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Characterising the incidence and mode of visceral stent failure after fenestrated endovascular aneurysm repair (FEVAR)

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Abstract

Background: In FEVAR, visceral stents provide continuity and maintain perfusion between the main body of the stent and the respective visceral artery. The aim of this study was to characterise the incidence and mode of visceral stent failure (type Ic endoleak, type IIIa endoleak, stenosis/kink, fracture, crush and occlusion) after FEVAR in a large cohort of patients at a high-volume centre.

Methods: A retrospective review of visceral stents placed during FEVAR over 15 years (February 2003-December 2018) was performed. Kaplan-Meier analyses of freedom from visceral stent-related complications were performed. The outcomes between graft configurations of varying complexity were compared, as were the outcomes of different stent types and different visceral vessels.

Results: Visceral stent complications occurred in 47/236 patients (19.9%) and 54/653 stents (8.3%). Median follow up was 3.7 years (IQR 1.7–5.3 years). There was no difference in visceral stent complication rate between renal, SMA and coeliac arteries. Visceral stent complications were more frequent in more complex grafts compared to less complex grafts. Visceral stent complications were more frequent in uncovered stents compared to covered stents. Visceral stent-related endoleaks (type Ic and type IIIa) occurred exclusively around renal artery stents. The most common modes of failure with SMA stents were kinking and fracture, whereas with coeliac artery stents it was external crush.

Conclusion: Visceral stent complications after FEVAR are common and merit continued and close long-term surveillance. The mode of visceral stent failure varies across the vessels in which the stents are located.

Keywords

Vascular, aneurysm, complex, fenestrated, endovascular, stent, complications

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Introduction

Fenestrated endovascular aneurysm repair (FEVAR) is an adaptation of EVAR in which the proximal seal is extended above the level of the renal arteries into the visceral segment of the aorta. Fenestrations in the main body of the graft permit adjunctive stenting into the visceral vessels enabling continued perfusion of the abdominal viscera while maintaining exclusion of the abdominal aortic aneurysm (AAA). It was first described in 1999[1] and since then has become an established method of repair for juxtarenal AAAs and aneurysms that involve the visceral segment of the aorta.

It has been demonstrated that FEVAR is a feasible treatment modality across multiple centres in large registries[2,3] as well as in several cases reporting mid-term

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follow-up.[4,5] However, the concern of endovascular aneurysm repair has always been long-term durability and FEVAR is no exception. The Globalstar registry, a prospective multicentre database highlights reintervention rates of 7% at 30 days and 30% at 3 years after FEVAR.[2]

Over time, the configuration of a standard FEVAR device has increased in complexity from initial experience being limited to fenestrations just for the renal arteries. Modern day practice routinely involves stenting all four visceral vessels (right renal artery, left renal artery, superior mesenteric artery and coeliac artery) through fenestrations.[6] This progression towards a higher seal in the visceral aorta has been with the intention of reducing the risk of proximal endoleak and therefore increasing durability by sealing in healthier aorta. However, this introduces more components and junctions to the device, thereby increasing the risk of developing other stent graft-related complications, particularly with respect to the visceral stents. These may include occlusion, fracture, kink and high pressure endoleaks from the interface between the visceral stent and the native visceral artery (Ic endoleak) or between the visceral stent and the fenestration (IIIa endoleak).

The aim of this study was to retrospectively characterise the incidence and mode of visceral stent failure after FEVAR and to identify predisposing factors in a large cohort of cases performed in a high-volume centre.

Methods

This study involved extending data collection from that of a previous study undertaken at our institution.[6] Clinical details regarding the implantation of FEVAR devices and follow-up protocols of our institution have been described earlier.[6] However, in brief, patients were enrolled onto a standardised post-FEVAR surveillance protocol, including plain abdominal X-ray before discharge, duplex ultrasonography and single arterial-phase CT angiography (CTA) after 1 month, with clinical review 6 weeks after surgery. Abdominal X-ray, duplex ultrasonography and CTA were repeated after 6 months, then annually. All patients were placed onto lifelong single antiplatelet and statin therapy if they were not already prescribed it pre-operatively.

