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Editor's Choice – Comparison of Renal Outcomes in Patients Treated by Zenith® Fenestrated and Zenith® Abdominal Aortic Aneurysm Stent grafts in US Prospective Pivotal Trials☆

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WHAT THIS PAPER ADDS

This is a multicentre study that adds information on renal outcomes following fenestrated endovascular aneurysm repair (FEVAR). It compares patterns of renal function deterioration after FEVAR and conventional endovascular aneurysm repair using a matched cohort design. It may influence the decision on the best type of repair in patients with preserved renal function, as the renal function impairment following the procedures is similar.

Objective/Background: Fenestrated endovascular repair (FEVAR) has been used to treat complex abdominal aortic aneurysms (AAAs). The risk of renal function deterioration compared with infrarenal endovascular aortic repair (EVAR) has not been determined.

Methods: Patients with preserved renal function (estimated glomerular filtration rate [eGFR] $>$ 45 mL/minute) enrolled in two prospective, non-randomised studies evaluating Zenith fenestrated and AAA stent grafts were matched (1:2) by propensity scores for age, sex, hypertension, diabetes, and pre-operative eGFR. Sixty-seven patients were treated by FEVAR and 134 matched controls treated by EVAR. Mean follow-up was 30 $\pm$ 20 months. Outcomes included acute kidney injury (AKI) defined by RIFLE and changes in serum creatinine (sCr), eGFR, and chronic kidney disease (CKD) staging up to 5 years.

Results: AKI at 1 month was similar between groups, with $>$ 25% decline in eGFR observed in 5% of FEVAR and 9% of EVAR patients ($p = .39$). There were no significant differences in $>$ 25% decline in eGFR at 2 years (FEVAR 20% vs. EVAR 20%; $p > .99$) or 5 years (FEVAR 27% vs. EVAR 50%; $p = .50$). Progression to stage IV–V CKD was similar at 2 years (FEVAR 2% vs. EVAR 3%; $p > .99$) and 5 years (FEVAR 7% vs. EVAR 8%; $p > .99$), with similar sCr and eGFR up to 5 years. During follow-up, there were more renal artery stenosis/occlusions (15/67 [22%] vs. 3/134 [2%]; $p < .001$) and renal related re-interventions (12/67 [18%] vs. 4/134 [3%]; $p < .001$) in patients treated by FEVAR. Rate of progression to renal failure requiring dialysis was low and identical in both groups (1.5% vs. 1.5%; $p > .99$).

Conclusion: Aortic repair with FEVAR and EVAR was associated with similar rates of renal function deterioration in patients with preserved pre-operative renal function. Renal related re-interventions were higher following FEVAR, although net changes in renal function were similar in both groups.

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INTRODUCTION

In the last two decades treatment of infrarenal abdominal aortic aneurysms (AAAs) has shifted from open surgical to endovascular aortic repair (EVAR). Development of fenestrated and branched stent grafts has further expanded the indications for EVAR to include patients with complex aneurysms involving visceral and renal arteries. Contemporary

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reports show high technical success and mortality in the range of 1–8% for pararenal and 5–17% for thoracoabdominal aortic aneurysms.[1–10]

Renal impairment is one of the most frequent complications following any type of aortic intervention. For aneurysms involving the renal arteries, open surgical repair carries higher risk of renal dysfunction because of the need to clamp the aorta above the renal and mesenteric arteries. Fenestrated endovascular aortic repair (FEVAR) avoids renal and mesenteric ischaemia, and has the potential to decrease renal dysfunction, although catheter manipulation, embolisation, and iodinated contrast are deleterious to the kidney. Compared with open surgical repair, FEVAR has been associated with lower rates of early transient renal impairment (15% vs. 20%, relative risk (RR) = 1.06 [95% confidence interval 1.01–1.12]; $p = .03$).[11] Martin-Gonzalez *et al*. recently published the renal outcomes in 225 patients treated by FEVAR, showing post-operative acute kidney injury (AKI) in 29% and an average 15% decline in estimated glomerular filtration rate (eGFR) in 3 years ($p = .001$).[12] Whereas FEVAR appears to be at least as safe and effective as open surgery and conventional EVAR,[13] its impact on long-term renal outcomes are not fully understood. The purpose of this study was to compare renal outcomes in two prospective cohorts of patients treated for AAA by standard EVAR and FEVAR.

