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Mortality and Morbidity Following Endovascular Repair of Abdominal Aortic Aneurysms: Analysis of Two Single Centre Experiences

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Objective: *to show how differences in anatomical and physiological risk factors can affect the outcome of endovascular repair of AAA by describing the experience of two centres with different selection policies.*
Methods: *one hundred and thirty-five patients (group I) were treated at Queen's Medical Centre (Nottingham, U.K.) using 101 in-house made and 34 manufactured stent-grafts. Median diameter, length and angulation of the proximal aneurysm neck were 26 mm, 27 mm, 40°, respectively. Seventy-six patients had ischaemic heart disease, 47 had left ventricular failure, median forced expiratory volume in one second (FEV1) was 83%, median creatinine was 100 µmol/l and median age was 72 years. Fifty patients (group II) were treated at Timone Hospital (Marseilles, France) using seven in-house made and 43 manufactured stent-grafts. Median diameter, length and angulation of the proximal aneurysm neck were 25 mm, 34 mm, 33°, respectively. Thirteen patients had ischaemic heart disease, two had left ventricular failure, median forced expiratory volume in one second was 101%, median creatinine was 108 µmol/l and mean age was 72 years.*
Results: *anatomical characteristics of the proximal neck were significantly worse in group I ($p = 0.02$ for the three variables). Cardiac comorbidities were more frequent and mean FEV1 was lower in group I ($p < 0.0001$ and $p = 0.001$, respectively. Median aneurysm diameter was significantly greater in group I (65 mm) than in group II (53 mm) ($p < 0.001$). Postoperative mortality was 9% and 0% in groups I and II respectively ($p = 0.03$). The incidence of technical complications (groin wound complications and side branches endoleaks being excluded) was 20% and 0% in groups I and II, respectively ($p = 0.0006$).*
Conclusion: *postoperative mortality and technical complication rates were significantly greater in group I than in group II, readily explained by poorer general condition and worse anatomical characteristics of the proximal neck in group I.*

Introduction

The technical feasibility of endovascular repair (EVR) of abdominal aortic aneurysm (AAA) is now well established.[1–8] Initially, in house-made (IHM) devices were used in patients generally precluded from conventional surgery.[1–3] Further development allowed the treatment of patients with increasingly complex anatomy.[4,5] Next, commercial device were tested in multicentre trials, with strict anatomical inclusion criteria and in patients with good surgical risk.[6–8]

Certain authors have shown that anatomical patient selection anatomy can influence the incidence of technical complications.[9,10] Others have shown that patient comorbidity also influences outcome.[11,12]

Endovascular AAA repair at the Queen's Medical Centre in Nottingham (U.K.) started in 1994. Most patients were high risk for conventional repair and treated with IHM devices. At the Timone Hospital in Marseilles (France), EVR started in 1997. Most patients were suitable for conventional surgery and were treated with commercial devices.

The aim of this study was to show how these differences influence outcome.

Methods

Patient group I

Between March 1994 and July 1999, 233 patients underwent EVR of a non ruptured AAA at the Queen's Medical Centre (Nottingham, U.K.). Complete routine work-up including lung function tests and echocardiography was performed from 1996. For this

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reason, 135 consecutive patients operated on from October 1996 onwards were included in this study. There were 10 females. Patients had preoperative contrast-enhanced spiral CT-scan with multiplanar bidimensional reconstructions. Angiography was not performed routinely. As previously described the following characteristics of the proximal aneurysm neck were analysed: length, maximum diameter, angulation between longitudinal axis and aneurysm lumen.[9] The maximum of these three estimates was recorded for analysis. Maximum AAA diameter was also recorded. In five patients (4%), diameter was between four and five centimeters. These patients had their aneurysm repaired because it was symptomatic (painful and or distal lower limb embolisation).

Pre-operative cardiac, renal and respiratory statuses were assessed. Ischaemic heart disease (IHD) was defined as angina or past history of myocardial infarction (MI). Left ventricular ejection fraction (LVEF) was assessed using an echocardiographic grading system ranging from I to V. According to this system, left ventricular failure (LVF) was defined as an LVEF grade I, II or III (grade III corresponding to an ejection fraction between 30 and 40%). Renal function assessment was based on serum creatinine. Respiratory function assessment was based on measurement of the forced expiratory volume in one second (FEV1).