Data collection

A prospectively maintained clinical database was interrogated to identify FEVARs that were undertaken at the Liverpool Vascular and Endovascular Service between February 2003 and December 2018. Patients who underwent an endovascular aneurysm repair with a branched device, a hybrid branched and fenestrated device or a FEVAR coupled with a proximal thoracic extension were excluded to avoid confounding of the anatomical cohort with thoracoabdominal aneurysms.

Retrospective data collection from electronic records (both clinical notes and imaging reports) was undertaken to retrieve details regarding patient demographics, FEVAR configuration, stent type (if present) and details of complications and reinterventions. A fenestration was defined as a deliberate defect either circular or elliptical below the proximal fabric margin and a scallop as a U-shaped gap in the proximal fabric of the graft.[7] Low complexity FEVAR was defined as those cases in which the most proximal visceral stents were in the renal arteries and high complexity FEVAR was defined as those cases in which the most proximal stents were placed in either the superior mesenteric artery or coeliac artery.

Study endpoints and follow up

The primary endpoint was development of any visceral stent-related complication. Secondary endpoints were re-intervention for any visceral stent-related complication and survival. The incidence of specific stent-related complications (occlusion, fracture, kink, visceral type Ic and type III endoleaks) was also recorded. Visceral type Ic endoleaks were defined as originating from a loss of seal between the distal visceral stent and the target visceral vessel. Type IIIa endoleaks were defined as originating from a loss of seal between the proximal visceral stent and its associated fenestration.

Patients were censored at the point of last data collection (1st June 2019) or the date of last follow-up if earlier. The date of last follow-up for patients was defined as the date of last surveillance scan (if patient was known to be alive and on surveillance) or the date of death.

Statistical analysis

Continuous data are presented as median (IQR). Simple descriptive statistics were used to describe patient demographics and incidence of various visceral stent related complications. Visceral stent complication rate and rate of re-intervention for visceral stent complication were subject to Kaplan-Meier analysis and log rank comparison using RStudio® (RStudio, Boston, Massachusetts, USA).

Results

Patient cohort

During the 15-year study interval, 236 patients underwent an elective fenestrated endovascular aneurysm repair and met the inclusion criteria for this analysis. 215 out of 236 patients (91%) were male and the

median age at the time of aneurysm repair was 75 (IQR 70–79). 11 patients died as an inpatient (in-hospital mortality of 4.7%). 30-day mortality was 2.5%. Median follow-up was 3.7 years (IQR 1.7 years – 5.3 years).

FEVAR stent graft configurations and visceral stent details

653 visceral stents were incorporated into the fenestrated endovascular repairs of 236 patients. There were 664 fenestrations in total (11 fenestrations were unstented). The median number of fenestrations was 3 (IQR 2–4). The median number of visceral stents per graft was 3 (IQR 2–3). The commonest most proximal stent across all FEVAR configurations was the SMA (97/236, 41%), followed by renal artery (84/236, 36%), followed by coeliac artery (55/236, 23%). The most common FEVAR configuration (Table 1) involved stenting up to and including the SMA, with a scallop for the coeliac artery, placed in 77 out of 236 patients (33%). This was followed by stents in the renal arteries with a scallop for the SMA, placed in 68 out of 236 patients (29%).

SMA, superior mesenteric artery; CA, coeliac artery

233/236 patients underwent repair with the Zenith Fenestrated platform (ZFEN, Cook Medical Bloomington, IN, USA) and 3/236 patients underwent repair with the Vascutek-Terumo Anaconda device (Inchinnan, Scotland, UK).

Of the 653 visceral stents (all balloon expandable), it was not possible to extract data regarding brand or covered/uncovered status for 25. Of the remainder, 68 (10.8%) were bare metal uncovered stents and 560 (89.2%) were PTFE covered stents (Table 2). The most common stents used in the study population were the Advanta covered stent (Atrium Medical, Hudson, NH, USA) and the Palmaz Genesis bare metal uncovered stent (Cordis, Miami Lakes, Florida, USA). Both covered and uncovered stents were used between 2003 and 2010 for the visceral vessels, with exclusive use of covered stents occurring between 2010 and 2018.