METHODS

Population

Matched cohorts were selected from the US Multicentre Trials of the Zenith Fenestrated Endovascular Graft (William A. Cook Australia PTY. Ltd., Brisbane, Australia) and the Zenith AAA Endovascular Graft (Cook Inc., Bloomington, IN, USA). These studies were approved by the institutional review boards of the participating institutions. All patients consented for participation in clinical research studies.

Sixty-seven patients enrolled in the Zenith Fenestrated Endovascular Graft Trial during the pre-approval phase were included in the study (January 2005–April 2012).[4] These patients were compared with a matched cohort of patients who underwent conventional infrarenal EVAR using the Zenith AAA Endovascular Graft as part of the US Multicentre Zenith Trial. The Zenith AAA Endovascular Graft Trial included 739 patients from both pivotal and continued access phases (January 2000–June 2003).[14,15] A propensity score method with a pre-specified variable optimal matching algorithm (SAS macro vmatch [2004 version] created by Jon Kosanke and Erik Bergstralh at The Mayo Clinic) was used to select, in a 1:2 ratio, the control cohort for each patient in the FEVAR group.[16] Variables for case matching included age, sex, hypertension, diabetes, and pre-operative eGFR and were based on pre-existing longitudinal studies determining risk factors for chronic kidney disease (CKD).[17] As no patient in the fenestrated group had pre-existing CKD classified as stage IV or V by the National Kidney Foundation (NKF) classification, patients with this condition were excluded from the control group. In the end, 37 patients from the Zenith AAA Endovascular Trial were excluded (23 patients with pre-operative eGFR < 30 mL/minute/1.73 m^2 or renal failure requiring dialysis; 14 patients with missing matching variables), and 702 patients were used in matching. Specific inclusion and exclusion criteria for the two trials have been described previously.[4,14] The follow-up imaging schedule was identical in both groups and included computed tomography angiography prior to hospital discharge and at 1 and 6 months, and yearly thereafter.

Endpoints

Major adverse events (MAEs) were analysed using the definition previously described in the two trials.[4,18] Serum creatinine (sCr) levels were measured pre-operatively and as part of clinical follow-up before discharge, at 1, 6, and 12 months, and yearly thereafter up to 5 years. eGFR was calculated by using the abbreviated Modification of Diet in Renal Disease study equation, as previously described.[19] AKI after endovascular repair was assessed according to the RIFLE (Risk, Injury, Failure, Loss, End stage) classification system.[20] Late renal outcomes were assessed using changes in sCr, eGFR, and the NKF staging system for CKD.[19]

Statistical analysis

Data were managed and analysed by Cook Research Inc. (West Lafayette, IN, USA) with the use of SAS for Windows 9.3 or higher (SAS Institute, Cary, NC, USA). Continuous variables are reported as mean ± SDs, unless otherwise stated. Categorical variables are reported as percentages. Comparison between groups was performed using the F-test for continuous variables and Fisher's exact test for categorical variables. Kaplan–Meier was used to analyse time to event outcomes. p-Values $< .05$ were considered significant.

RESULTS

Sixty-seven patients were treated with fenestrated devices and 134 matched controls in the conventional EVAR group. Both groups had similar demographics, pre-operative characteristics, and operative variables (Table 1), except for a larger diameter at the lowest patent renal artery (25.3 ± 3 mm vs. 23.9 ± 3 mm; $p = .003$) and longer total operative time (236 ± 80 min vs. 196 ± 61 min; $p < .001$) in the fenestrated group. In the FEVAR group, there were 178 target vessels incorporated by fenestrations (mean 2.65 ± 0.6 per patient). Mean follow-up was 32 ± 20 months in the FEVAR group and 30 ± 19 months in the AAA group ($p = .60$).

Survival and MAEs

The rate of 30 day or in hospital mortality was 1.5% for both groups (1/67 in the FEVAR and 2/134 in the EVAR group). Patients treated with FEVAR had higher overall survival, with freedom from all-cause mortality of 97%, 96%, and 92% at 1, 2, and 5 years, respectively, versus 93%, 86%, and 80% in the EVAR group (log-rank $p = .046$; Fig. 1). There were no significant differences in the freedom from MAEs between groups (log-rank $p = .151$; Fig. 2).

Table 1. Baseline characteristics.

