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Frequency and Outcome of Re-interventions after Endovascular Repair for Abdominal Aortic Aneurysm: A Prospective Cohort Study

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Purpose. To describe frequency, type, and outcome of re-intervention after endovascular aortic aneurysm repair (EVAR).

Methods. Between September 1996 and December 2003, 308 patients were treated, with data collected prospectively. No patient was lost to follow up, but two were excluded (one primary conversion, and one post-operative death). Vanguard, Talent, Excluder, Zenith, and Quantum devices were used. Follow up required a CT scan before discharge. Initially, a CT scan was done at each follow up. Subsequently, we used duplex ultrasound and abdominal X-ray, with CT scan used selectively.

Results. Mean follow-up was 36 ± 22 months. Re-interventions were required in 47 (15%) patients, 31 (66%) elective and 16 (34%) emergency cases. In 32 patients, the primary re-intervention was successful; in 15 patients an additional 13 secondary and four tertiary re-interventions were required. A total of 72 adjunctive manoeuvres were performed: 49 endovascular (68%) and 23 open (32%). The success of endovascular re-interventions was 80%. The success of open re-interventions was 96%. Open conversions were required in nine patients (3%). There was no mortality.

Conclusion. EVAR was associated with a low burden of re-interventions, with only 15% patients requiring re-intervention. Our long-term follow up, without regular CT, was simple and effective.

Key Words: Conversion; Endoleak; Migration; Re-intervention; Rupture.

Introduction

Since the introduction of endovascular aneurysm repair (EVAR) by Parodi in 1991, the technique has been embraced as a viable alternative to open repair.¹ Reported advantages of EVAR are the lower mortality and morbidity, and the rapid recovery.^{2,3} The EURO-STAR registry reported a 30-day mortality of 2.5% in a series of 4392 patients.⁴ EVAR, however, is associated with late complications such as migration of the prosthesis, endoleaks, endograft occlusion, and even rupture.^{5–15} Re-interventions to preserve the function of the endograft are reported in 10–34% of cases.^{5,8,12,14–19} However, the frequency of re-intervention after EVAR, the burden of single and multiple procedures for the individual patient and the overall outcome of these re-interventions all require further investigation.

The purpose of this study was to describe the long-term results of EVAR in a consecutive cohort of patients treated in a single academic institution, and

to report the frequency, type, and outcome of re-interventions.

Material and Methods

Patients

This is a prospective cohort study of 308 consecutive elective patients treated with EVAR between September 1996 and December 2003 at a tertiary academic vascular centre by a single endovascular team. Surgery was indicated for aneurysms greater than 5 cm in diameter. An aortic aneurysm greater than 4 cm was also an indication for surgery if it was saccular or if it was associated with iliac artery aneurysms greater than 3.5 cm.

Type of endoprosthesis

Five different types of stent-grafts were used during the primary procedure (Table 1). In the first 32 patients,

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Table 1. Type of endoprosthesis used

	Primary intervention N (%)	Re-intervention N (%)
Excluder†	56 (18)	2 (4)
Quantum‡	12 (4)	–
Talent††	52 (17)	6 (12)
Vanguard*	68 (22)	32 (47)
Zenith**	120 (39)	7 (6)
Total patients	308	47

†Excluder™ (W.L. Gore, Flagstaff, AZ, USA).

‡Quantum™ (Cordis, Johnson and Johnson, Fort Lauderdale, FL, USA).

††Talent™ (World Medical/Medtronic Corp., Sunrise, FL, USA).

*Vanguard™ (Boston Scientific Corp., Waterston, MA, USA).

**Zenith™ (Cook, Bloomington, IN, USA).

we used the only available device, Vanguard. When other products were commercially approved, we used them according to a strategy that gave preference to the Talent for large infrarenal necks (>28 mm), the Zenith for short necks (<20 mm), and the Excluder for straight long necks but angulated or small iliac vessels. The most recent device, Quantum, only has been used in 12 patients. A bifurcated stent-graft design was used in 298 patients (96.8%), a tube graft in five patients (1.6%), and an aorto-uniiliac graft in five patients (1.6%).