Overall visceral stent complications

Visceral stent complications (fracture, stenosis/kink, crush, occlusion, dislocation, type Ic endoleak and type IIIa endoleak) occurred in 47 out of 236 patients (20%) and 54 out of 653 stents (8.3%) during the 15-year study period (7 patients had more than 1 visceral stent affected by complications). Of the 54 stents affected, 19 stents were in the right renal artery, 18 in the left renal artery, 13 in the SMA and 4 in the coeliac artery (Table 3).

Loss of visceral stent patency (crush or occlusion) (Table 3)

18 stents in 18 different patients suffered from either occlusion or crush from an extrinsic crushing force. Primary visceral stent patency was therefore 97.2% by stent (635/653 stents patent) or 92.3% by patient (218/236 patients free from stent occlusion). 13 stents occluded (12 renal arteries and 1 SMA) and in addition to this, stent crushes (extrinsic) occurred in 5 cases (1 renal artery, 1 SMA and 3 coeliac arteries). In these cases, there was either no flow or disturbed flow seen through these stents on imaging. These were categorised as crushes as opposed to occlusions due to the extrinsic mechanism of action.

Of the 13 stent occlusions, 9 seemed to occur de novo and 4 occurred after or in association with stent fracture. 2 of the stent occlusions (both renal stents) were peri-operative complications, 2 additional renal

Table 2. Stents used in study population.

Stent type	Stent name	Manufacturer	n	%
Uncovered	Palmaz Genesis	Cordis	53	10.8
	AVE Bridge	Medtronic	14	
	Racer	Medtronic	1	
Covered	Advanta	Atrium	502	89.2
	BeGraft	Bentley	31	
	LifeStream	Bard	15	
	Jostent	Jomed	12	
Unclassified	n/a	n/a	25	n/a

Table 1. FEVAR configurations utilised in study population.

Most proximal stent	SMA involvement	CA involvement	n	%
Renal	Nil	Nil	14	36
	Unstented fenestration	Unstented fenestration	1	
	Unstented fenestration	Nil	1	
	Scallop	Nil	68	
SMA	Stent	Nil	10	41
	Stent	Unstented fenestration	10	
	Stent	Scallop	77	
Coeliac	Stent	Stent	55	23

Table 3. Incidence of visceral stent complications.

	n stents with complications	Crush	Dislocation (without EL)	Fracture	Kink/stenosis	Occlusion	TIb EL	TIIIa EL
Left Renal	18	1	2	3	1	5	5	6
Right Renal	19	0	1	5	3	7	1	5
SMA	13	1	0	6	5	1	0	0
CA	4	3	0	0	1	0	0	0

SMA,superior mesenteric artery; CA, coeliac artery; EL, Endoleak; TIb, Type 1b; TIIIa, Type 3a

stents occluded within the first year after FEVAR, with the remainder occurring after 1 year. Median time to stent occlusion was 1 year 8 months (range 0 days – 4 years 9 months). Stent crush was iatrogenic at open laparotomy in the case of 1 renal stent at 10 years 9 months, idiopathic in 1 SMA stent at 1 year 11 months, and secondary to median arcuate ligament compression in 3 coeliac artery stents (at 1 month, 1.4 months and 1 year 1 month after surgery respectively).

Fractures, kinks, dislocations and endoleaks (Table 3)

There were 14 stent fractures in total, 8 in renal stents and 6 in SMA stents. 4 of the renal stent fractures led to visceral stent occlusion. 10 stents displayed velocity changes on duplex ultrasonography that led to a diagnosis of kinking/stenosis. 5 out of 10 kinked/distorted stents were in the SMA.

Type Ic and IIIa endoleaks occurred exclusively in association with renal artery stents, with no endoleaks identified around SMA or coeliac artery stents. Dislocations at the level of the fenestration led to type IIIa endoleaks in 6 left renal stents and 5 right renal stents. There were 3 additional dislocations that did not cause an identifiable endoleak on imaging. Dislocations at the level of the visceral target vessel led to a loss of seal and type Ic endoleak in 5 left renal stents and 1 right renal stent.