	ZFEN ($n = 67$)	ZAAA ($n = 134$)	p
Matching variables			
Sex, male	81	86	.41
Mean ± SD age (y)	74 ± 8	73 ± 8	.26
Hypertension	90	80	.11
Diabetes	24	18	.35
Mean ± SD eGFR (mL/min/1.73 m^2; y)	75 ± 22	71 ± 24	.27
Cardiovascular comorbidities			
Arrhythmia	31	28 [a]	.62
MI	30	33 [a]	.75
Peripheral vascular disease	23 [b]	20	.71
CVD	16	13 [c]	.52
Symptomatic congestive heart failure	10	14 [c]	.51
Thrombo-embolic event	10	6 [c]	.27
Renal characteristics			
CKD stage			.33
No CKD/stage I	21	16	
Stage II	55	51	
Stage III	24	34	
Mean ± SD sCR (mg/dL)	1.1 ± 0.3	1.2 ± 0.3	.11
Other comorbidities			
COPD	36 [b]	28 [a]	.26
Cancer	36	28 [c]	.26
Aneurysm anatomy (mean ± SD)			
Maximum aneurysm diameter (mm)	60 ± 10 [d]	57 ± 10 [c]	.14
Diameter at lowest patent renal artery (mm)	25 ± 3 [d]	24 ± 3 [a]	.003
Operative variables (mean ± SD)			
Total procedure time (min)	236 ± 80	196 ± 61	< .001
Contrast load (mL)	144 ± 73	141 ± 63	.81

Note. Data are % unless otherwise indicated. ZFEN = Zenith fenestrated; ZAAA = Zenith infrarenal; eGFR = estimated glomerular filtration rate; MI = myocardial infarction; CVD = cerebrovascular disease; CKD = chronic kidney disease; sCR = serum creatinine; COPD = chronic obstructive pulmonary disease.

[a] Data from 132 patients.

[b] Data from 66 patients.

[c] Data from 133 patients.

[d] Data from 63 patients.

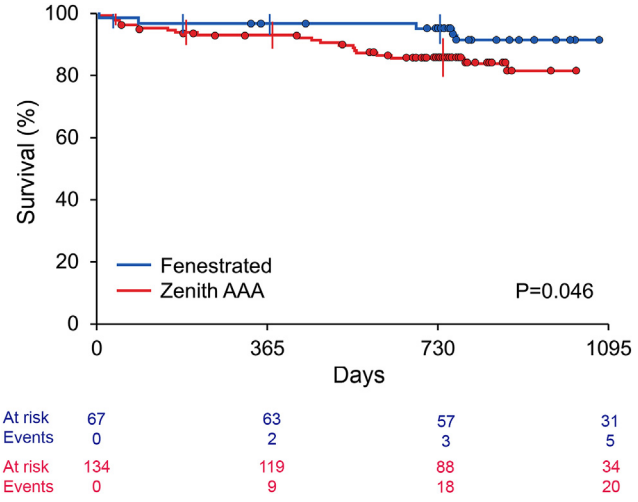

Figure 1. Freedom from all-cause mortality. *Note.* Zenith AAA = Zenith infrarenal.

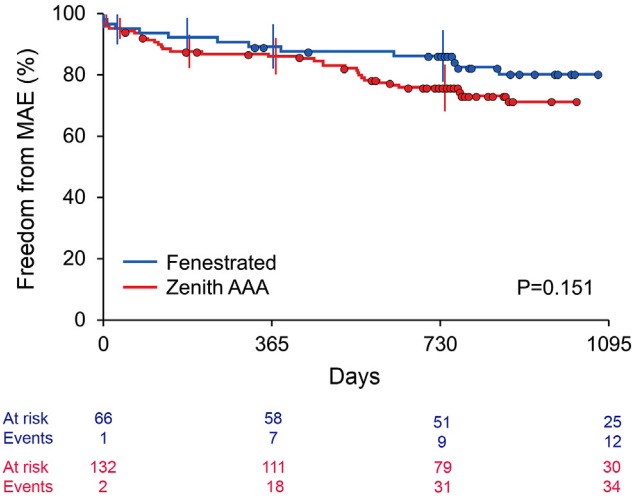

Figure 2. Freedom from major adverse events (MAEs). *Note.* Zenith AAA = Zenith infrarenal.

Table 2. Early renal outcomes.