Patients selected for EVR had anatomical features of the aorta and iliac arteries that would allow treatment using the IHM Malmö–Nottingham stent graft.[2] The only anatomical exclusion criteria for the proximal neck was circumferential thrombus. Poor general condition precluding conventional repair did not represent an exclusion criteria. If the patient's general condition would not preclude conventional open repair, the two therapeutic options were offered after having clearly explained the advantages and drawbacks of the two techniques. If the patient was at high risk for conventional surgery, then EVR was presented as the best therapeutic option.

One hundred and one patients were treated using an IHM stent-graft. A detailed description of the stent-graft and delivery system has been given elsewhere.[2] Twenty-two IHM stent-grafts were supported at their proximal and distal end only and 79 were fully supported. Fifty-two stent-grafts had a suprarenal uncovered stent. The fixation of the remaining stent-grafts was infra-renal. Ninety-nine patients had an aorto-uni-iliac IHM stent-graft, with contralateral iliac occlusion and femorofemoral crossover. One of these patients had a conical neck which diameter was 36 mm at the level of the renal arteries and 42 mm at the lowermost part of the neck; a 38 mm top end diameter stent-graft was used. Two patients had aorto–aortic IHM stent-grafts. Thirty-four patients were treated using a bifurcated manufactured stent-graft. There were 29 Zenith® (Cook Europe, Bjaeverskov, Denmark), three AneuRx® (Medtronic, Sunnyvale, CA) and two Vanguard® (Boston Scientific).

All procedures were performed in the operating theatre, using portable C-arm fluoroscopy and contrast pump injector. In patients treated using IHM aorto-uni-iliac stent-grafts, the following gelatin sponge was used to include side branches endoleaks.[13] An intra-oprative completion angiography was performed at the end of the procedure. A spiral CT-scan was performed before the patient was discharged or not later than eight days following the procedure.

Patient group II

Between February 1997 and December 2000, 50 patients underwent EVR of a non ruptured AAA at the Timone Hospital (Marseilles, France). There were three females. Spiral contrast-enhanced CT-scan with multiplanar and MIP reconstructions and calibrated angiography were performed in all patients. Assessment was identical to group I. One patient had maximum aortic diameter of 27 mm; indication for repair in this case was bilateral lower limb embolisation. Thirteen patients (26%) had aneurysm diameter between four and five centimeters. Indication for repair of these aneurysms was maximum greater than twice the diameter of the proximal neck ($n=6$) or aneurysm growth greater or equal to 10 mm during the last year of follow-up ($n=7$). Physiological risk factors were assessed as in group I. The only difference was the echocardiographic assessment of LVEF, which was quantitative and expressed in percentage. Left ventricular failure was defined by a LEVF equal or less than 40%.

Patients selected for EVR had anatomical features of the aorta and iliac arteries that would allow treatment using an available commercial stent-graft. The risks and benefits of conventional and endovascular repair were presented as for group I.

For seven patients an aorto-uni-iliac or IHM device was used as previously described.[5] Remaining patients were treated with commercial devices as follows: aorto–aortic Bard® ($n=1$), Baxter® ($n=2$); 12 bifurcated and 1 aorto-uni-iliac AneuRx® (Medtronic, Sunnyvale, U.S.A.); 17 bifurcated and 2 aorto-uni-iliac Powerlink® (Endologix, Irvine, U.S.A.); 2 aorto-uni-iliac and 1 bifurcated Zenith® (Cook Europe, Bjaeverskov, Denmark); 3 bifurcated Lifepath® (Edwards); 1 bifurcated

Table 1. Anatomical characteristics of the proximal neck, aneurysm size and physiological risk factors in groups I and II.

