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Elective Fenestrated and Branched Endovascular Thoraco-abdominal Aortic Repair with Supracoeliac Sealing Zones and without Prophylactic Cerebrospinal Fluid Drainage: Early and Medium-term Outcomes

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WHAT THIS PAPER ADDS

This single centre study demonstrates that fenestrated and branch endovascular aortic repair with supracoeliac sealing zones can be performed with low mortality and good medium-term survival. In patients treated with >40 mm supracoeliac coverage, selective staging without prophylactic cerebrospinal fluid drainage was associated with a significant reduction in the incidence of disabling spinal cord ischaemia. Achieving a more durable aortic repair with more complex endografts does not need to be at the expense of a higher risk of adverse events. To allow meaningful interpretation and comparison, patient outcomes should be reported according to the extent of the endovascular repair rather than the anatomical extent of the aneurysm.

Objective: To report the outcome of elective fenestrated and branch (FEVAR–BEVAR) endovascular aortic repair with supracoeliac (SC) sealing zones and the impact of staged repair without prophylactic cerebrospinal fluid (CSF) drainage on the incidence of spinal cord ischaemia (SCI).

Methods: Two hundred and seventy consecutive patients (217 men; mean [SD] age, 72.8 ± 6.3 years; median (IQR) diameter 65 mm [62–75 mm]) with juxtarenal (JRAAA) ($n = 69$) or thoraco-abdominal aortic aneurysms (TAAAs) ($n = 201$) underwent elective FEVAR ($n = 192$) or BEVAR ($n = 78$) with renovisceral stent grafting, proximal SC (Zones 1–5; <40 mm [$n = 83$]; ≥40 mm [$n = 187$]) and distal infrarenal aorto-iliac sealing zone (Zones 9–11) between December 2008 and September 2017. A spinal cord protection protocol (SCPP) including staging without prophylactic CSF drainage was introduced in September 2012.

Results: A total of 1026 renovisceral vessels (mean 3.8 ± 0.5 per patient) were targeted for preservation. One patient (0.4%) died in the institution within 30 days and 31 (11.4%) developed 36 major non-fatal complications including unplanned permanent dialysis ($n = 1$, 0.4%) and non-ambulatory SCI ($n = 6$, 2.2%). In patients with <40 mm SC coverage, none were staged or had prophylactic CSF drains and none developed SCI. In patients with ≥40 mm SC coverage, SCI occurred in 3.3% (pre-SCPP: 4/20 [20%; none staged, 13 prophylactic CSF drains] vs. post-SCPP: 2/167 [1.2%; 89 staged, no prophylactic CSF drains]; $p = .001$ [OR = 19.9]). Estimated survival (±SE) at one, two and three years was 92.6% ± 1.6%, 86.5% ± 2.4%, and 73.8% ± 3.5%, respectively, with no significant difference comparing extent of aneurysm or SC coverage. Forty-three (15.9%) patients required late re-intervention. Estimated freedom from re-intervention at one, two and three years was 91.9% ± 1.8%, 85.1% ± 2.5%, and 79.5% ± 3.2%, respectively.

Conclusion: Elective endovascular thoraco-abdominal aortic repair with SC sealing zones can be performed with low peri-operative risk and good medium-term outcomes. Selective staging without prophylactic CSF drainage contributed to a significant reduction in the incidence of SCI.

Keywords: Complex endovascular repair, Supracoeliac seal zone, Spinal cord ischaemia
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INTRODUCTION

The extent of endovascular repair (determined by proximal and distal sealing zones, length of aortic coverage, and number of branch vessels requiring preservation), rather than the anatomical extent of the aneurysm, is a major determinant of early and late outcome in patients undergoing fenestrated (FEVAR) and branch (BEVAR)

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endovascular repair for juxtarenal (JRAAA) and thoracoabdominal aortic aneurysms (TAAAs). The Society for Vascular Surgery (SVS) developed a classification for sealing zones[1] to reflect this relationship but few publications have used it[2–4] with the majority preferring to use anatomical extent, which can make interpretation and comparison between series difficult. FEVAR–BEVAR with renovisceral branch vessel stent grafting and endograft sealing in the supracoeliac (SC) aorta represents one of the most technically complex of aortic procedures with significant potential for adverse outcomes. While extent I–III/V and the majority of extent IV TAAA require this extent of repair, it may also be necessary for some JRAAA depending on a number of morphological (including para-visceral aortic diameter and location of the renovisceral branch vessels) and clinical factors (including the requirement for a durable repair and future treatment of more proximal disease) as well as constraints on endograft design. FEVAR incorporating the coeliac axis (CA) with a scallop may be suitable for some extent IV TAAAs and a significant proportion of JRAAA and represents a lower level of procedural complexity.

The aim of the present study was to report the early and medium-term outcomes of elective fenestrated and branched endovascular thoraco-abdominal aortic repair with a proximal sealing zone in the supracoeliac aorta (SVS classification Zones 1–5) and a distal sealing zone in the infrarenal aorta or iliac arteries (Zones 9–11). The effect of a spinal cord protection protocol (SCPP), which included selective staging of the repair but did not include prophylactic cerebrospinal fluid (CSF) drainage, was determined in this group of patients.

METHODS

Study cohort

Interrogation of a prospectively maintained database identified 270 consecutive patients who underwent elective FEVAR–BEVAR with renovisceral stent grafting, a proximal sealing zone above the proximal edge of the CA (SVS classification 1 Zones 1–5), and a distal sealing zone in the infrarenal aorta or iliac arteries (Zones 9–11). All patients were treated in a single institution (Heartlands Hospital, Birmingham, UK) between December 2008 and September 2017. A total of 214 (79%) patients were referred from 31 vascular units throughout the UK and Ireland.

Before the study period, the learning curve was 15 patients who underwent elective FEVAR with proximal sealing in Zone 6 and below. During the study period, the following groups were excluded from analysis: FEVAR with proximal SC sealing zone and distal sealing zone above the renal arteries (RAs) ($n = 2$); FEVAR incorporating the CA with a scallop ($n = 80$) or sealing below the CA ($n = 44$); and urgent/emergency FEVAR–BEVAR ($n = 65$). The proportion of elective FEVAR-BEVAR with SC sealing zones compared to elective cases with infracoeliac sealing zones and non-elective cases per annum (ending September 2017) is shown in Fig. 1.