	ZFEN ($n = 63$)	ZAAA ($n = 121$)	p
Mean ± SD serum creatinine (mg/dL)	1.1 ± 0.3	1.3 ± 0.6	.08
Serum creatinine > 2 mg/dL	2	7	.17
Mean ± SD eGFR (mL/min/1.73 m^2; y)	72 ± 20	69 ± 24	.31
eGFR decline > 25%	5	9	.39
CKD stages			.75
No CKD/stage I	18	16	
Stage II	54	46	
Stage III	29	36	
Stage IV	0	2	
Stage V	0	1	

Note. Data are % unless otherwise indicated. ZFEN = Zenith fenestrated; ZAAA = Zenith infrarenal; eGFR = estimated glomerular filtration rate.

Renal outcomes

At 30 days, AKI assessed by the RIFLE criteria was similar between FEVAR and AAA groups ($p = .80$). No evidence of AKI occurred in 95% of FEVAR and 91% of EVAR patients. Three patients in the FEVAR group (5%) and nine patients in the EVAR group (7%) were classified as in *Risk* for AKI. Only two patients (2%) treated by standard EVAR had *Injury* or *Failure*, one of whom required transient dialysis (1%). A decline of greater than 25% in eGFR occurred in 5% of FEVAR and 9% of EVAR patients ($p = .39$). Other renal outcomes, including CKD stage, and changes in eGFR and sCr were also similar between the groups at 30 days (Table 2).

At 2 and 5 years, there were no significant differences in > 25% decline in eGFR (20% vs. 20% [$p > .99$] and 27% vs. 42% [$p = .5$]) or progression to CKD stage IV or V (2% vs. 3% [$p > .99$] and 7% vs. 8% [$p > .99$]) between patients treated by FEVAR or EVAR, respectively. Both groups had similar mean sCr (Table 3) and eGFR (Fig. 3) up to 5 year follow-up. Rates of renal failure requiring permanent dialysis were low in both groups (1.5% vs. 1.5%; $p > .99$).

There were more patients with post-operative renal artery stenosis/occlusions (22% [15/67] vs. 2% [3/134]; $p < .001$) and more renal related re-interventions (18% [12/67] vs. 3% [4/134]; $p < .001$) in the FEVAR group compared with the infrarenal EVAR group. However, renal arterial duplex ultrasound studies were obtained routinely in all

Table 3. Mean serum creatinine (mg/dL).

Time point	ZFEN		ZAAA		p
	n	Mean ± SD	n	Mean ± SD	
Pre-procedure	67	1.1 ± 0.3	134	1.2 ± 0.3	.11
Immediate post-procedure	67	1.0 ± 0.3	134	1.1 ± 0.4	.21
30 d	63	1.1 ± 0.3	121	1.3 ± 0.6	.08
1 y	56	1.2 ± 0.3	104	1.3 ± 0.4	.43
2 y	49	1.2 ± 0.4	92	1.3 ± 0.4	.50
3 y	23	1.3 ± 0.5	18	1.3 ± 0.6	.98
4 y	15	1.5 ± 1.0	21	1.7 ± 1.0	.59
5 y	15	1.4 ± 0.5	26	1.5 ± 0.7	.41

Note. ZFEN, Zenith fenestrated; ZAAA, Zenith infrarenal.

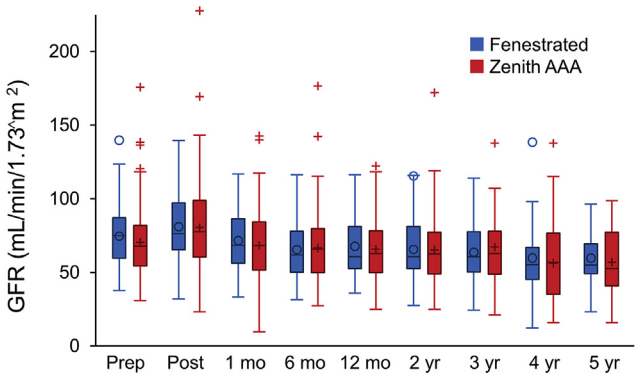

Figure 3. Mean estimated glomerular filtration rate (GFR) at different time points. *Note.* Zenith AAA = Zenith infrarenal.

FEVAR patients, and were only indicated in the presence of deteriorating renal function or blood pressure management among EVAR patients. Freedom from renal artery stenosis/occlusion and freedom from renal related re-interventions are presented in Figs. 4 and 5.