Follow up

From September 1996 to January 1999, physical examination, duplex ultrasound scanning (DUS), and computed tomography angiography (CTA) or magnetic resonance angiography (MRA) were performed at discharge, at 1, and at 3 months after the intervention; every 6 months for the first 2 years, and yearly thereafter. From February 1999 to March 2004 with increasing experience, and as suggested by other authors, the protocol was changed: following an initial CT scan before discharge, patients were followed at 1, 6 and 12 months with physical examination, DUS and a four plane abdominal X-ray.^{20,21} CTA or MRA was used only if there was an increase in size of the aneurysmal sac or the suspicion of an endoleak on DUS, or if there was evidence of migration or of compromise of the structural integrity of the stent-graft on the abdominal X-ray.

Definitions

In the context of this study, complications refer only to those related to the aneurysm and the stent-graft.

An endoleak was defined as perigraft blood flow

due to an inadequate seal and arising from the proximal or distal attachments of the endograft,²² from retrograde visceral or lumbar vessels,²² or from disconnection of modular endografts (type III).^{23,24}

Re-intervention was defined as an endovascular or open surgical intervention performed after the initial EVAR in order to maintain the function or patency of the endograft. When more than one re-intervention was necessary during follow-up, the classification of primary, secondary, and tertiary re-intervention was used.

Patient re-interventions/follow up: after EVAR, patients may require multiple procedures during one re-intervention and multiple re-interventions over time. As a measure of the overall impact of EVAR on patients treated with this approach, we introduced the definition of patient re-interventions/follow up. This refers to the number of re-interventions in separate surgical treatments, divided by the total number of patients entering the follow up.

Clinical success of a re-intervention was defined as follows. If a proximal aortic cuff was used, success was defined as disappearance of a type I endoleak, no further downward migration of the prosthesis and no further aneurysmal growth. If a distal extension or a recanalisation of an occluded limb or a bridging stent-graft was used, clinical success was defined as a patent limb without type I or type III endoleak. If embolisation or ligation of side branches was used, clinical success was defined as an aneurysm without type II endoleak or further expansion. Clinical success of cross-over bypasses was defined by a patent graft and successful revascularisation of the ischaemic limb. Clinical success of open conversions was defined as patient survival.

An open conversion was defined as a laparotomy with the removal of the endograft and insertion of a bifurcated prosthesis. The term laparotomy implied non-conversion laparotomies only.

Statistics

Summary data for continuous variables are expressed as mean \pm standard deviation. Data were prospectively collected in an Access database (Microsoft Corporation). Primary outcomes were clinical success, graft patency, and patient survival. Time-to-event variables were studied with Kaplan–Meier survival analysis and comparison of time-to-event curves conducted with Peto log-rank test, using SPSS 11.0 (SPSS, Chicago, IL, USA). A *P* value less than 0.05 was considered statistically significant.

Results

In 308 patients undergoing EVAR, the mean age was 70 ± 11 years and 94% were males. The mean diameter of the aneurysm was 59 ± 9 mm (range 40–100 mm). Preoperative risk factors for the patients are shown in Table 2. One patient required conversion to open repair because of technical reasons, and one died of a myocardial infarction the day after surgery (hospital mortality, 0.3%) leaving a group of 306 patients for analysis of long-term results, of whom none was lost to follow up.

Patients were followed for a mean of 36 ± 22 months. A total of 126 late complications occurred in 102 patients (33%) (Table 3). However, re-interventions only were performed in 47 patients (15%). There was no difference in demographic and risk factors between patients who did and did not develop complications after EVAR. Details of the primary re-interventions in the 47 patients are shown in Table 4. Re-interventions were performed electively in 31 patients (66%), and on an emergency basis in 16 (34%). In the latter group, surgery was required for either acute limb ischaemia in 14 patients (88%) (nine treated with thrombolysis followed by additional stenting, and five with a cross-over bypass) or acute aneurysm (stent-graft disconnection with type III endoleak in two patients). One of these aneurysms was ruptured and treated with open repair, and the other was an impending rupture and treated with a bridging stent-graft.