	Group I $n=135$	Group II $n=50$	p value
Maximum neck diameter (mm)	26 (16–42)	25 (18–33)	0.02
Maximum neck angulation (deg)	40 (5–90)	33 (5–75)	0.02
Neck length (mm)	27 (8–70)	34 (17–69)	0.02
Mean aneurysm diameter	65 (40–117)	53 (27–82)	<0.001
Age (year)	72 (53–85)	72 (51–86)	0.54
Ischaemic heart disease	76	13	<0.0001
Left ventricular failure	47	2	<0.0001
FEV1 (%)	83 (15–131)	101 (57–180)	0.001
Serum creatinine (μmol/l)	100 (51–898)	108 (79–180)	0.29

For categorical variables, values are number of patients who had the comorbidity. For continuous variables values are median represent range.

Talent® (Medtronic, Sunnyvale, U.S.A.) and 1 bifurcated Excluder® (Gore, Flagstaff, U.S.A.).

All procedures were performed in the operating theatre using a portable C-arm fluoroscopy and a contrast pump injector. Intraoperative completion angiography and pre-discharge CT-scan was performed on all patients.

Definition of technical complications

The following complications were considered to be specific to the technique: endoleaks (type I and II), stent-grant stenosis or thrombosis, iatrogenic injury of the iliac arteries or the aorta, unilateral or bilateral occlusion of renal artery (ies) or visceral arteries, paraparesis or paraplegia, haematoma, lymph leak or lymphocoele and infection of the groin wound. Endoleaks detected during the intraoperative completion angiography and successfully treated using endovascular techniques were not considered as technical complications. Endoleaks persisting (or discovered) on the pre-discharge CT-scan were.

Risk factors and early outcome analysis

Anatomical and physiological risk factors were analysed in groups I and II. Post-operative mortality as well as technical and systemic complication rates in the two groups were then analysed. The same analysis was then performed in IHM and commercially available stent-grafts from both groups. Finally, risk factors analysis was performed in the patients who died postoperatively and in the survivors.

Table 2. Anatomical characteristics of proximal neck in groups I and II (qualitative analysis).

	Group I $n=135$ (%)	Group II $n=50$ (%)	p value
Diameter >28 mm	42 (31)	7 (14)	0.02
Length <15 mm	11 (8)	0 (0)	0.04
Length <10 mm	4 (3)	0 (0)	0.2
Angulation >45°	50 (37)	10 (20)	0.03

Values are number of patients and values between brackets are percentages of total number of patients in each group.

Statistical analysis

Mann–Whitney and Chi-squared tests were performed for the comparison of continuous and categorical variables, respectively.

Results

Anatomical characteristics of the aorta and physiological risk factors (Table 1)

Quantitative analysis of anatomical features of the proximal neck has shown that, in group I, proximal necks were significantly shorter, wider and more angulated. Qualitative analysis (Table 2) has shown that in group I, a greater proportion of patients were outside the range for the proximal neck inclusion criteria of most commercially available stent-grafts. Mean aneurysm diameter was significantly greater in group I. Cardiac comorbidities were significantly more frequent in group I. Mean FEV1 was significantly lower in group I. There was no significant difference according to age and serum creatinine.

Table 3. Causes of post-operative mortality in group I.

Systemic complications	6
Myocardial infarction*	4
Acute respiratory failure	1
Acute renal failure	1
Technical complications	6
Aneurysm rupture	2
Surgical conversion	1
Aortic rupture	1
Stent-graft thrombosis	1
Bilateral renal artery occlusion	1

* One occurred following septicaemia secondary to the crossover graft infection.

Mortality

In group I, twelve patients (9%) died during the post-operative period (i.e. during the first 30 days following the operation or later if the patient was not discharged before he died). The causes of death are reported in Table 3.

*Postoperative deaths in group I related to technical complications (*n = *6)*

Two patients had aneurysm rupture secondary to proximal perigraft endoleak.

One patient had surgical conversion to treat a proximal perigraft endoleak by the application of periaortic ligatures[4] and died of multiorgan failure in the following days.

In one patient, the stent-graft was too long and the ipsilateral internal iliac artery was covered; the distal end of the graft was pushed upwards with the shoulder of the introducer; this resulted in a tear of the proximal neck probably caused by the proximal end of the stent-graft; this patient died of multiorgan failure following conversion.