DISCUSSION

Renal function impairment is a common and feared complication after any aortic intervention. Because FEVAR requires extension of the proximal landing zone above the renal and mesenteric arteries, it is logical to assume that there is greater risk of renal function decline than with standard EVAR. FEVAR is associated with a longer procedure time, and requires more contrast and significant catheter manipulation to place stents in the renal and mesenteric arteries. Therefore, there is potential risk of embolisation of atherosclerotic debris or chronic thrombus, and arterial perforation or dissection can occur from placement of guidewires and stents in the renal arteries. Late re-interventions have been driven by in-stent restenosis and endoleaks, which primarily affect the renal branches. However, this study shows that FEVAR and EVAR have similar early and late renal outcomes in matched cohorts treated in prospective pivotal trials.

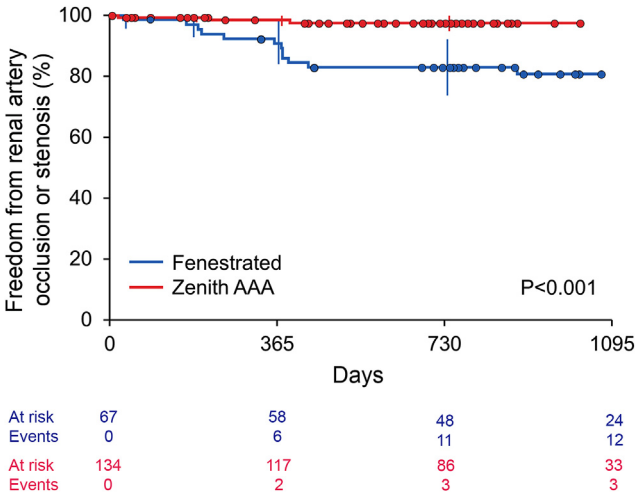

Figure 4. Freedom from renal artery stenosis or occlusion. *Note.* Zenith AAA = Zenith infrarenal.

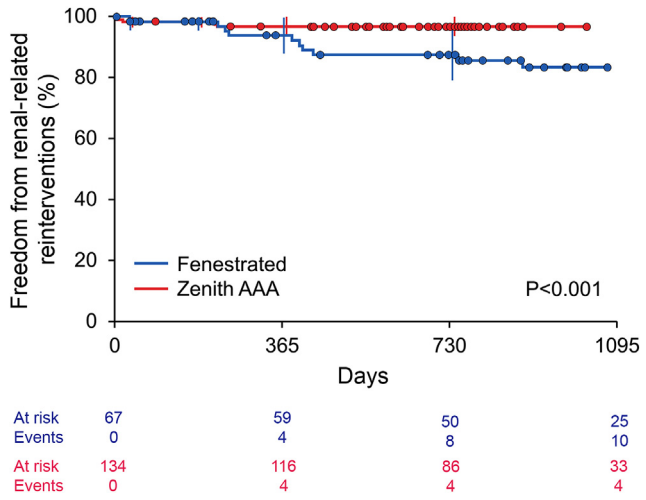

Figure 5. Freedom from renal related re-interventions. *Note.* Zenith AAA = Zenith infrarenal.

The United Kingdom EVAR Trial investigated the impact of multiple interventions on renal function. There was no difference in renal function deterioration between EVAR and open surgical repair or in patients who had secondary endovascular re-interventions.[21] Whereas it is logical to assume that patients with AAAs are at greater risk of renal deterioration than the general population, there is no study confirming this theory. In addition, there is no randomised trial comparing renal outcomes in patients treated by FEVAR, EVAR, or open surgical repair. In a systematic review, Nordon *et al*. compared outcomes of FEVAR and open surgical repair of juxtarenal aortic aneurysms.[11] In that study, open surgical repair was associated with a greater risk of renal impairment (relative risk 1.06, 95% confidence interval 1.01—1.12; $p = .03$), but permanent dialysis occurred in 1.4% of the patients in both groups.[11] Tsilimparis *et al*.,[22] using data from the American College of Surgeons Quality Improvement Program (ACSQIP), also found FEVAR improved 30 day renal outcomes compared with open repair for complex aortic aneurysms (10% vs. 1.5%; $p < .001$). Another study compared the results of two high volume centres with FEVAR and open surgical repair. Although FEVAR was associated with greater risk of early morbidity, there was no difference in renal complications.[23] A recently published study, also analyzing the ACSQIP database, compared FEVAR and EVAR in 458 and 19,060 patients, respectively. Thirty day mortality was similar between the two groups, but FEVAR was associated with greater risk of early morbidity (24% vs. 14%; $p < .001$). However, renal insufficiency (0.4% vs. 0.6%; $p = .45$) and need for dialysis (1.5% vs. 0.8%; $p = .08$) were comparable in both groups.[24]