After re-interventions, patients returned to the regular follow-up programme. No further problems during follow-up occurred in 32 patients (68%) (i.e. the primary re-intervention was successful). However, in 15 patients, new complications and adverse events occurred. In two patients re-intervention was not necessary: one because a failed embolisation of the inferior mesenteric artery was not associated with an endoleak on subsequent CT-scan, and the second

because the occlusion of a limb of the graft resulted in only mild claudication. The remaining 13 patients required secondary re-interventions (12 single, and one multiple simultaneous procedures), and four patients also required tertiary re-interventions (three single, and one multiple simultaneous procedures). Details of these events are summarised in Table 5. Overall a total of 64 re-interventions were performed in 47 patients for a patient-interventions/follow up of 21% (64/306).

Since multiple procedures may be performed during the same surgical session, Table 6 summarises the results in terms of clinical success for the 72 adjunctive manoeuvres performed in 47 patients. The overall clinical success of endovascular re-interventions was 80%. Distal extension stent-grafts were not successful in four of 19 procedures: two occluded and two disconnected. One occluded stent-graft was not treated because, as stated above, it only caused mild claudication; the other resulted in a conversion. The two disconnections led to a conversion, one directly, the second after a bridging stent-graft which occluded 8 months later. Four out of the nine recanalisations with thrombolysis were not successful: in one instance because the limb of the graft could not be reopened, in two because the limb of the stent-graft re-occluded (one at 3 and the other at 30 days), and in one because of a kink in the graft. The first three patients were treated with a cross-over bypass and the last with insertion of a Wallstent.

The clinical success of open re-interventions was 96%. All cross-over grafts remained patent. In five patients with a type II endoleak, a laparotomy was performed because the aneurysm diameter had increased. After opening the aneurysmal sac, the lumbar arteries were ligated with sutures and the sac wrapped around the stent-graft. During follow-up, however, in one of these patients a disconnection between the body of the endoprosthesis and one of the limbs occurred and required additional open treatment (laparotomy, ligation of the contra-lateral limb and cross-over bypass). The mean hospital stay of the remaining four patients was 12 days (range, 10–17).

Nine patients (3%) underwent open conversion: one because of a ruptured aneurysm, three because the complexity of the problem made endovascular treatment untenable and five after failure or complications associated with previous endovascular re-intervention (Table 7). Laparotomy was performed with a midline incision and infra-renal clamping was used in seven patients, and temporary suprarenal clamping in two. All nine patients survived and were discharged after a mean of 11 days (range, 10–11).

The cumulative intervention-free survival for the

Table 2. Pre-operative SVS-ISCVS risk score in patients treated with EVAR ($N = 308$)³⁰

	SVS-ISCVS risk score†			
	0	1	2	3
Co-morbidities (%)				
Diabetes	92	3	4	1
Tobacco use	44	27	24	5
Hypertension	46	33	17	4
Hyperlipidemia	54	27	6	14
Cardiac status	47	26	22	5
Carotid disease	94	3	3	1
Renal disease	87	11	1	1
Pulmonary status	68	17	12	3

†Society of Vascular Surgery—International Society of Cardiovascular Surgery, North American Chapter.

Table 3. Patients with delayed complications and re-interventions after EVAR

Patients	N (%)
Patients with complications non requiring re-interventions	55 (18)
Number of complications	57
Type of complication	
Migration	25
Kink	5
Type II endoleak†	26
Limb occlusion	1
Patients with complications requiring re-interventions	47 (15)
Number of complications	69
Patients without complications	204 (67)
Total patients	306
Total complications	126

†Disappearing within 6 months or without growth of the aneurysm.

different types of stent-graft used is shown in Fig. 1. The only statistically significant difference was found between the Vanguard device and all other types of stent-grafts ($P < 0.05$).

None of the 47 patients died after the secondary procedure. Five of them (11%) died of causes not related to the secondary procedure after a mean of 35 months (range 29–48).