One patient had intraoperative graft thrombosis treated by thrombectomy; both internal iliac arteries were occluded on the completion angiogram; he developed postoperative paraparesis and died of myocardial infarction (MI) one month later. The graft thrombosis may have been caused by an inappropriately low dose of systemic heparin (3000 units instead of the usual 5000).

One patient had bilateral occlusion of the renal arteries because the stent-graft migrated upwards while retrieving the delivery system; this displacement was due to the fact that the stent-graft pusher was caught in the top uncovered stent; laparotomy and ilio-renal dacron bypass graft were performed; the patient died of MI on the fourth post-operative day.

*Postoperative deaths in group I not related to technical complications (*n = *6)*

Four patients died of MI. In this group, one had septicaemia secondary to an infection of the crossover graft. One patient died of acute respiratory failure due to gastric content aspiration.

One patient had cardiac arrest caused by a brutal hyperkaliaemia in the setting of an acute renal failure.

There was no postoperative death in group II.

The difference in postoperative mortality between group I and II was significant ($p = 0.03$).

Morbidity (systemic complications in survivors)

In group I, seven patients (5%) had a non lethal systemic complication. There were two pulmonary emboli, three MI, one leg deep venous thrombosis, one pulmonary oedema. In group II, four patients (8%) had systemic complication. There was one respiratory failure in a patient who had chronic obstructive airway disease, one pneumonia, one severe bradycardia and one septicaemia due to methicillin resistant *Staphyloccocus aureus.* There was no significant difference in the incidence of systemic complications between the two groups ($p = 0.47$).

Renal complications in survivors

In group I, nine patients (7%) had postoperative renal failure (defined by an increase in serum creatinine of more than 20% of the preoperative value). In two patients, transient haemodialysis was necessary. In group II, four patients (8%) had a significant increase in serum creatinine without the need for dialysis.

Technical complications

Incidence of technical complications in the two groups is reported in Table 4. Non lethal and lethal complications have been considered.

The incidence of all technical complications was not significantly different in both groups: 42/135 versus 11/50 ($p = 0.22$). However, the incidence of proximal perigraft endoleak was greater in group I: 13/135 versus 0/50 ($p = 0.02$). Furthermore, the incidence of complications relevant to the technical success of the endovascular procedure (i.e. after exclusion of groin

Table 4. Incidence of technical complications in groups I and II.

	Group I $n=135$	Group II $n=50$	p value
Proximal perigraft endoleak	13	0	0.02
Distal perigraft endoleak	3	0	0.3
Side-branches	3	7	0.001
Aorto-iliac injuries	3	0	0.3
Stent-graft thrombosis	2	0	0.4
Distal end stenosis of the stent-graft	1	0	0.6
Renal artery(ies) occlusion	4	0	0.2
Paraparesis	1	0	0.6
Groin wound complications	12	4	0.8

Table 5. Analysis of anatomical and physiological risk factors according to the type of stent-graft (IHM versus commercial).

	IHM $n=108$	Commercial $n=77$	p value
Maximum neck diameter (mm)	27 (16–42)	26 (20–35)	0.3
Maximum neck angulation (deg)	42 (5–90)	34 (5–90)	0.04
Neck length (mm)	31 (8–70)	37 (12–69)	0.03
Aneurysm diameter (mm)	64 (40–117)	57 (27–117)	0.2
Age (year)	72 (56–85)	72 (51–86)	0.3
Ischaemic heart disease	64	25	0.0003
Left ventricular failure	37	12	0.004
FEV1 (%)	75 (15–131)	96 (23–180)	<0.0001
Serum creatinine (μmol/l)	129 (61–898)	116 (66–332)	0.3

wound complications and side branches endoleaks) was significantly greater in group I: 27/135 versus 0/50 ($p=0.0006$).

Analysis according to IHM and commercially available stent-grafts

The analysis of anatomical and physiological risk factors in IHM and commercially available stent-grafts of groups I and II is reported in Table 5. The incidence of cardiac disease reflected by IHD and LVF was higher and the mean FEV1 was significantly lower in the IHM group. Neck length was shorter and angulation was greater in the IHM group. All patients who died post-operatively ($n=12$) were treated using IHM stent-grafts. No patient treated using a commercially available stent-graft died postoperatively. This difference was significant ($p=0.002$).

