR procedures performed over time

	Overall		Study quartile	•		P value
	(N=53)	1st (N=13)	2nd (N=13)	3rd (N=13)	4th (N=14)	
Male – N (%)	49 (92.5)	12(92.3)	13(100)	12(92.3)	12(85.7)	0.895
Age (years) – mean ± SD	69.9±7.7	69.2±7.1	71.6±7.3	71.1±5.4	68.1±10.2	0.610
Hypertension – N (%)	45 (84.9)	12(92.3)	12(92.3)	10(76.9)	11(78.6)	0.593
Diabetes – N (%)	8 (15.1)	3(23.1)	1(7.7)	1(7.7)	3(21.4)	0.593
Coronary artery disease – N (%)	14 (26.4)	4(30.8)	3(23.1)	4(30.8)	3(21.4)	0.927
Chronic heart failure – N (%)	9 (17.0)	3(23.1)	3(23.1)	0(0.0)	3(21.4)	0.288
COPD - N (%)	18 (34.0)	3(23.1)	5(38.5)	7(53.8)	3(21.4)	0.273
Stroke/TIA - N (%)	8 (15.1)	1(7.7)	2(15.4)	4(30.8)	1(7.1)	0.401
Basal creatinine, mg/dL – mean ± SD	1.2±1.0	1.1±0.4	0.95±0.2	1.4±1.1	1.2±0.6	0.318
ASA score						
I – N (%)	2 (3.8)	0(0.0)	0(0.0)	1(7.7)	1(7.7)	0.858
II – N (%)	5 (9.6)	2(15.4)	1(7.7)	1(7.7)	1(7.7)	
III – N (%)	40 (76.9)	9(69.2)	12(92.3)	10(76.9)	9(69.2)	
IV – N (%)	5 (9.6)	2 (15.4)	0(0.0)	1(7.7)	2(15.4)	
Presentation						
Elective – N (%)	46 (86.8)	12(92.3)	19(76.9)	11(84.6)	13(92.9)	0.407
Symptomatic – N (%)	6 (11.3)	1(7.7)	3(23.1)	2(15.4)	0(0.0)	
Ruptured – N (%)	1 (1.9)	0(0.0)	0(0.0)	0(0.0)	1(7.1)	
Aneurysm extension						
Juxta-renal – N (%)	19 (35.8)	5(38.5)	4(30.8)	6(46.2)	4(28.6)	0.118
Para-renal – N (%)	13 (24.5)	5(38.5)	0(0.0)	3(23.1)	5(35.7)	_
Thoraco-abdominal – N (%)	21 (39.6)	3(23.1)	9(69.2)	4(30.8)	5(35.7)	
Extent I – N (%)	4 (7.5)	0(0.0)	2(15.4)	0(0.0)	2(14.3)	
Extent II – N (%)	6 (11.3)	1(7.7)	1(7.7)	1(7.7)	3(21.4)	
Extent III – N (%)	2 (3.8)	0(0.0)	1(7.7)	1(7.7)	O(0.0)	-
Extent IV – N (%)	6 (11.3)	0(0.0)	4(30.8)	2(15.4)	0(0.0)	
Extent V – N (%)	3 (5.7)	2(15.4)	1(7.7)	0(0.0)	O(0.0)	
Aortic dissection – N (%)	5 (9.4)	O(0.0)	1(7.7)	1(7.7)	3(21.4)	0.373
Maximum aortic diameter (mm) – mean ± SD	64.6±9.8	59.3±6.4	62.9±11.3	68.3±9.4	67.5±9.9	0.060

COPD: Chronic Obstructive Pulmonary Disease; **TIA:** Transient ischemic attack; **SD:** Standard Deviation

Six patients (11.3%) underwent arch procedures. Most cases (44 cases, 83%) had four target vessels incorporated, with 24 (45.3%) fEVAR, 19 (35.8%) bEVAR, and 10 (18.9%) customised endoprostheses with combinations of fenestrations and branches. The technical success rate of visceral vessel incorporation was 90.6%. All technical failures were due to

aortic side branch cannulation failures. Mean procedural times, in minutes, were 273.8 \pm 69.1 in the first quartile, 436.5 \pm 149.1 in the 2nd quartile, 499.4 \pm 167.8 in the 3rd quartile and 428.3 \pm 110.9 in the 4th quartile. Procedural characteristics are presented in Table 2.