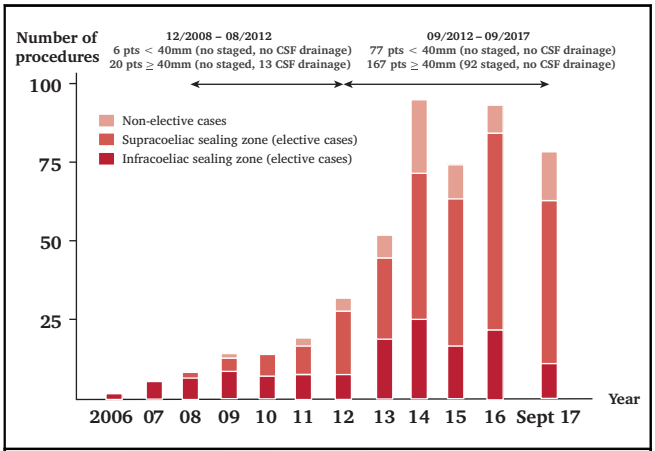

Figure 1. The proportion of elective fenestrated and branched endovascular aortic repairs with SC sealing zones compared to the elective cases with infracoeliac sealing zones and non-elective cases per annum (ending September 2017). CSF = cerebrospinal fluid; SC = supracoeliac.

Pre-operative assessment, imaging, and graft planning

Patients were assessed in a dedicated one stop clinic comprising investigations of fitness (biochemical/haematological analysis, cardiopulmonary exercise testing, echocardiography, and pulmonary function testing), CT angiography from arch vessels to femoral bifurcations, and review by an endovascular surgeon and vascular anaesthetist. Patients were discussed in a multidisciplinary team meeting consisting of vascular/endovascular surgeons, interventional radiologists and cardiac surgeons if appropriate. Aneurysm morphology on computed tomography angiography (CTA) was assessed with post-processing evaluations (multiplanar, three dimensional, centre lumen line reconstructions) using dedicated software for vessel analysis (Aquarius 3D; TeraRecon, Foster City, CA, USA). All patients were treated with commercially available customised or off the shelf Cook (Cook Medical, Bloomington, IN, USA) devices with a proximal landing zone of at least 20 mm of healthy aorta.

Procedural details and peri-operative care

All procedures were performed by one or both of two experienced endovascular surgeons (D.A., M.C.) initially in a standard operating theatre equipped with a mobile C-arm (OEC 9900 Plus, General Electric, Salt-Lake-City, UT, USA) and from October 2015 in a hybrid operating theatre (Discovery IGS 730; GE Healthcare, Chalfont St Giles, UK). All procedures were performed under general anaesthesia with surgical exposure of the access vessels in the majority. A 5000 IU bolus of intravenous heparin was given prior to introduction of the endograft and further 1000–2000 IU boluses were given hourly after the first 2 h. Intra-operative activated clotting time was not measured. Fenestrations were aligned using balloon expandable covered stents (Maquet, Atrium, Hudson, NH, USA), and directional branches with either self expanding covered stents (Fluency, C.R. Bard Inc., Tempe, AZ, USA) or balloon expandable covered stents. After the fenestration target vessels were secured, the delivery system

was either removed completely or retracted below the internal iliac artery (IIA) to optimise lower limb/spinal cord perfusion. For endografts incorporating fenestrations, separate 7F target vessel sheaths were used rather than a single large diameter sheath, thereby maintaining ipsilateral pelvic and lower limb perfusion.

After the procedure, all patients were admitted to the critical care unit for a minimum of 24 h. Prophylactic CSF drainage was used in selected patients prior to September 2012 when a dedicated spinal cord protection protocol (SCPP) (Table 1) was introduced for all elective patients undergoing complex EVAR with proximal SC sealing zones, which did not include prophylactic CSF drainage but did include selective staging of the endovascular repair. In patients requiring SC coverage $\geq$40 mm, the decision to perform a staged repair and the approach used was made after review of the CTA to determine patency of the left subclavian (LSA) and IIAs, and the number and size of intercostal and lumbar arteries which would be sacrificed. Prophylactic CSF drainage was removed from the standard operating procedure for complex EVAR as a consequence of a fatal drain related complication in a patient with an acute symptomatic non-ruptured extent II TAAA who underwent staged BEVAR with the intention of completing the repair within 7 days. A prophylactic CSF drain was inserted but the patient did not develop SCI and CSF drainage was not commenced. The drain was removed on post-operative day three and the patient suffered a fatal intra-cerebellar haemorrhage within 24 h that was considered CSF drain related.

Patients were followed up with CTA at one, six and 12 months and annually thereafter. No patients were lost to follow up. The primary outcome (survival status) was verified by cross referencing local electronic patient records with the NHS wide mortality databases (Primary Care Mortality Database, Spine, NHS Digital) derived from death records from the Office for National Statistics. Patients who lived far from the institution were followed up by the referring centre which provided information of any late complications and/or re-interventions and transferred CTA images electronically for assessment.

Table 1. In house spinal cord protection protocol

Stop antihypertensive medication three days before operation
Preserve antegrade perfusion of left subclavian and at least one hypogastric artery
Minimise embolisation during graft manipulation
Minimise lower limb ischaemia–reperfusion injury (early removal of delivery sheaths, separate sheaths for target vessel cannulation, pre-loaded devices)
Minimise intra-operative blood loss and post-operative risk of GI haemorrhage (PPI)
Staged procedures where appropriate (based on extent of coverage and spinal collateral network)
Maintain MAP > 80 mmHg
Patient recumbent at 30° for 36 h minimum
CVP < 15 mmHg
Maintain oxygen delivery for entire hospital admission (Hb > 10, pO_2 > 9, SaO_2 > 95%)
Correct any coagulopathy (aim for platelet count > 100, PTR < 1.5)
Gradual mobilisation from 48 h and gradual re-introduction of antihypertensives
No prophylactic CSF drainage

GI = gastro-intestinal; PPI = proton pump inhibitor; MAP = mean arterial pressure; CVP = central venous pressure; Hb = haemoglobin, PTR = prothrombin ratio; CSF = cerebrospinal fluid.