The incidence of technical complications (except groin wound complications and side branches endoleaks) was higher in the IHM group (22/108) compared to the commercial group (2/77). This difference was significant ($p=0.0004$).

Analysis according to postoperative deaths and survivors

The analysis of anatomical and physiological risk factors in patients who died postoperatively and in survivors is reported in Table 6. In the survivors, neck angulation and age were significantly lower, and IHD was less frequent.

Discussion

Postoperative mortality and morbidity and technical complications were significantly higher in group I. This, together with the patients' poorer general condition may explain the high mortality rate.

Anatomical features of the proximal aneurysm neck were clearly less favourable in group I. Neck angulation was significantly greater in patients who died postoperatively.[9] It seems logical to preclude from EVR patients with severe neck angulation, particularly if they are good risk patients.

Anatomical features of the iliac arteries were not assessed in this study for the following reasons. First, it appeared clear that proximal perigraft endoleak and renal arteries occlusion were the most frequent and

Table 6. Analysis of anatomical and physiological risk factors according to postoperative survival.

	Postoperative deaths $n=12$	Survivors $n=173$	p value
Maximum neck diameter (mm)	28±9 (20–38)	26±6 (16–42)	0.3
Maximum neck angulation (deg)	53±25 (40–75)	40±27 (5–90)	0.02
Neck length (mm)	25±22 (9–66)	31±24 (8–70)	0.23
Aneurysm diameter (mm)	67±19 (55–80)	62±15 (27–117)	0.1
Age (year)	78±9 (64–81)	73±9 (51–86)	0.03
Ischaemic heart disease	11	78	0.002
Left ventricular failure	6	43	0.06
FEV1 (%)	83±36 (47–108)	85±36 (15–180)	0.6
Serum creatinine (μmol/l)	137±104 (89–356)	102±46 (61–898)	0.1

severe technical complications of EVR in this study and thus anatomical features of the proximal aneurysm neck were probably the most relevant. Second, clinical experience suggested that calcifications and tortuosities were the factors most relevant to the introduction of the delivery system. It was difficult to make an objective assessment of those factors from CT-scan or angiography. An assessment based on a "none, moderate, severe" type of classification is widely subjective and was felt inappropriate to the scope of this study.

In group I, all patients who died postoperatively and most of patients who had technical complications were treated with IHM devices. However, their comorbidity was greater and the anatomy proximal neck was worse. Furthermore, none of the technical complications was specific to the IHM devices.[7,8,14,15] There was no disruption of the stent-graft and delivery system components. In one patient, the delivery system was caught in the stent-graft and led to renal arteries occlusion.[16] There was no technical failure in group II using IHM devices. These data suggest that the poorer results in group I are related to anatomy and physiological condition, rather than to the use of IHM devices.

Preoperative and intraoperative errors were probably relevant to technical complications in both groups. Surgeons in centre I were pioneers in the development of EVR. In centre II, every procedure with a new stent-graft was proctored. This probably minimised the "learning-curve" effect.

Referral patterns were significantly different between the two groups. Many patients in group I were referred from other centres because they were considered unfit for open repair and were unsuitable for commercial devices. In group II, no patient was referred from another centre; most of them were considered fit for open surgery and all were eligible for inclusion in a manufactured stent-graft protocol.

Side branches endoleaks were more frequent in group II compared to group I (Table 4). This may be due to the use of absorbable gelatine sponge in group I.

Conclusion

The analysis of two experiences of EVR of AAA different by patient selection, has shown significant differences between technical complications and postoperative mortality rates. EVR of AAA is feasible with minimal technical complications and post-operative mortality rates, if patients fit for open repair are selected using restrictive anatomical criteria. EVR is feasible using unrestricted anatomical criteria in patients precluded from open repair with increased technical complication and post-operative mortality rates. Increased mortality and technical complication rates in the IHM group may be explained by the selection of more difficult patients as well as a learning curve effect, rather than by technical defects specific to the stent-graft and delivery system.

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