Predictors of visceral vessel complications

There was no difference in the incidence of visceral stent complications between renal stents, SMA stents and coeliac artery stents (freedom from complications 89%, 86% and 90% respectively at 10 years, $p = 0.25$, Figure 1). The incidence of visceral stent complications was higher in uncovered stents compared to covered stents (freedom from complications 64.5% vs 92% respectively at 10 years, $p = 0.0003$, Figure 2 and Table 4). There was a significant difference in

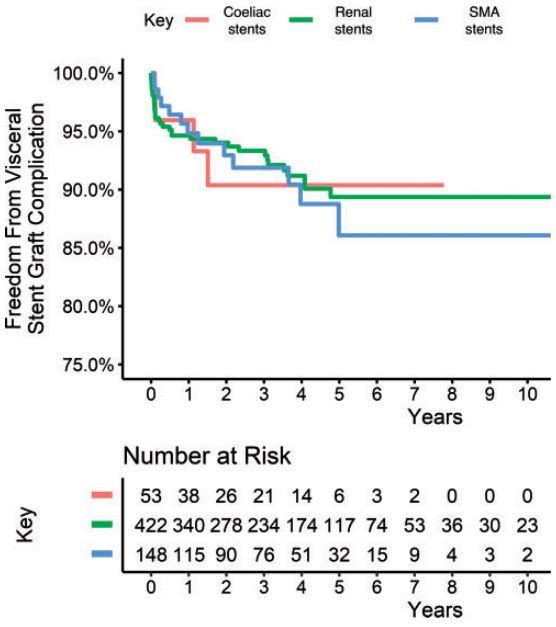

Figure 1. Kaplan Meier curves demonstrating freedom from visceral stent complications between coeliac, renal and SMA stents.

complication rate between stents of different brand ($p < 0.0001$, Figure 3). Of covered stents, LifeStream stents (Bard Peripheral Vascular, Tempe, AZ, USA) appear to have a high rate of developing stent related complications (Figure 3 and Table 4). There were more visceral stent complications in high complexity FEVARs, where there are stents in the SMA and/or coeliac artery, as compared to low complexity FEVARs, where there are stents in the renal arteries alone (freedom from complications 66% vs 85% respectively at 10 years, $p = 0.02$, Figure 4). Renal stents were not more likely to suffer from a stent complication if they were part of a high complexity FEVAR configuration compared to a low complexity FEVAR configuration (freedom from complications 86% vs 92% respectively at 10 years, $p = 0.84$, Figure 5).

Re-intervention for visceral stent complications

Of the 47 patients who developed a visceral stent complication, 26 underwent a re-intervention and 21 were managed conservatively. Rate of re-intervention specifically for visceral stent complications is therefore 11% (26/236 patients). 25/26 patients underwent 1 or more endovascular re-interventions (96.2%) to their visceral stent, which was either re-lining, stent extension or angioplasty (including re-locking at the fenestration). Only 1 patient required an open re-intervention (an ilio-SMA bypass for a bare metal SMA stent fracture within 3 months of the original FEVAR). There were significantly more re-interventions to the visceral stents of high complexity FEVARs compared to those in low complexity FEVARs (freedom from re-intervention 70% vs 90% at 10 years, $p = 0.0015$, Figure 6).

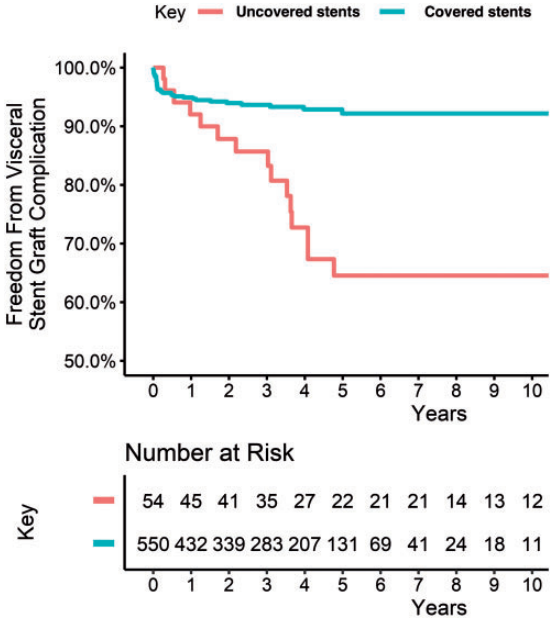

Figure 2. Kaplan Meier curves demonstrating freedom from visceral stent complications between covered and uncovered stents.