Definitions and data collection

TAAA anatomical extent was defined by the modified Crawford classification and JRAAA was defined as involving the infrarenal abdominal aorta adjacent to or including the lower margin of the renal artery origins. The extent of endovascular repair was reported using the SVS standards.[1] The proximal extent of SC aortic endograft coverage was defined using the SVS classification: proximal to the innominate artery (IA) origin (Zone 0); distal to the IA but proximal to the left common carotid artery (LCCA) origin (Zone 1); distal to the LCCA but proximal to the LSA (Zone 2); within 2 cm of the LSA without covering it (Zone 3); from 2 cm distal to the LSA and within the proximal half (proximal to T6) of the descending thoracic aorta (DTA) (Zone 4); and in the distal half of the DTA (distal to T6) but proximal to the CA (Zone 5). The length of SC coverage was defined as the length of endograft fabric proximal to the upper edge of the CA fenestration or the upper margin of the CA itself in patients treated by BEVAR. The distal extent of endograft coverage was also defined using the SVS classification: infrarenal aorta (Zone 9); common iliac artery (Zone 10); and external iliac artery (Zone 11).

The following data were retrieved: demography; comorbidity; endograft design, length of SC coverage; operative duration, adjunctive procedures, staging approach; 30 day mortality, target vessel loss, major complications, unplanned re-interventions, total hospital and critical care length of stay; patient survival, re-intervention and target vessel patency during follow up. Disabling spinal cord ischaemia (SCI) was defined according to the SVS grading system as Grade 3a–3c (non-ambulatory able to move against gravity, not able to move against gravity, or no movement, respectively).[1]

Statistical analysis

This was performed using R environment (version 3.4.1, The R Foundation for Statistical Computing, Vienna, Austria; https://www.r-project.org). Continuous variables were presented as mean (SD) or median (IQR) as appropriate and categorical data were presented as proportions. The Student *t* test and Wilcoxon rank sum test were used to compare continuous data, and the Pearson chi-square test and Fisher's exact test were used to analyse categorical data as appropriate. Median follow up was reported as the observed follow up in all subjects (irrespective of outcome). Overall survival, target vessel patency, and freedom from re-intervention were assessed by calculating the Kaplan–Meyer product limit estimator with right censoring of survival data. The effect of covariates (clinical, anatomical, and procedural factors) was estimated using univariable (log

Table 2. Baseline comorbidity information on 270 aneurysm patients undergoing fenestrated or branched EVAR without prophylactic cerebrospinal fluid drainage

Comorbidity	Number of patients (%)
Prior aortic reconstruction	76 (28.1)
Ascending aortic repair ± aortic valve replacement	3 (1.1)
Ascending and aortic arch repair with floating elephant trunk	9 (3.3)
Ascending and aortic arch repair with frozen elephant trunk	9 (3.3)
Open descending thoracic aortic aneurysm repair	6 (2.2)
Open thoraco-abdominal aortic aneurysm repair	5 (1.9)
Endovascular thoracic aortic aneurysm repair	10 (3.7)
Endovascular infrarenal aortic aneurysm repair (bifurcated/aorto-uni-iliac)	12 (4.4)/3 (1.1)
Fenestrated endovascular aortic aneurysm repair	1 (0.4)
Open infrarenal/juxtarenal aortic aneurysm repair	27 (10)
ASA grade	
II	49 (18.1)
III	218 (80.7)
IV	3 (1.1)
Hypertension	199 (73.7)
COPD	95 (35.2)
CKD stage 3A–5	94 (34.8)[a]
CAD	88 (32.6)
Current or ex-smokers	98 (36.3)

COPD = chronic obstructive pulmonary disease; CAD = coronary artery disease; CKD = chronic kidney disease (stage 3A–5 = estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2); EVAR = endovascular aneurysm repair.
[a] 13 patients had a pre-operative eGFR <30 mL/min/1.73 m^2.

Table 3. Adjunctive open and endovascular procedures to fenestrated or branched EVAR in 270 patients presenting with juxtarenal or thoraco-abdominal aortic aneurysm

Adjunctive procedure	Number of patients (%)
Proximal arterial access	129 (47.8)
Infraclavicular axillary artery approach (left/right)	58 (21.5)/57(21.1)
Proximal brachial artery approach (left/right)	13 (4.8)/1 (0.4)
Open procedures	
Left carotid-subclavian bypass	15 (5.6)
Unilateral common iliac to external iliac/femoral bypass	10 (3.7)
Temporary common iliac artery conduit	4 (1.5)
Femoro-femoral cross over bypass	4 (1.5)
Common femoral artery interposition graft	3 (1.1)
Bilateral revision of iliac limbs of open aorto-bi-iliac repair	2 (0.7)
Unilateral external iliac to internal iliac artery bypass	2 (0.7)
Common iliac artery exposure for direct endograft delivery	1 (0.4)
Temporary axillo-femoral bypass	1 (0.4)
Endovascular procedures	
Unilateral iliac branch device	13 (4.8)
Arch fenestrated device	4 (1.5)[a]
Left subclavian artery chimney endograft	1 (0.4)
Occluder plug to endograft sidebranch or fenestration	7 (2.6)
Iliac angioplasty	4 (1.5)
Iliac endografting/endoconduit	3 (1.1)
Axillo-femoral wire access	1 (0.4)

[a] Four arch fenestrated EVAR devices incorporated two innominate scallops, two left common carotid artery fenestrations, one left common carotid artery scallop, and one left subclavian artery fenestration. EVAR = endovascular aneurysm repair.

rank test) and multivariable (Cox proportional hazards model) analysis. Selection of covariates for multivariable models was based on univariable $p < .1$. A p value $< .05$ was considered significant.