Discussion

This cohort study shows that, in appropriately selected patients, EVAR using predominantly bifurcated prostheses has an excellent peri-operative success rate with low surgical mortality and conversion (each 0.3%). At 36-month follow up, 261 patients (85%) had their aneurysm successfully excluded by EVAR, without

Table 4. Re-interventions performed in 47 patients

	N
Single procedure	41
Aortic cuff	5
Extensions†	13
Bridging stent-graft	2
Recanalisation	9
Aortic Palmaz stent	1
Embolisation of IMA	1
Cross over bypass	5
Laparotomy	1
Open conversion	4
Multiple procedures in one session	6
Proximal cuff + extension	3
Extension + embolisation of IMA	1
Bridging stent-graft + embolisation of IMA	1
Bridging stent-graft + extension	1

†In this group are included patients who received 4 wallstents; IMA: inferior mesenteric artery.

need for further intervention. Re-interventions² were required in 47 patients (15%), with no mortality. In patients requiring re-intervention, endovascular rescue procedures were possible in 68% with a success rate of 80%; and open re-intervention was necessary in 32% with a clinical success rate of 96%. Overall 285 of 306 (93%) patients had their aneurysm treated with endovascular procedures alone, and 297 (97%) with a combination of endovascular and open surgery (cross-over bypass or laparotomy for closure of endoleaks). Conversion to open aneurysm repair was required in only 3% of the entire cohort of patients. Complications, which did not require interventions, but needed careful surveillance developed in an additional 18% of patients.

The concept of patient-interventions/follow up helps to clarify the overall impact of multiple procedures for patients undergoing EVAR. The service impact of repeated procedures is similar if many patients receive one re-intervention or only a few patients receive multiple re-interventions in different sessions. In our series, EVAR was associated with a low patient-interventions/follow up (21%). This also was an expression of the effectiveness of re-interventions after EVAR.

The majority of the elective re-interventions were required because of a persistent endoleak, graft migration, or failure of the aneurysmal sac to reduce in size. The majority of emergency re-interventions (88%) were required for acute leg ischaemia. Only two patients were treated acutely for reasons other than limb occlusion, both because of a prosthetic limb disconnection. The first presented with a ruptured and the second with a symptomatic aneurysm, at 44 and 21 months, respectively, after the primary repair. The first patient underwent open conversion, and the second received a bridging stent-graft, both successful. Retrospectively, it was clear that the abdominal X-ray of the patient with symptomatic aneurysm had shown an initial migration of the contra-lateral limb. At this stage a bridging stent-graft could have been easily inserted preventing the complete dislocation, which required a more complex procedure. This further illustrates the importance of regular and meticulous follow-up after EVAR.

In our experience endovascular re-interventions for problems related to the proximal end of the prosthesis (cuff extensions) were invariably successful, while distal extensions and recanalisation of occluded limbs failed in 21 and 44% of cases, respectively. We believe that the current success of proximal cuff extensions is related to the position of the cuffs very close to the orifices of the renal arteries and to the use of cuffs with suprarenal fixation with hooks and barbs. The relatively high failure rate of distal extensions and

Table 5. Details of patients with complications and with newly arisen problems after initial secondary intervention

Patient (no.)	Primary re-intervention	Complication	Secondary re-intervention	Complication	Tertiary re-intervention
1	Aortic cuff	Endoleak type II	Laparotomy	–	–
2	Aortic cuff	Endoleak type II	Laparotomy	Disconnection	Laparotomy
3	Aortic cuff + extension	Limb Occlusion	Conversion	–	–
4	Extension	Limb Occlusion	–	–	–
5	Extension	Endoleak type II	Laparotomy	–	–
6	Extension	Migration (P + D)	Cuff + extension	Disconnection	Conversion
7	Extension	Disconnection	Bridging stent-graft	Limb Occlusion	Conversion
8	Bridging	Limb occlusion†	Cross over bypass	–	–
9	Recanalisation	Migration/kink (D)	Wallstent	–	–
10	Recanalisation	Limb occlusion	Cross over bypass	–	–
11	Recanalisation	Limb occlusion	Cross over bypass	–	–
12	Recanalisation	Limb occlusion	Cross over bypass	Migration (P)	Cuff + Wallstent
13	Embolisation	Technical failure	–	–	–
14	Cross over bypass	Migration (P)	Conversion	–	–
15	Cross over bypass	Migration (P)	Conversion	–	–

P, proximal; D, distal.