Discussion

The 15-year study period in this retrospective review is longer than in any published study in the current

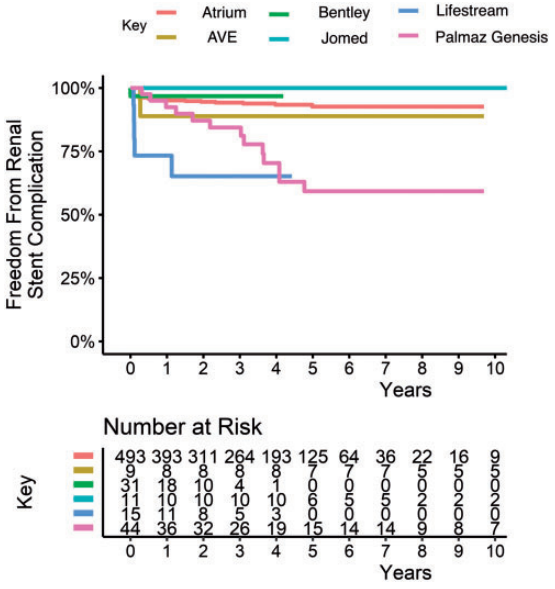

Figure 3. Kaplan Meier curves comparing incidence of visceral stent complications between different brands of stent.

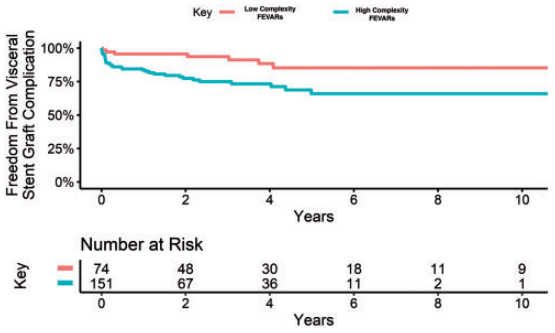

Figure 4. Kaplan Meier curves comparing incidence of visceral stent complications between low complexity and high complexity FEVARs.

Table 4. Incidence of visceral stent complications by brand of stent.

Stent type	Stent name	Manufacturer	n	Number of complications	Complication rate in that brand of stent (%)
Uncovered	Palmaz Genesis	Cordis	53	13	24.5
	AVE Bridge	Medtronic	14	1	7.1
	Racer	Medtronic	1	1	100
Covered	Advanta	Atrium	502	31	6.1
	BeGraft	Bentley	31	1	3.2
	LifeStream	Bard	15	5	33.3
	Jostent	Jomed	12	1	8.3
Unclassified	n/a	n/a	25	1	–

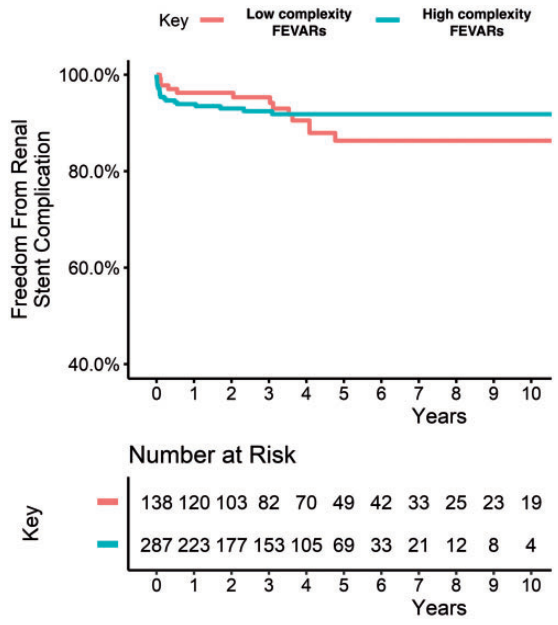

Figure 5. Kaplan Meier curves comparing incidence of renal stent complications between low complexity and high complexity FEVARs.