RESULTS

Patient characteristics

A total of 270 consecutive patients (217 men; mean age, 72.8 ± 6.3 years; median aneurysm diameter 65 mm [62–75 mm]) underwent elective FEVAR–BEVAR for JRAAA ($n = 69$) and TAAA ($n = 201$; 117 extent I–III/V, 84 extent IV). Eleven patients had chronic post-type B dissection TAAA. Seventy-six (28%) patients had undergone 85 prior aortic reconstructions (10 of 69 [14%] JRAAA, 19 of 84 [23%] extent IV, 47 of 117 [40%] extent I–III/V TAAA; $p < .001$). Comorbidity data are shown in Table 2.

Procedural details

Patients were treated with custom made FEVAR ($n = 192$), BEVAR ($n = 69$), or the off the shelf t-branch ($n = 9$) device. In 83 patients, SC coverage was <40 mm (median 32 mm, range 12–39 mm) and in 187 patients SC coverage was ≥40 mm (median 153 mm, range 40–460 mm). The extent of proximal SC coverage was Zone 1, 2, or 3 in 51 patients; Zone 4 in 30 patients; and Zone 5 in 189 patients. The median (range) length of SC coverage for Zone 1, 2, or 3 was 336 mm (153–460 mm); for Zone 4 was 235 mm (119–381 mm); and for Zone 5 was 43 mm (12–229 mm).

A total of 1026 renovisceral vessels ((241 CA, 268 SMA, 517 RA; mean 3.8 ± 0.5 per patient) were targeted for preservation with 817 fenestrations (174 CA, 203 SMA, 440 RA), 208 directional branches (67 CA, 65 SMA, 76 RA), and one scallop for a RA bypass graft arising from an aortic prosthetic graft. Twenty-two target vessels (CA = 18, RA = 4) occluded between graft planning and implantation leaving 1004 (mean 3.7 ± 0.5 per patient) (223 CA, 268 SMA, 513 RA) patent at the time of repair. Of these, 984 vessels (208 CA, 268 SMA, 508 RA; mean 3.6 ± 0.6 per patient) were secured with stent grafts: four or five renovisceral target vessels were successfully stent grafted in 181 (67%) patients. Five (1%) patent RAs were not stent grafted:

intentionally for a double width scallop ($n = 1$); intra-operative occlusion ($n = 3$); and misaligned fenestration ($n = 1$). Fifteen (7.2%) patent CAs were not stent grafted: intentionally due to good alignment with no endoleak ($n = 11$); and intra-operative occlusion ($n = 4$).

Adjunctive procedures are shown in Table 3. In 29 patients where a target vessel had occluded between graft planning and implantation ($n = 22$) or intra-operatively ($n = 7$), six had an endoleak which was treated using an Amplatzer II vascular plug (AVP; Abbott Vascular, IL, USA) to occlude a balloon expandable stent graft deployed within the endograft sidebranch ($n = 2$; both CA) or fenestration ($n = 4$; 2 CA, 2 RA). This manoeuvre was also performed after left external iliac artery (EIA) to RA bypass in one patient with a misaligned RA fenestration. Intentional unilateral internal iliac artery sacrifice was performed in eight patients. Four patients had iatrogenic rupture of access vessels (3 EIA, 1 LSA) successfully managed with covered stents. The median total operating time (including all stages) was 268 min (98—659 min): 236 min (110—553 min) for patients with <40 mm SC coverage and 274 min (98—659 min) for those with ≥40 mm SC coverage ($p = .002$).

Prior to September 2012, the first 26 patients underwent non-staged FEVAR ($n = 14$) or BEVAR ($n = 12$) with SC coverage ≥ 40 mm in 20 patients and prophylactic CSF drainage in 13 patients. From September 2012, a total of 77 patients underwent single stage FEVAR with SC coverage <40 mm and none had prophylactic CSF drainage; and 167 patients were treated with SC coverage ≥40 mm of whom 92 (51 BEVAR, 41 FEVAR) had a staged repair and 75 (15 BEVAR, 60 FEVAR) a single stage repair, none with prophylactic CSF drainage. In the 92 patients who had staged repair, this was performed during the same admission in 31 patients, and separate admissions in 61 where the median interval between stages was 31 days (11—85 days). The different staged approaches are shown in Table 4.

Early outcomes

One patient died in the institution within 30 days (30 day mortality, 0.4%; #170 JRAAA; on post-operative day 9 from myocardial infarction after acute upper gastrointestinal haemorrhage), and two further patients died in the institution beyond 30 days (in hospital mortality, 1.1%): after 62 days (no. 9 extent II TAAA; respiratory failure requiring tracheostomy and prolonged ventilator support, temporary haemofiltration, small bowel resection for ischaemia secondary to an internal hernia); and 85 days (no. 39 extent III TAAA; respiratory failure requiring prolonged ventilator support, temporary haemofiltration). Thirty-one (11.4%) further patients (3 [4.3%] JRAAA, 7 [8.3%] extent IV, 21 [18%] extent I—III/V TAAA; $p < .001$, OR 5.77 for JRAAA/extent IV vs. extent I-III/V TAAA) suffered 36 major non-fatal complications within the first 30 days of single or staged repair, 14 of whom required unplanned re-intervention (Table 5).

One (0.4%) patient commenced unplanned permanent dialysis. This patient had poor iliac access and severe aorto-iliac tortuosity necessitating an axillo-femoral wire for delivery of the endograft and athero-embolisation was considered to be the cause of the acute kidney injury. Another patient with a history of glomerulonephritis and chronic kidney disease (CKD) Stage 5 had an arteriovenous fistula created before BEVAR and planned permanent dialysis was commenced in the immediate post-operative period.

