A prospective comparison of secondary interventions and mortality in open and endovascular infrarenal abdominal aortic aneurysm repair

P. P. MISTRY, M.B. CH.B.

P. BECKER, M.SC., PH.D.

J. VAN MARLE, M.B. CH.B., M.MED. (CHIR.), F.C.S. (S.A.)

Medi-Clinic Unit for Peripheral Vascular Surgery, Department of Surgery, Pretoria Academic Hospital and University of Pretoria

Summary

Endovascular aneurysm repair (EVAR) has provided a safe and effective alternative to the standard open repair of abdominal aortic aneurysms (AAAs). It has, however, been associated with a high requirement for secondary interventions. This prompted us to compare the two procedures with regard to secondary interventions and mortalities. The sample size was 278 patients, of whom 156 had undergone the open operation and 122 had undergone EVAR. The perioperative morbidity and mortality, as well as the major and minor secondary intervention rates, were obtained for these patients. The results suggest that there is no significant difference in secondary interventions and mortality between the two groups, despite the EVAR group being at significantly higher risk.

Open surgical repair is regarded as the gold standard for the management of abdominal aortic aneurysms (AAAs). The advantage of open repair is that it is a proven procedure that is durable and is perceived to have significant freedom from surgical complications. The disadvantage of open repair is an increased perioperative morbidity[1] and mortality,[2] substantial functional impairment[3] and lengthy hospitalisation.[4]

Since its introduction by Parodi et al.[5] in 1991, endovascular aneurysm repair (EVAR) has provided a viable alternative to open surgery. The advantages of EVAR are lower perioperative morbidity and mortality, shorter hospitalisation and a shorter recovery period.[2,6,7] The major concern about EVAR is that it is reported to be plagued by many secondary interventions resulting from complications such as endoleaks, graft migration, graft occlusion and rupture.[8-13]

This perception of poor efficacy of EVAR over the long term prompted us to compare the two procedures with regard to co-morbidities, mortality and secondary interventions.

Study design

A total of 278 patients with AAAs who presented between June 1998 and June 2005 were studied. The indications for repair were aneurysms greater than 5 cm in diameter or that increased in size by more than 1 cm per annum.

The patients enrolled were subjected to either open surgical repair or endovascular repair. The younger, fitter patients underwent open repair. EVAR was reserved mainly for older, higher-risk patients with multiple co-morbidities, provided that they had suitable anatomy for the procedure. Patients with unsuitable anatomy for EVAR underwent open surgical repair. Exclusion criteria included suprarenal, inflammatory and ruptured aneurysms.

Open surgical repair included aortic tube grafts, aorto bi-iliac bypasses and bi-femoral bypasses, depending on the condition of the iliac arteries. Patients were routinely followed up at 30 days, 3 months, 6 months, 1 year and thereafter annually. Patients were examined clinically and special investigations were requested on the basis of the individual's symptoms and signs. The EVAR candidates underwent duplex Doppler examinations after 30 days and 3 months, while computed tomography (CT) scans were performed at 6 months and annually to exclude endoleaks.

The parameters measured were anaesthesic risk according to the criteria of the American Society of Anesthesiologists (ASA), the type of procedure and the size of the aneurysm. The outcomes reported were perioperative and long-term mortalities, as well as complications resulting in the need for major and minor secondary procedures. The major and minor procedures were classified according to the type of complication, morbidity and duration of hospitalisation.

Open repair was performed under general anaesthesia. Twenty per cent of the endovascular repairs were performed under epidural anaesthesia, and 80% under general anaesthesia. Patients who underwent open repair were managed postoperatively in an intensive care unit, whereas the EVAR patients were managed in a high-care facility.

Results

A total of 156 patients underwent open surgical repair (OSR). There were 139 males and 17 females. Of the 122 patients who underwent endovascular repair, 117 were males and 5 were females. The median age of the open repair group was 66 years (mean 66.25 years, range 54 - 83 years). The median age of the EVAR group was 66 years (mean 66.2 years, range 69 - 85 years). The median size of the aneurysms in the open repair group was 55 mm (mean 57.06 mm, standard deviation (SD) 10.41 mm, range 36 - 98 mm). The

median size of the aneurysms in the EVAR group was 60.3 mm (mean 57.1 mm, SD 10.4 mm, range 35 - 94 mm). A Dacron bypass graft was used in all the patients who underwent open repair. The stent grafts placed in the EVAR group included 91 Talent, 16 Excluder, 7 AneuRx, 6 Zennith and 2 Endologyx stents.