Table 2. Procedural variables of patients treated with f/bEVAR, included in the study, stratified by chronological quartile.

			Study quartile	•		P value
	Overall (N=53)	1st (N=13)	2nd (N=13)	3rd (N=13)	4th (N=14)	
Staging – N (%)	20 (37.7)	4(30.8)	4(30.8)	6(46.2)	6(46.2)	0.044
TEVAR - N (%)	9 (17)	2(15.4)	3(23.1)	4(30.8)	O(0.0)	_
Arch procedures, open – N (%)	6 (11.3)	O(0.0)	1(7.7)	O(0.0)	5(35.7)	_
Conduit – N (%)	5 (9.4)	2(15.4)	O(O.O)	2(15.4)	1(7.1)	
Number of target arteries						
2 – N (%)	1 (1.9)	O(0.0)	0(0.0)	1(7.7)	0(0.0)	0.418
3 – N (%)	7 (13.2)	3(23.1)	2(15.4)	2(15.4)	0(0.0)	_
4 – N (%)	44 (83)	10(76.9)	11(84.6)	10(76.9)	13(92.9)	_
5 – N (%)	1 (1.9)	0(0.0)	0(0.0)	0(0.0)	1(7.7)	
Device type						
Fenestrated – N (%)	24 (45.3)	7(53.8)	4(30.8)	6(46.2)	7(50.0)	0.639
Branched – N (%)	19 (35.8)	4(30.8)	6(46.2)	6(46.2)	3(21.4)	_
Any combination of fenestra- ions and branches – N (%)	10 (18.9)	2(15.4)	3(23.1)	1(7.7)	4(28.6)	
liac branch device – N (%)	5 (9.4)	1(7.7)	2(15.4)	1(7.7)	1(7.7)	0.930
Number of device components – mean ± SD	8.4±2.0	7.9±1.2	9.2±1.7	8.5±3.1	8.1±1.4	0.407
Access						
Femoral only – N (%)	32 (60.4)	7(53.8)	5(38.5)	7(53.8)	13(92.9)	0.017
Femoral and brachial – N (%)	21 (39.6)	6(46.2)	8(61.5)	6(46.2)	1(7.1)	_
Type of femoral access						
Percutaneous – N (%)	39 (73.6)	9(69.2)	8(61.5)	10(76.9)	12(85.7)	0.513
Open – N (%)	14 (26.4)	4(30.8)	5(38.5)	3(23.1)	2(14.3)	
Conduit						
Open – N (%)	4 (7.5)	2(15.4)	0(0.0)	1(7.7)	1(7.1)	0.808
Endovascular – N (%)	2 (3.8)	0(0.0)	1(7.7)	1(7.7)	0(0.0)	
Fusion imaging – N (%)	13 (24.5)	0(0.0)	0(0.0)	1(7.7)	12(85.7)	<0.001
Proctoring – N (%)	18 (34)	9(69.2)	5(38.5)	1(7.7)	3(21.4)	0.007
Technical success – N (%)	48(90.6)	13(100)	12(92.3)	10(76.9)	13(92.9)	0.308
Lumbar drainage	10(30.0)	.5(100)	12(32.3)			
Prophylactic – N (%)	14(26.4)	7(53.8)	3(23.1)	3(23.1)	1(7.1)	0.078
			· · ·			- 0.076
Therapeutic – N (%)	1(1.9)	0(0.0)	0(0.0)	0(0.0)	1(7.1)	

TEVAR: Thoracic Endovascular Aortic Repair; **SD:** Standard Deviation

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Thirty-day mortality was 11.3%, and 30-day MAE was 13.2%, <u>Table 3</u>. When analysing by study quartile, the 4th study quartile demonstrated higher proportions of open arch procedures (35.7% in the last quartile). There was also a higher numbers of vessels incorporated (92.9% of patients in the 4th quartile having four vessels incorporated vs 76.9%

in the first quartile), increased use of femoral-only access (92.9% in the $4^{\rm th}$ quartile vs 53.8% in the $1^{\rm st}$ quartile, p=0.017), higher implementation of fusion imaging (85.7% in the $4^{\rm th}$ quartile, p<0.001). A proctor was present in 34% of cases, primarily in the first two study quartiles.