†Contra-lateral side.

recanalisation is secondary to the increased burden of graft material in a narrow lumen environment, and perhaps to the progression of pathology (dilatation, kinking, and calcification) in the native arteries.

The Vanguard device was associated with the most complications. However, 80% of all complications also occurred in the first 100 stent-grafts, suggesting that the learning curve might have played a role in the high incidence of complications observed with the Vanguard device. The learning curve for EVAR depends on measurement issues, choice of size of prostheses and different physical characteristics of the grafts. Even with the increased availability of different devices, we do share the opinion that the ideal graft is yet available and continue to tailor the choice of graft based on the aorto-iliac anatomy and the physical characteristics of the stent-graft currently available. Early in our cohort we used the Talent device for large infrarenal necks (>28 mm), since it was the only

suitable device. Currently, for large (>28 mm) or short necks (<20 mm) we prefer to use the Zenith device because of its strong suprarenal fixation, and the Excluder device for straight long necks but angulated or small iliac vessels. Even in these hostile iliac arteries we have not observed limb occlusion with an Excluder endograft.

In agreement with other authors, our strategy for management of type II endoleaks is conservative if the aneurysm is shrinking or remains stable.^{8,25,26} Laparotomy is performed for an increase in aneurysm size. The aneurysmal sac is opened, the lumbar arteries or the inferior mesenteric artery are suture ligated and the sac wrapped around the endograft. We do not remove the prosthesis at this time since this is a complex, unwarranted procedure. Other treatment options include thrombin or glue injection, coil embolisation, and laparoscopic clipping.^{8,12,16,22,27} We have not used any of these adjunct treatments.

The importance of follow-up is underscored by the late acute complications, which may develop after EVAR. Aortic rupture after insertion of endoprosthesis is one dramatic example. This in the EUROSTAR report has been estimated to occur with a frequency of 1% per year. Recognised risk factors for rupture are graft migration, type I and type III endoleaks.²⁸ However, in our experience, perhaps because of early detection and treatment of complications, EVAR was associated with a rupture rate of only 0.3%. Our initial follow-up protocol required a CT scan at discharge, 1, 3, 6, 12, 18 and 24 months, and yearly thereafter. This was too onerous both for patients and physicians. With data emerging from the EUROSTAR registry suggesting that CT scan imaging could be reduced to annually, and other authors reporting on the role of abdominal X-ray and DUS in the follow up

Table 6. Clinical outcome of all secondary procedures performed in 47 patients

Re-interventions	N (%)	Clinical success N (%)
Endovascular	49 (68)	39 (80)
Aortic cuff	10	10 (100)
Extension	19	15 (79)
Recanalisation	9	5 (56)
Bridging stent-graft	5	4 (80)
Embolisation	3	2 (66)
Palmaz stent	1	1 (100)
Wallstent	2	2 (100)
Open surgical	23 (32)	22 (96)
Cross-over bypass	9	9 (100)
Laparotomy	5	4 (80)
Open conversion	9	9 (100)
Total	72	61 (85)