The median follow-up period for the open repair group was 28 months (mean 33.61 months, range 0 - 85 months). The median follow-up period for the EVAR group was 24 months (mean 32.9 months, range 0 - 88 months). The perioperative mortality of the open repair group was 4.49% ($N = 7/156$), whereas that of the EVAR group was 3.28% (4/122). The long-term mortality was 6.41% (10/156) in the open group and 13.93% (17/122) in the EVAR group (Table I). There was a significant difference in the ASA categories between the two groups ($p = 0$), with the open repair group having 66.67% (104/156) in the lower-risk ASA II category, and the EVAR group having 61.48% (75/122) in the higher-risk ASA III category (Table II). None of the long-term deaths in both groups were related to the aneurysm repair. The Kaplan-Meier survival estimates between the two groups demonstrated no significant difference (Figs 1 - 3).
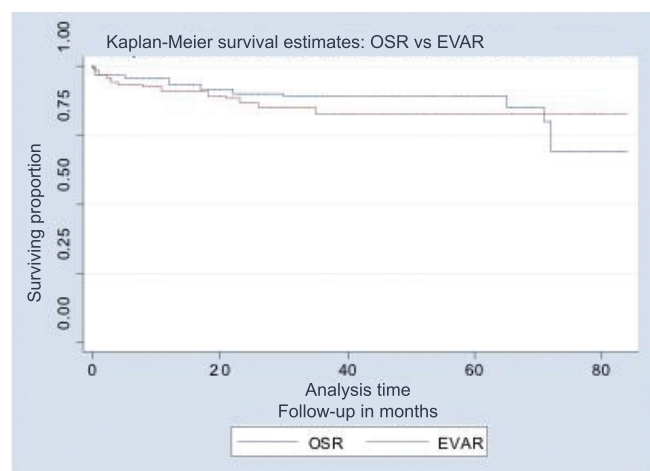

Fig. 1. Comparison of survival, all patients.

A total of 26 secondary interventions were recorded for the open repair group. Of these, 16 (rate of 10.26%) were found
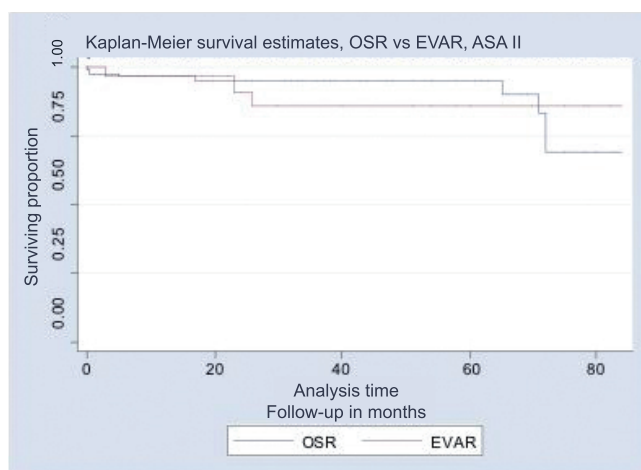

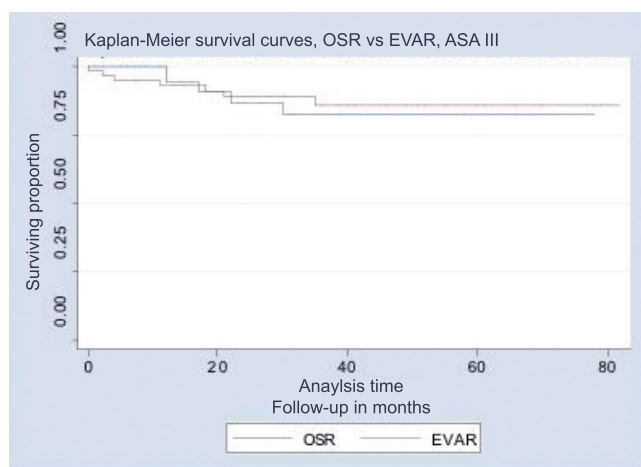Fig. 2. Comparison of survival, ASA II patients.

Fig. 3. Comparison of survival, ASA III patients.

to be major interventions. These included the following procedures: 9 incisional hernias, 1 trash foot, 1 graft occlusion, 1 graft sepsis, 1 bowel obstruction, 1 false aneurysm, 1 retroperitoneal bleeding, and 1 secondary closure. The minor secondary interventions included 10 superficial skin necroses and lymphoceles (rate of 6.4%). All the above procedures were performed under general anaesthesia.

TABLE I. RESULTS IN THE OPEN REPAIR AND EVAR GROUPS

Parameter	Open repair	EVAR	p-value (< 0.05)	Significant difference
Gender				
Male (**N** (%))	139 (89.10)	117 (95.90)	0.037	No
Female (**N** (%))	17 (10.90)	5 (4.10)	0.037	No
Age (yrs)	66	66		No
Aneurysm size (mm)	55	60.3		No
Perioperative mortality (**N** (%))	7 (4.49)	4 (3.28)		
Long-term mortality (**N** (%))	10 (6.41)	17 (13.93)	0.128	No
Total mortality (N (%))	17 (10.90)	21 (16.21)	0.102	No
Major secondary intervention (**N** (%))	16 (10.26)	14 (11.48)	0.621	No
Minor secondary intervention (**N** (%))	10 (6.4)	5 (4.1)	0.695	No

TABLE II. ASA CATEGORIES IN THE OPEN REPAIR AND EVAR GROUPS				
ASA	Open repair	EVAR	*p*-value	Significant difference
II (*N* (%))	104 (66.67)	37 (30.33)	0	Yes
III (*N* (%))	52 (33.33)	75 (61.48)	0	Yes

The EVAR group had a total of 19 secondary procedures. Fourteen of these (rate of 11.48%) were major interventions which included 1 conversion to open repair for a ruptured iliac artery, 5 femoro-femoral bypasses, 6 endoleaks, 1 ruptured aneurysm which was managed with a stent, and 1 endoscopic clipping of a patent inferior mesenteric artery. There were 5 minor interventions (rate of 4.1%) consisting of superficial skin necroses and lymphoceles of the groin.