Disabling SCI occurred in six (2.2%) patients (one extent IV, five extent I—III/V TAAA; three immediate, two within 24 h, one between 24 and 48 h). Before September 2012, four of 26 (15%) patients developed disabling SCI of whom three had prophylactic CSF drainage. All four of these patients were treated with ≥40 mm SC coverage: no. 1, Zone 5 repair with 157 mm SC coverage; no. 2, Zone 5 with 107 mm coverage; no. 3, Zone 4 with 235 mm coverage; no. 4, Zone 4 with 249 mm coverage. Since September 2012, two of 244 (0.8%) patients developed disabling SCI and both were treated with ≥40 mm SC coverage. Both patients had good cardiac

Table 4. Staged approach to endovascular treatment of juxtarenal or thoraco-abdominal aortic aneurysm in 92 patients

Stage 1	Stage 2	Stage 3	Number of patients (%)
Arch FEVAR	FEVAR		3 (1.1)
TEVAR	BEVAR/FEVAR		38 (14.1)
TEVAR	BEVAR/FEVAR	Limb	6 (2.2)
TEVAR	FEVAR	Distal body + limb	1 (0.4)
TEVAR	BEVAR	IBD	1 (0.4)
TEVAR	FEVAR	CA fenestration	2 (0.7)
TEVAR	Ilio-renal bypass	FEVAR	1 (0.4)
BEVAR/FEVAR	Limb		11 (4.1)
BEVAR/FEVAR	Distal body + limb/IBD		4 (3/1) (1.5)
BEVAR	One branch (CA/SMA/RA)		20 (18/1/1) (7.4)
BEVAR	One branch (CA/RA) + limb		2 (1/1) (0.7)
BEVAR	All branches	Limb	1 (0.4)
BEVAR	Amplatzer II plug to false lumen		1 (0.4)
FEVAR	Ilio-renal bypass + fenestration occlusion		1 (0.4)

FEVAR = fenestrated endovascular aortic repair; BEVAR = branched endovascular aortic repair; IBD = iliac branched device; CA = coeliac axis; SMA = superior mesenteric artery; RA = renal artery; Distal body = implantation of distal bifurcated body endograft extension; Limb = implantation of iliac limb endograft extension; One branch = implantation of single branch vessel endograft. All approaches were second or third stage procedures undertaken to exclude the aneurysm after a period of temporary aneurysm sac perfusion.

Table 5. Major non-fatal peri-operative (30 day or in hospital, whatever is longer) complications in 270 patients undergoing fenestrated or branched EVAR for juxtarenal or thoraco-abdominal aortic aneurysm

Complication	Number of patients (%)
Medical	
Severe disabling spinal cord ischaemia (SVS Grade 3a–3c)	6 (2.2)
Myocardial infarction	3 (1.1)[a]
Pneumonia requiring ventilation (non-invasive)	2 (0.7)
Non-disabling stroke	3 (1.1)
Intracerebral haemorrhage	1 (0.4)
Unplanned permanent renal dialysis	1 (0.4)
Temporary haemofiltration	1 (0.4)
Ischaemic hepatitis	1 (0.4)
Colon ischaemia – medical management	1 (0.4)
Brachial plexus neuropraxia	1 (0.4)
Unplanned re-intervention	
Drainage of haematoma	5 (1.9)
Axillo-brachial artery exploration and revascularisation	3 (1.1)
External iliac to left renal artery bypass	1 (0.4)
Limb occlusion thrombectomy and re-stenting	1 (0.4)
Popliteal artery exploration and thrombectomy	1 (0.4)
Evacuation of spontaneous retroperitoneal haematoma	1 (0.4)[b]
Splenectomy and sigmoid colectomy	1 (0.4)[c]
Upper limb fasciotomy for compartment syndrome	1 (0.4)[d]

EVAR = endovascular aneurysm repair; SVS = Society for Vascular Surgery.
[a] Two underwent coronary stenting.
[b] Secondary to heparin induced thrombocytopenia.
[c] Secondary to haemorrhagic shock due to spontaneous splenic rupture.
[d] Secondary to arterial line removal in the presence of coagulopathy.

function and patent LSA and bilateral IIAs at the end of the procedure. The first developed immediate SCI after staged repair of an extent III TAAA (Zone 4 repair with 240 mm SC coverage) most likely secondary to athero-embolisation and there was no improvement with blood pressure optimisation and CSF drainage. The second patient with an extent II TAAA had an uncomplicated first stage left carotid–subclavian bypass with TEVAR to 20 mm above the CA. Six weeks later, a one piece four vessel FEVAR device was implanted uneventfully (Zone 3 repair with 368 mm SC coverage) but the patient developed immediate post-operative SCI that did not improve with blood pressure optimisation. Two further patients developed temporary paraparesis after the second stage of their repair which was managed with blood pressure optimisation in both and CSF drainage in one: no. 1, Zone3 with 333 mm SC coverage; no. 2, Zone 4 with 279 mm coverage. None of the 83 patients treated with <40 mm SC coverage developed SCI. In 187 patients treated with ≥40 mm SC coverage, there was a significant reduction in the incidence of disabling SCI after the introduction of the SCPP (pre-SCPP 4/20 [20%] vs. post-SCPP 2/167 [1.2%]; $p = .001$ [OR = 19.9]). The median critical care stay was three days (2–5 days) and total hospital stay was nine days (5–14 days).

Medium-term outcomes

The median observed follow up was 24 months (11.6–39.9 months). During follow up, two patients died from aneurysm related causes. The first patient underwent four vessel FEVAR for an asymptomatic saccular para-visceral aneurysm which was complicated by an iatrogenic intra-operative dissection of the SMA which required more distal stent grafting. Five weeks later, the patient presented to another institution with aortic rupture in the area of the uncovered stent and underwent TEVAR but did not survive. The second patient presented with aortic rupture secondary to SMA bridging stent graft disconnection 56 months after BEVAR for an extent III TAAA despite no issues identified on their last surveillance CTA. The patient underwent successful redo stent grafting of the SMA branch but suffered a fatal CVA.

The estimated survival (±SE) at one, two and three years was 92.6% ± 1.6%, 86.5% ± 2.4%, and 73.8% ± 3.5%, respectively (Fig. 2). Age, active smoking status, ischaemic heart disease, pre-operative eGFR (and hence CKD), aneurysm diameter, total procedure time, and number of target vessels were associated with reduced long-term survival on univariable analysis. However, only age (HR 1.06 [0.02]; $p = .0104$), active smoking status (HR 3.67 [0.58]; $p = .0252$), ischaemic heart disease (HR 1.82 [0.29]; $p = .0413$), and number of target vessels (HR 0.55 [0.24]; $p = .0125$) were independent predictors of long-term survival on multivariable analysis (Table 6).