There is considerable variation in the definitions of acute and chronic kidney disease in the literature regarding FEVAR outcomes. The standard classification proposed by the NKF was used to define CKD. The RIFLE criteria were adopted for the classification of AKI. This classification has been shown to be accurate in identifying affected patients, and exhibits good prognostic accuracy in terms of mortality and renal morbidity.[25] Considering only patients who completed 30 day follow-up, < 5% of FEVAR patients in this series were classified at *Risk* for AKI. This was comparable to RIFLE criteria for the EVAR group, and similar to findings of post-operative renal dysfunction in other reports (Table 4).[2,3,12,18,26—37]

Long-term outcomes of renal fenestrations have been studied in a number of single centre studies. Mastracci *et al*. analysed the durability of 1679 branches (650 patients) over 9 years of follow-up.[38] Freedom from branch related intervention was 89% over 5 years, but the renal arteries accounted for most re-interventions to treat either in-stent restenosis or type III endoleaks.[38] Martin-Gonzalez *et al*. reported 5 year freedom from renal artery occlusion and secondary intervention of 91% and 94%, respectively.[12] The present findings were similar to these studies. Despite the greater need for renal re-interventions after FEVAR compared with EVAR, the proportion of patients with significant eGFR decrease, progression to CKD stages IV or V, and the need for permanent dialysis were comparable in both groups and were similar to other reports (Table 4).[2,3,12,18,26—37] The present results reinforce the need for constant and careful follow-up surveillance of renal artery targets in patients treated by FEVAR. Patients undergoing FEVAR should be informed pre-operatively of the risks of renal injury, renal re-interventions, and continued surveillance with contrast enhanced CT over time. Nonetheless, if FEVAR is indicated on the basis of anatomy, the findings indicate that the risk of renal dysfunction is nearly identical to standard EVAR.

Although not the main objective of the present work, it was remarkable that patients in the FEVAR group had comparable freedom from MAEs at least up to 3 years, and a significantly improved 5 year survival compared with EVAR patients. Similar results were published earlier.[39] The only significant difference between the groups in the present study was in the diameter of the aorta at the level of the lowest patent renal artery (mean of 1.4 mm larger in the FEVAR group), which was expected given different aneurysm extent. It is important to highlight the limitation that the groups were treated in different eras (EVAR in 2000—03 and FEVAR in 2005—12). Therefore, it is likely that patient selection and improvements in medical management of cardiovascular risk factors accounted for the improved survival in the FEVAR cohort. In addition, improvements in endovascular techniques and post-operative intensive care have also occurred in the last decade and may have accounted for the differences in survival between the two prospective study cohorts.

The present study has important limitations. Although both cohorts were prospectively followed under strict pivotal trial protocols, this study applied retrospective design to investigate changes in renal function and outcomes. Both protocols were fairly similar, with the exception of closer renal surveillance in the FEVAR group. Duplex ultrasound of the renal arteries was not routinely performed in the EVAR trial. Confounding is accentuated in multiple cohort designs, as cohorts originated from distinct populations that were not concurrent in time. An attempt to control this bias was made by matching the cohorts to

Table 4. Literature review.