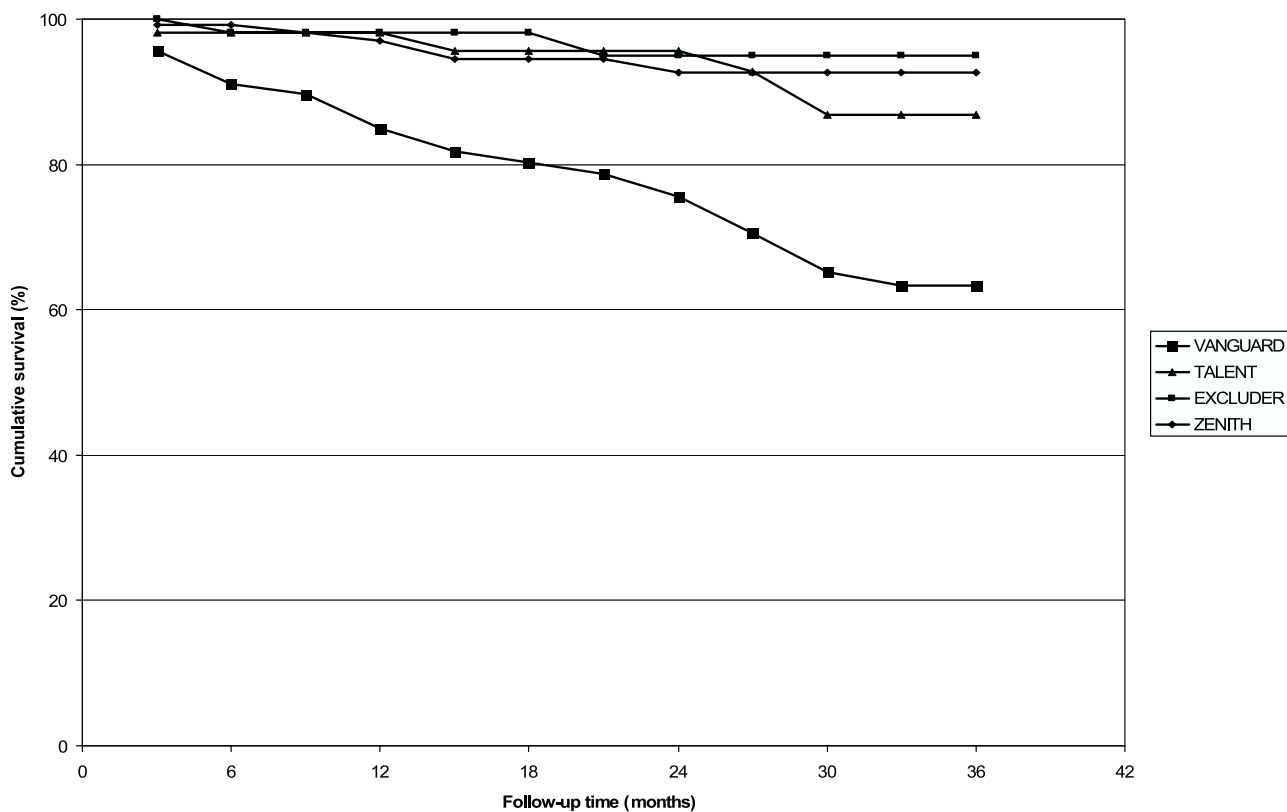
Table 7. Details of open conversions

Patient (no.)	Stent-graft (type)	Time since EVAR (months)	Previous re-interventions	Indication for conversion	Urgent treatment	Outcome (at 30 days)
1	Vanguard	54	Cuff + extension	Limb Occlusion	No	Survived
2	Vanguard	57	Extension; cuff + extension	Disconnection	No	Survived
3	Vanguard	64	Extension; bridging	Limb Occlusion	No	Survived
4	Vanguard	44	No	Migration (P + D)	No	Survived
5	Talent	27	No	Migration; Limb Occlusion	No	Survived
6	Vanguard	44	No	Migration; Limb Occlusion	No	Survived
7	Vanguard	45	No	Rupture	Yes	Survived
8	Vanguard	41	Cross over bypass	Migration (P)	No	Survived
9	Vanguard	24	Cross over bypass	Migration (P)	No	Survived

P, proximal; D, distal.

of EVAR, we felt appropriate to change our strategy.^{20, 29} We included only a CT scan before discharge, and at 6 and 12-month follow-ups, and thereafter yearly examination using abdominal X-ray and DUS, performed and interpreted by experienced vascular technicians and physicians. Parameters studied at

each interim follow-up are the diameter of the aneurysm and the proximal neck, the presence or absence of endoleaks, and the position and integrity of the stent-graft. If any of these parameters are abnormal, a CT scan or an MRA are performed. Problems identified with these imaging techniques may trigger



Numbers at risk:							
Vanguard	67	64	58	51	48	40	33
Talent	52	50	48	39	36	32	26
Excluder	56	53	43	37	28	21	15
Zenith	119	111	93	70	54	36	22

Fig. 1. Cumulative intervention free survival rates.