Eight target vessels (1 CA, 7 RA) occluded in six patients during follow up: one patient with bilateral RA and CA occlusions required permanent dialysis and another with an occluded solitary RA underwent successful endovascular recanalisation. Estimated target vessel patency (±SE) at one, two and three years was 98.3% ± 0.4%, 98.3% ± 0.4%,

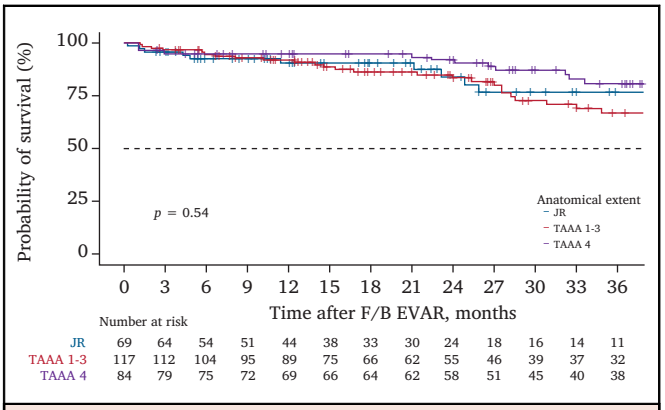

Figure 2. Cumulative Kaplan Meier survival estimates according to anatomical extent of the aortic aneurysm in 270 patients undergoing fenestrated endovascular aortic repair and branch endovascular aortic repair with supracoeliac sealing zones. JR = juxtarenal; TAAA = thoraco-abdominal aortic aneurysms; F/B EVAR = fenestrated/branched endovascular aortic repair.

Table 6. Parameters associated with longterm mortality after F/B EVAR on univariable anaylsis and final model of multivariable analysis

Predictor	*p* - value (univariable)	Longterm mortality (multivariate)	
		HR (95% CI)	*p* - value
Age	.009	1.06 (1.01-1.11)	.01
Sex	.38		
ASA[a]	.25		
Active smoking status[b]	.003	3.67 (1.17-11.46)	.03
Ischaemic heart disease	.06	1.82 (1.02-3.23)	.04
Hypertension	.90		
Chronic kidney disease[c]	.06	–	–
Pre-operative eGFR	.05	–	–
COPD	.81		
Previous aortic surgery	.51		
Anatomical extent of aneurysm[d]	.54		
Aneurysm diameter	.004	1.02 (1.00-1.04)	.09
Primary procedure (FEVAR or BEVAR)[e]	.10		
Staging of the repair	.91		
Total procedure time	.03	1.002 (1.00-1.004)	.09
Number of target vessels	.003	0.55 (0.34-0.88)	.01
Proximal sealing zone[f]	.18		
Length of supracoeliac coverage	.56		

Results of multivariate analysis for continuous variables are presented as hazard ratio (HR) with 95% confidence interval (CI) per unit change age (year); aneurysm diameter (mm); total procedure time (min); target vessels (number of vessels). ASA = American Society of Anaesthesiology score; COPD = chronic obstructive pulmonary Disease; eGFR = estimated glomerular filtration rate; F/B EVAR = fenestrated/branched endovascular aortic repair.

[a] Comparator: ASA 3 and 4 vs. ASA 1 and 2.

[b] Comparator: active smokers vs. ex-smokers and non-smokers.

[c] Chronic kidney disease was not included in the multivariable model due to correlation with pre-operative eGFR.

[d] Comparator: juxtarenal vs. TAAA extent I-V.

[e] Comparator: Branch EVAR vs. Fenestrated EVAR.

[f] Comparator: zone 3 vs. zone 4 and 5.

Table 7. Details of late re-interventions in 43 out of 270 patients undergoing F/B EVAR of juxtarenal or thoraco-abdominal aortic aneurysm

Indication	Re-intervention	Number of patients (%)
Target vessel stenosis/occlusion	Re-stent grafting	5 (1.9) (CA 2, RA 2, IIA 1)
Fenestration/branch related EL	Re-stent grafting	12 (4.4) (CA 1, SMA 4, RA 7)
	Angioplasty	7 (2.6) (CA 1, SMA 2, RA 4)
Distal type 1b EL	Iliac limb extension	3 (1.1)
	Iliac branch device	1 (0.4)
	Distal bifurcated endograft	1 (0.4)
Type 2 EL	Embolisation	7 (2.6)
Type 3 EL	Endograft cuff	2 (0.7)
	Occluder plug	1 (0.4)
	EVAS device	1 (0.4)
Proximal disease progression	TEVAR	8 (3.0)
Iliac stenosis/ occlusion	Re-stent grafting	2 (0.7)
	Femoro-femoral cross over bypass	2 (0.7)
	Aorto-bifemoral bypass	1 (0.4)
CFA pseudoaneurysm	Interposition vein graft	1 (0.4)
	Ligation	1 (0.4)

EL = endoleak; CFA = common femoral artery; EVAS = endovascular aneurysm sealing; TEVAR = thoracic endovascular aortic repair; CA = coeliac axis; SMA = superior mesenteric artery; RA = renal artery; IIA = internal iliac artery.

and 97.9% ± 0.5%, respectively. Forty-three (15.9%) patients underwent re-intervention for 55 late complications with 18 of these patients treated in their referring institution (Table 7). The estimated freedom from re-intervention (±SE) at one, two and three years was 91.9% ± 1.8%, 85.1% ± 2.5% and 79.5% ± 3.2%, respectively. No factors were associated with freedom from re-intervention on univariable or multivariable analysis.

DISCUSSION

The present study describes a large single centre experience of FEVAR—BEVAR with supracoeliac (SC; Zone 5 and above) proximal sealing zones in patients presenting with a wide range of aortic pathology including primary atherosclerotic JRAAA and TAAA, chronic post-type B dissection TAAA, and aneurysms arising secondary to disease progression or late treatment failure after prior open and/or endovascular repair. Even with such heterogeneity and changes in practice (particularly with regard to spinal cord protection) over the study period, FEVAR-BEVAR with SC sealing zones was associated with excellent early and medium-term outcomes in this high volume specialist centre.