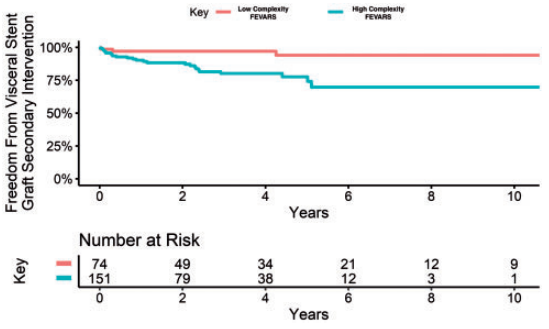

Figure 6. Kaplan Meier curves comparing re-intervention rates for visceral stent complications between low complexity and high complexity FEVARs.

literature to our knowledge. The study population is comparable to other large cohorts in terms of basic patient demographics and survival rates.[2,4] Loss of patients to follow-up as a result of out-of-region surveillance as well as natural attrition from death explain the median follow-up of 3.7 years. Specific visceral stent complications, other than loss of patency, are rarely reported in case series reporting FEVAR outcomes due to a focus on mortality and overall complication or reintervention rates in early experiences of FEVAR. Our centre has established experience with FEVAR, and this provided an opportunity to characterise more specific complications affecting visceral stents.

Our results demonstrate that visceral stent complications are common, affecting 20% of patients undergoing FEVAR. Half of these complications warranted re-intervention (11% of the overall study population). Given that stent-related complications and their reinterventions after standard EVAR are of similar incidence and are considered the technology's Achilles' heel,[8] then visceral stent complications after FEVAR should also be considered significant sequelae. Visceral stent complications can lead to death, either through visceral organ malperfusion or aneurysm rupture after high-pressure endoleak. Neither scenario was seen in this study population suggesting that the decision making for reintervention was entirely appropriate and that certain visceral stent complications may have a benign natural history.

Stent patency in our cohort was >90% of all stents or patients during follow-up which is comparable to the published rate in the literature.[2,9,10] Interestingly, stent occlusion was seen to occur either de novo, after stent fracture or due to extrinsic compression of the coeliac artery by the median arcuate ligament (MAL).

Visceral type Ic and IIIa endoleaks were only seen in association with renal artery stents. This has also been described in a cohort of 18 hybrid fenestrated/branched EVAR cases (F/BEVAR), all treated with the LifeStream visceral stent specifically.[11] In that cohort, type IIIa endoleaks occurred at 22% of all fenestrations, the majority (5 out of 7 type IIIa endoleaks) occurring at the renal artery fenestrations. This high rate of type IIIa endoleak development was attributed to the mechanical properties of the LifeStream stent. In our case series, 33% of 15 LifeStream stents suffered from stent complications, a greater proportion than any of the other PTFE covered stents, although low numbers precluded statistical analysis. Our analysis demonstrated that PTFE covered stents suffered from fewer complications than bare metal uncovered stents. This finding is not novel[12] and covered stents are now standard practice for FEVAR deployment across the world. It is however useful to note that in long-term follow-up, covered stents continue to outperform the bare metal stents that were used only in the early days of FEVAR practice. It is also useful to recognise this as patients will continue to present to FEVAR centres with complications to uncovered visceral stents in the long-term.

Our analysis has demonstrated quite clearly that the mode of stent graft failure varies between the different visceral arteries. Coeliac stents are prone to crush from the median arcuate ligament, whereas SMA stents are prone to fracture and kinking. An explanation might be the possibility of there being a relatively high level of movement in this segment of the FEVAR graft. The caudal direction of the SMA also necessitates an angulated passage of the stent through the fenestration which may apply additional forces greater than those acting on stents located in the renal arteries. Renal

stents were the only visceral vessels affected by type Ic and type IIIa endoleaks, perhaps related to smaller diameter stents being placed in larger fenestration sizes (6×6 mm and 6×8 mm) and the short engagement lengths often utilised within the renal artery due to early branches. Additionally, graft tapering of the fenestrated piece often commences at the level of the renal arteries, potentially reducing wall apposition at this level. These hypotheses cannot be investigated fully in the absence of anatomical data from pre-operative CT scans and their relationship to sizing of the FEVAR graft.