	Year	Study type	Patients (*n*)	Vessels (*n*)	Device	Early outcomes 30 d mortality	AKI	Transient dialysis	Late outcomes Follow-up (mo)	Renal artery stenosis [a]	Renal artery occlusion [a]	Renal related re-intervention (%) [a]	CKD	Permanent dialysis
Martin-Gonzalez *et al.*[12]	2015	C, R, S	225	433	ZFEN ZTBR	14 (6)	64 (29)	13 (6)	Median 37 (95% CI 35—40)	4 (2)	8 (4)	13 (6)	NR	5 (2)
Grimme *et al.*[2]	2014	C, R, S	138	392	ZFEN	2 (1)	22 (16)	0	Median 13 (range 1—97)	24 (17)	5 (4)	NR	70 (51)	2 (1)
Kristmundsson *et al.*[3]	2014 2009	C, P, S	54	134	ZFEN	2 (4)	19 (35)	0	Median 67 (IQR 37—90)	NR	NR	5 (4)	7 (26) [b]	1 (1)
Quiñonez-Baldrich *et al.*[29]	2013	C, P, M	31	NR	VENT	0	NR	1 (3)	Mean 16	NR	NR	3 (10)	NR	1 (3)
GLOBALSTAR[27]	2012	C, P, M	318	889	ZFEN	13 (4)	11 (3)	NR	Median 6	NR	NR	18 (6)	NR	1 (<1)
Tambyraja *et al.*[30]	2011	C, R, M	29	79	ZFEN	0	NR	0	Median 20 (range 8—22)	NR	NR	NR	NR	NR
Amiot *et al.*[26]	2010	C, P, M	134	403	ZFEN	3 (2)	NR	6 (4)	Median 15 (range 2—53)	NR	4 (3)	6 (4)	NR	2 (1)
Verhoeven *et al.*[31]	2010	C, R, M	100	275	ZFEN	1 (1)	NR	NR	Median 24 (range 1—87)	NR	12 (12)	4 (4)	25 (25)	2 (2)
Greenberg *et al.*[18]	2009	C, P, M	30	77	ZFEN	0	NR	0	NR	4 (13)	2 (7)	5 (17)	NR	0
Scurr *et al.*[32]	2008	C, R, S	45	82	ZFEN	2 (4)	1 (2)	0	Median 24 (range 1—48)	NR	2 (4)	0	0	0
Ziegler *et al.*[33]	2007	C, R, S	63	180	ZFEN ZTBR	0	8 (13)	0	Median 14 (range 6—77)	NR	8 (12)	5 (8)	6 (10)	1 (2)
O'Neill *et al.*[34]	2006	C, P, S	119	302	ZFEN	1 (1)	NR	NR	Mean 19 (range 0—48)	12 (10)	10 (8)	6 (5)	NR	3 (3)
Semmens *et al.*[37]	2006	C, R, M	58	116	ZFEN	2 (3)	4 (7)	0	Mean ± SD 17 ± 14	NR	NR	NR	NR	NR
Muhs *et al.*[36]	2006	C, P, S	38	87	ZFEN ZTBR	1 (3)	NR	0	Mean ± SD 26 ± 13	NR	NR	NR	2 (5)	0
Haddad *et al.*[35]	2005	C, R, S	72	NR	ZFEN	NR	NR	2 (3)	NR	10 (14)	5 (7)	5 (7)	24 (33)	4 (6)

Note. Data are *n* (%) unless otherwise indicated. AKI = acute kidney injury; CKD = chronic kidney disease; C = cohort; R = retrospective; S = single centre; ZFEN = Zenith fenestrated; ZTBR = Zenith branched; CI = confidence interval; NR = not reported; P = prospective; IQR = interquartile range; M = multicentre; VENT = Ventana.

[a] Data on renal arteries is given by patients owing to variability in previous reports.

[b] Only considering patients with normal pre-operative renal function.

the main pre-operative variables, and recognising the potential risk of overmatching. Minor differences in pre-operative renal function, which were not significant but may have favoured the FEVAR group, are also acknowledged. Although patients were matched for age, hypertension, diabetes, and CKD, other determinants of renal function loss could have contributed to this outcome. Moreover, longer follow-up is needed to further analyse the impact of the treatment on renal function deterioration. However, this study is the first multicentre analysis of prospective trials to compare renal outcomes between patients treated for AAA by FEVAR or EVAR.

CONCLUSION

Renal function deterioration is similar in patients with AAA and initially preserved renal function treated by FEVAR and conventional EVAR. Renal related re-interventions were more frequent following FEVAR, but renal function impairment was similar in both groups. Careful follow-up is recommended after FEVAR to detect branch stenosis. The present data show that FEVAR carries a higher risk of renal related re-interventions than EVAR. However, renal function outcomes were nearly identical reinforcing that the decision on the type of repair in patients with preserved renal function should be based on anatomical parameters and whether FEVAR is indicated or not to achieve aneurysm seal.

CONFLICTS OF INTEREST

G.S.O. is a consultant for Cook Medical and WL Gore, and receives research support from Cook Medical and WL Gore; all fees are paid to the Mayo Clinic. M.A.F. is a consultant for Cook Medical, WL Gore, Medtronic, and Endologix; and receives research support from Cook Medical and clinical trial support from Cook Medical, WL Gore, Medtronic, and Endologix. S.H. is a consultant, receives research support, and has intellectual property from Cook Medical. F.J. is an employee at Cook Research Incorporated, a Cook Medical Company.

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