Several contemporary studies have examined the outcomes of FEVAR—BEVAR according to proximal sealing zones rather than the anatomical extent of the aneurysm. A report from the Royal Free Hospital used a modified SVS classification of proximal sealing zones and reported a 24% mortality rate in 25 patients treated with endografts sealing "around or covering the CA".[3] More recently, the Mayo Clinic described 127 patients with JRAAA ($n = 47$) and TAAA ($n = 80$) treated with FEVAR—BEVAR devices sealing in the SC aorta, 19 of whom were treated with an endograft incorporating the CA with a scallop.[2] There was no 30 day mortality or requirement for permanent dialysis, 0.8% incidence of permanent disabling SCI, and one year survival and freedom from re-intervention was 96% and 93%, respectively. Compared with the Mayo Clinic series, the present report included the learning curve, the patients were higher risk (82% ASA III/IV vs. Mayo: 20%) with larger (median 65 mm vs. Mayo: 59 mm) and more extensive

aneurysms (43% extent I-III TAAA vs. Mayo: 30%) and those treated with endografts incorporating the CA with a scallop were excluded to reduce heterogeneity. A further publication from the Mayo Clinic, which included their learning curve, reported a 30 day mortality of 4.3%, permanent disabling SCI in 3.6% and five year survival of 60% in 185 patients with TAAA treated with surgeon modified and custom manufactured FEVAR—BEVAR.[5] The Hamburg group reported a 30 day mortality of 8% in 58 patients undergoing elective four vessel FEVAR—BEVAR, predominantly for JRAAA and extent IV TAAA, over a six year period.[4] While other studies have examined the relationship between the extent of total and/or thoracic aortic coverage and outcome for patients undergoing FEVAR-BEVAR, unlike the present study, these have specifically focused on those patients whose aneurysm disease was defined by anatomical extent as TAAA and those with JRAAA undergoing FEVAR—BEVAR with SC sealing zones were not included.[6–9] The early and medium-term outcomes in the present study compare favourably with large contemporary single and multicentre European and North American series of FEVAR—BEVAR for TAAA.[2,4,5,7–15] Not unexpectedly, multivariable analysis demonstrated that increasing age, active smoking status, and the presence of ischaemic heart disease were associated with reduced long-term survival. Furthermore, a lower number of target vessels independently predicted long-term survival and this is likely to represent advanced generalised atherosclerosis resulting in occlusion of predominantly renal arteries and/or the coeliac axis before presentation.

In general, complex EVAR is associated with lower early mortality than open repair, and the magnitude of difference appears to increase as the corresponding open surgical insult increases. In an attempt to quantify this, Canavati et al.[16] compared the early outcomes of FEVAR and open repair for JRAAA in their institution and calculated the risk adjusted mortality for the FEVAR cohort if open repair had been performed. The FEVAR cohort had more significant comorbidity and a higher proportion would have required a more proximal aortic cross clamp (62% suprarenal) than the open repair cohort (15% inter renal, 33% suprarenal, 7% supravisceral). There was a 2.5 fold difference in observed mortality (FEVAR 3.7% vs. open repair 9.2%) which increased to 3.6 fold and a 13.2% risk adjusted mortality for the FEVAR cohort undergoing open repair. As only 7% of patients undergoing open repair had a supravisceral aortic cross clamp, it is reasonable to assume that the actual (and risk adjusted) mortality for open repair (of suprarenal, extent IV, and a proportion of JRAAA) requiring this approach would have been higher than for JRAAA requiring suprarenal cross clamping. In the present series, the 30 day mortality for complex EVAR for JRAAA was 1.4% and there were no deaths after extent IV (or extent I—III/V) TAAA repair. From data such as these, one might speculate that delivering complex EVAR with very low peri-operative mortality might result in a significant medium-term survival advantage compared with open repair (particularly for aneurysms requiring a supravisceral clamp) and this would have major implications for clinical equipoise, consent, and ethical considerations for any randomised controlled trial.

The collateral network concept of spinal cord perfusion has had a major impact on spinal cord protection in complex EVAR.[17] Preservation of the left subclavian and at least one internal iliac artery is now mandatory[18] and a staged approach has been shown to be beneficial[19] with Kasprzak and colleagues[11,20] the first to demonstrate a significantly lower risk of disabling SCI after staged BEVAR with temporary aneurysm sac perfusion particularly if coverage of more than 15 spinal arteries was required. Prophylactic CSF drainage did not protect against SCI[20] and the same conclusion was reached by the Munster group.[7] Furthermore, the Munster group[7] demonstrated a significant CSF drain related complication rate similar to that reported by the Malmo group.[21] To date, the largest study of SCI after FEVAR—BEVAR for TAAA (performed with routine prophylactic CSF drainage) found prolonged operative duration ($>$300 min) to be an independent risk factor for SCI, which appears to support the use of staged (and shorter) procedures.[9] The principal drawback to staging is the risk of interval rupture and Kasprzak and colleagues[11] have recommended completion within four weeks provided the patient has recovered satisfactorily from the first stage. In the present study the median interval between stages was 31 days, and one patient (not included in the cohort) ruptured five weeks after TEVAR without an attempt to complete the repair. In the present series, 55% of patients with SC coverage $\geq$40 mm underwent a staged repair whereas only about 20% of patients may have actually benefited from such an approach. There remains, therefore, a fundamental need to identify this subgroup of patients thus avoiding the potential dire consequences of unnecessary staging. While peri-operative neuromonitoring has been used to this end in patients undergoing complex EVAR, currently its efficacy remains unproven and guidelines only recommend that it should be considered in high risk patients with the caveat that SCI is multifactorial and neuromonitoring is not a panacea.[22,23]