Table 8. Literature summary of secondary interventions and open conversions

Author	Publication (year)	No. of patients	Type of graft	Follow-up period (months, mean)	Patients requiring re-intervention† (%)	Open conversions N (%)
Ohki et al. ¹⁴	2001	239	Ac, An, Ex, MEGS, V, T, Z	16	10	5 (2.1)
Hölzenbein et al. ¹²	2001	166	Ex, St, T, V, Z	18	22	Unknown
Fariès et al. ⁵⁹	2002	366	T	7	9	4 (1.0)
Dattilo et al. ⁸	2002	362	An, EVT, Ex, MGH, V, Z	18	13	8 (2.2)
Alric et al. ⁵	2002	88	Z	21	7	4 (4.5)
May et al. ^{5,13}	2003	190	An, B, Bx, Ch, EVT, P, T, V, WY	84	34	25 (13)
Parodi et al. ¹⁹	2003	100	V	28	22	–
Sampram et al. ¹⁵	2003	703	Ac, An, Ex, Elx, T, Z	12	14	11 (1.6)
Becquemini et al. ¹⁶	2004	250	An, EVT, Ex, S, T, V	18	27‡	11 (4.4)
Present study	–	306	Ex, Q, T, V, Z	36	15	9 (3.0)

Ac, Aneur; An, Aneurx; B, Bard; Bx, Baxter; C, Chuter; Elx, Endologix; EVT, Endovascular Technologies; Ex, Excluder; MEGS, Montefiori Endovascular Graft; MGH, Massachusetts General Hospital custom-made graft; P, Parodi; Q, Quantum; S, Stentor; St, Stenway; T, Talent; V, Vanguard; WY, White-Yu; Z, Zenith.

†This includes primary, secondary and tertiary re-intervention.

‡This is the number of patients, but overall 112 secondary procedures (primary, secondary, tertiary, quaternary) were performed for 45% patient-interventions follow up.

an intervention or, if the problem does not appear to be life or limb threatening, a further follow up at 6 months. The lack of temporal trends in the frequency and type of acute complications requiring surgery and the low incidence of aortic rupture after insertion of endoprosthesis are a pragmatic proof of the effectiveness of our follow-up strategy.

Bias is inherent to cohort studies of this type, and future development in graft technology may alter the natural history of endoprosthesis. However, strengths of our study include the prospective design, the large number of patients included, the fact that no patients were lost to follow up, the consistency of events over time, the finding that, with the exception of the Vanguard device, no difference in re-intervention-free survival was identified among different types of devices, and the similarity of results with those identified by other authors (Table 8). For these reasons we feel that our results are realistic and are generalisable to similar tertiary centres taking care of patients with infra-renal aortic aneurysms.

The implication of this work for clinical practice is that a strategy of using bifurcated endoprosthesis in selected patients is effective for the management of infra-renal aortic aneurysms, when the appropriate learning curve has been accomplished and when the type of graft is individualised to the particular aortoiliac anatomy. Endovascular re-interventions should be preferred where possible, particularly for proximal extension cuffs, which are usually associated with a high success rate. In the management of graft limb complications, thrombolysis and distal endograft extensions also are effective, but a higher failure rate should be anticipated. Finally, our type of follow-up is simple, practically feasible, and it was not associated with increased mortality and morbidity.

In addition to a meticulous description of the indications, techniques, and strategy of follow up, we suggest that future studies of re-interventions after EVAR include in their results the patient-re-interventions/follow-up as an expression of the burden of multiple interventions on patients undergoing this strategy of management of infrarenal aortic aneurysm.

Conclusions

Our findings, derived from a large prospective cohort of patients treated by a single endovascular team at a tertiary vascular centre, confirm that with appropriate surveillance and re-intervention, EVAR can spare an open aneurysm repair in 97% of individuals with suitable aortic anatomy. The burden of repeated procedures to patients (15%) was relatively low. Our

simplified follow-up was effective and an integral part of management of aneurysms treated with EVAR, in order to avoid life or limb threatening complications.

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