The observations made in this analysis may help inform decision making at the planning and intra-operative stages of FEVAR. Covered renal stents could possibly be lined with a bare metal stent across the fenestration in an attempt to improve sealing and avoid type IIIa endoleak. SMA stents could be similarly reinforced in an attempt to improve stability during the phases of the cardiac cycle in which the stent will be maximally flexed. Coeliac arteries could either be left unstented in cases where there is pre-operative radiological evidence of MAL compression or alternatively reinforced with a second stent intra-operatively or with the use of high pressure ballooning. These suggestions are hypothetical and would merit further investigation.

Over time, FEVAR has become more complicated with regards to the proximal extent of seal zone and the number of visceral vessels involved.[6] This has occurred with the intention of increasing long-term durability, as sealing in more proximal 'healthier" aorta will increase the likelihood of achieving a successful seal. However, the trade-off is an increase in the amount of stent graft material, the number of components and the number of junctions at which novel complications can develop.

Increasing complexity of FEVAR configuration is associated with an increased incidence of visceral stent graft-related complications. Two hypotheses could explain this: firstly, that the more complex FEVARs have more junctions and components and will therefore experience more complications by default. However, it is also possible that high complexity FEVAR is a surrogate marker for more complex anatomy and an unhealthier visceral segment of the aorta. It is known that type IIIa endoleaks in particular are more common when the fenestrated piece is less apposed to the native aortic wall, i.e. in cases of ectatic or aneurysmal aorta.[11] Therefore, it is plausible that visceral stent complications are more common in cases of more severe visceral segment disease. This could independently influence the incidence of visceral stent complications. However, we have shown that renal stents are no more likely to experience complications in high complexity FEVAR (configurations involving SMA/CA stents) compared to low complexity FEVAR (configurations involving renal stents only). This suggests that the discrepancy could potentially be explained solely by the fact that there are more stents to potentially fail in the complex cases.

We adopt an aggressive clinical strategy at our institution for salvaging failing visceral stents. Kinks, dislocations, endoleaks and fractures are all treated on an urgent basis once identified on surveillance imaging or on-table if identified on completion imaging. With respect to occlusions of the SMA or CA, revascularisation was only performed in 1 case due to symptoms of acute mesenteric ischaemia. Renal stent occlusions were never treated. We did not report any deaths due to visceral stent complications in our series. Data has not been interrogated for changes in renal function after complications to renal artery stents, although this may be the subject of future work.

The strengths to this analysis include the fact that it analysed a large cohort of patients over a long time period in a high-volume vascular centre. Data were extracted from prospectively maintained clinical records that were electronically interrogated with little missing data. Limitations to this study include the retrospective nature to data collection, the loss of patients to follow-up resulting in a median follow-up of only 3.7 years, and the small numbers recorded for each type of visceral stent complication (with the subsequent potential for type II error) as well as the lack of data on anatomical factors which could act as confounders. Furthermore, our experience over nearly 20 years of FEVAR practice would have be subject to an initial learning curve and the impact of multiple operators.

Conclusion

Visceral stent complications are common after FEVAR, occurring in 20% of patients. They are associated with bare metal stents more than covered stents and they occur more frequently in high complexity FEVAR configurations compared to low complexity configurations. This could be explained by the fact that more complex FEVAR configurations involve a greater number of components, stents and junctions that could fail. The mode of visceral stent failure varies across different visceral vessels. Future work should explore the potential anatomical influences on these findings and the possible intraoperative strategies that could be exploited to mitigate these risks.

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No ethical approval was required.

Guarantor

SRP.

Contributorship

SP, as primary author, undertook data collection and writing of the manuscript under supervision from senior author RK. IR performed all the statistical analyses. RM, JB, SV, SN, JS and RF performed the FEVARs and contributed data to the prospectively maintained database. All authors contributed to manuscript editing.

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