The present and previous studies suggest that prophylactic CSF drainage in complex EVAR may not be required.[7,11,20] In this practice, there are currently no situations where prophylactic CSF drainage would be considered. Early on, a three stage repair was used in a small number of patients with good outcomes and currently this multistage approach (combined with a higher peri-operative mean blood pressure [$\geq$ 100 mmHg] and a longer interval between stages) is employed for the subgroup of patients (such as those with a "shaggy" aorta or bilateral internal iliac artery occlusions) at potentially increased risk of SCI, when the procedure has been prolonged and complicated, or there has been a high likelihood of athero-embolisation. While staging may have played an important part in the 20 fold reduction in the risk of disabling SCI to 1.2% for patients treated with $\geq$40 mm SC coverage, a number of other factors also contributed: minimising peri-operative blood loss, maintaining stable supranormal arterial blood pressure to optimise oxygen delivery, prompt correction of coagulopathy, limiting lower limb ischaemia and reperfusion and, perhaps most importantly, increasing clinical and technical experience with careful patient selection (with ASA IV patients rarely being offered repair due to their reduced medium-term survival).[10,14]

In conclusion, the present study has demonstrated that endovascular thoraco-abdominal aortic repair with SC sealing zones can be performed with low peri-operative mortality and good medium-term outcomes in a specialist aortic centre. Introduction of a SCPP with selective staging and without prophylactic CSF drainage contributed to a significant reduction in the incidence of SCI. Achieving a more durable aortic repair with more complex endografts does not need to be at the expense of a higher risk of adverse events. Meaningful interpretation and comparison of patient outcomes from complex EVAR requires more emphasis on reporting according to the extent of the endovascular repair rather than the anatomical extent.

Limitations of the study

Excellent outcomes have been reported in terms of SCI with the adoption of a staged approach and abandonment of CSF drains, the number of patients undergoing repair with $\geq$40 mm SC coverage ($n = 187$) is still relatively small and a larger cohort of consecutive patients is required to truly confirm or refute the conclusion that prophylactic CSF drainage is not required in this group of patients. The median follow up in the present study was relatively short such that less than one third of the study cohort were available for analysis beyond three years. Longer follow up will be required to determine the true durability of FEVAR–BEVAR with SC sealing zones.

CONFLICTS OF INTEREST

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COUP D'OEIL

Effect of Multiple Punctures on Early Cannulation PTFE Grafts

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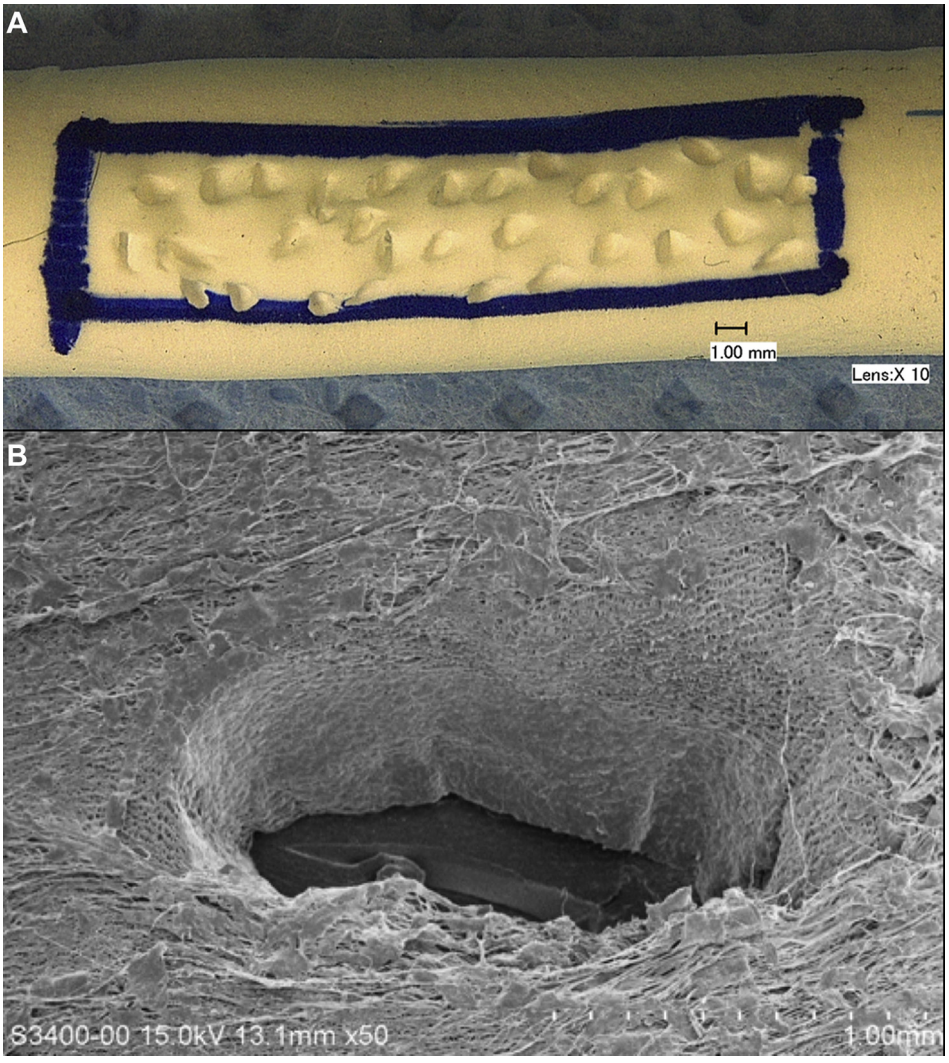

Early cannulation arteriovenous grafts (AVG) using polytetrafluoroethylene (PTFE) are often employed for vascular access for haemodialysis. In clinical practice, even using these dedicated prostheses major early graft deterioration was observed with haematoma or false aneurysm formation. An ex vivo experimental study was initiated to analyse the catheterisation effect on the AVG membrane. (A) A lack of substance in a commercial PTFE AVG (Flixene Maquet, Atrium Medical, Hudson, USA) after 30 punctures in a 1 cm^2 area, clearly corroborated by electron microscopy (B). These degradation phenomena were observed with all PTFE AVGs tested.

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