Table 3. Post-operative outcome variables of patients treated with f/bEVAR, included in the study, stratified by chronological guartile.

	Study quartile				
3rd 4th P value (N=13) (N=14)	2nd 3rd (N=13) (N=13)		Overall (N=53) 1st (N=13		
3(23.1) 1(7.1) 0.638	2(15.4) 3(23.1))	7(13.2) 1(7.7)	7(13.2)	30-day MAE – N (%)
3(23.1) 1(7.1)	1(7.7) 3(23.1))	6(11.3) 1(7.7)	6(11.3)	Death – N (%)
1(7.7) O(0.0)	0(0.0) 1(7.7)))	1(1.9) 0(0.0)	1(1.9)	Stroke – N (%)
O(O.O) O(O.O)	1(7.7) 0(0.0)))	1(1.9) 0(0.0)	(%) 1(1.9)	Acute limb ischemia – N (%)
0(0.0) 0(0.0) 0.140	O(0.0) O(0.0)	D)	3(8.1) 3(25.0	3(8.1)	One-year MAE – N (%)
1(14.3) 2(33.3) 0.853	3(25.0) 1(14.3)	7)	8(21.6) 2(16.7	N (%) 8(21.6)	One-year reintervention – N (%)
(20.0) 2(40.0)	2 (40.0) 1(20.0)))	5 (50.0) 0(0.0)	5 (50.0)	Endoleak – N (%)
O(0.0) O(0.0)	0(0.0)	5)	1(8.3) 1(12.5)	1(8.3)	Rupture* – N (%)
0(0.0)	1(12.5) 0(0.0)))	1(8.3) 0(0.0)	1(8.3)	Occlusion – N (%)
O(O.O) O(O.O)	O(0.0)	5)	1(8.3) 1(12.5)	1(8.3)	Infection – N (%)
0(0.0) 0(0.0)	1(12.5) O(0.0)))	1(8.3) 0(0.0)	1(8.3)	Occlusion – N (%)

MAE: Major adverse events. * This rupture was before a planned iliac extension.

DISCUSSION

This study characterised trends in a single-centre 10-year experience with f/bEVAR, showcasing changes in both acquired experience and the adoption of new devices and techniques, with improved outcomes observed in the most recent quartile, despite increasing case complexity. The use of fusion imaging and the increased use of the transfemoral approach, made possible by the use of steerable sheaths, also contribute to the improvement of results in the last study quartile.

One-year reintervention rates remain high (21.6% overall). A recent multicentric study reported one-year reintervention rates of 18.3%. The majority (50.0%) of reinterventions were due to endoleak, which increased during the study period, also reflecting increased complexity. (6)

At our centre, the number of vessels incorporated has been steadily increasing, with all cases in the last quarter involving four or more visceral vessels. Starnes et al reported an increase in cases with two or more fenestrations with increased experience. This is also in line with data suggesting that less complex designs might increase the risk of type I endoleak. Mirza et al also reported improved MAE and mortality over time, despite increased aneurysm complexity.

It's important to note that the 30-day MAE in our centre is mainly derived from mortality, which may reflect failure to rescue (FTR). FTR is defined as the percentage of deaths in patients who had a complication within 30 days of surgery. 3 Previous reports on standard EVAR have associated lower FTR rates with increased volume of EVAR.^[10] FTR may also

explain the higher-than-expected mortality rates when compared to published literature reporting 30-day mortality rates of around 6%. [9,11] However, the WINDOWS trial reported a similar in-hospital mortality rate (10.1%). [12]

Prophylactic cerebrospinal fluid (CSF) drainage has also decreased during the study period, from 53.8% to 7.1%. This is in line with current recommendations, with prophylactic drainage being reserved for patients with poor collateral networks or a previous history of spinal cord ischemia.⁽³⁾

This study is limited by its retrospective and singlecentre nature. Moreover, practices adopted have been heterogeneous and might confound outcomes, as well as the small number of patients included in each study period.

CONCLUSION

The findings of this study highlight the importance of specialised training, proctorship in early experience, and the value of cumulative institutional expertise in managing complex aortic pathologies with f/bEVAR, as well as improving outcomes in this population.

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Informed Consent: No written informed consent was required due to the study design

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