Discussion

The primary objective in the treatment for AAA, whether open or endovascular, is to prevent rupture of the aneurysm. This is best achieved by excluding the aneurysm from the circulation. The open repair achieves this by clamping the proximal aorta, opening the aneurysm and inserting a Dacron graft. In short, the endovascular technique involves excluding the aneurysm from the circulation using an intraluminal stent graft which is inserted via the femoral arteries. These procedures should be accomplished with a low operative mortality and morbidity, and a good functional outcome.

As previously stated, our indications for intervention were an aneurysm diameter of more than 5 cm or an aneurysm enlarging by more than 1 cm per annum during follow-up. These indications are similar to those used in the UK Small Aneurysm Trial.[14] The EUROSTAR registry reports a 1% annual rupture rate for EVAR devices in both small and large aneurysms.[15] Similar rupture rates were observed during surveillance of patients randomised in the UK Small Aneurysm Trial.[14] The EUROSTAR registry also suggests that EVAR does very little to improve the progression of a small aneurysm.[15] This justifies our decision not to consider EVAR in patients with aneurysms smaller than 5 cm.

The use of EVAR has increased, mainly because it is a minimally invasive technique and has a low perioperative mortality. The EUROSTAR registry[15] reported a 2.5% 30-day mortality in a series of 4 392 patients undergoing EVAR. The UK Small Aneurysm Trial[14] reported a 5.8% perioperative mortality for elective open surgery. More recently, in a prospective randomised study, the EVAR1 trial[16] proved a two-thirds reduction in perioperative mortality with EVAR compared with the open repair (1.6% versus 4.6%). The DREAM Trial Group[7] also showed similar results, with 1.2% perioperative mortality in the EVAR group compared with 4.6% in the open group. Our perioperative mortalities for EVAR and open repairs are 3.28% and 4.49% respectively, and are comparable to those found in the international litterature.[13-14] If one considers that our EVAR group consisted mainly of higher-risk patients (61.48% being ASA III), this difference in perioperative mortality, although small, is clinically important.

The mean follow-up periods for the open and EVAR groups were 33.61 months and 32.9 months respectively. There was no significant difference in outcomes between these two groups. The Kaplan-Meier survival estimates between the two groups are quite similar, with no significant difference in *p*-values (Figs 1 - 3). Taking everything into consideration, the hazard ratio for EVAR versus open surgery is slightly higher, but once again is of no statistical significance (*p* = 0.592).

Both procedures are known to have complications. Some complications occurring in open repair are shared with EVAR, e.g. graft sepsis, false aneurysms, graft occlusion, impotence and buttock claudication. Endoleaks, graft migration, enlargement of the aneurysmal sac and rupture of the AAA are complications specific to EVAR.[17] In our EVAR group, most of the secondary interventions were directly related to the stent graft and thus had direct bearing on the aneurysm repair. Nevertheless, most of the complications could be managed with minimally invasive techniques under local or regional anaesthesia. The complications secondary to the open surgery were mainly wound-related, but required more invasive surgery under general anaesthesia, and longer hospitalisation.

Much of the criticism directed at EVAR does not take into consideration the progressive improvements in clinical results.[18] A study performed by the EUROSTAR collaborators[19] endeavoured to establish whether improvements in endograft design have resulted in improved clinical outcomes. Analysis of the Eurostar data strongly suggests that current or newer devices have indeed improved the outcome of EVAR by halving the secondary interventions needed and significantly decreasing the number of conversions to open repair.

Conclusion

The finding that perioperative mortality and the secondary intervention rate is similar for open and endovascular repairs proves that EVAR is not inferior to the open repair over the shorter term. Time will decide as to the longevity of EVAR as a procedure. However, EVAR has shown excellent results in the ASA III group and should therefore be indicated in older and higher-risk patient with multiple co-morbidities, whereas open repair remains the procedure of choice for the younger, fitter patient.

REFERENCES

1. Blankensteijn JD, Lindenburg FP, Van der Graaf Y, *et al*. Influence of study design on reported mortality and morbidity rates after abdominal aortic aneurysm repair. *Br J Surg* 1998; 85: 1625-1630.
2. The EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1). 30-day operative mortality results: randomised controlled trial. *Lancet* 2004; 364: 843-848.
3. Williamson WK, Nicoloff AD, Taylor LM, Moneta GL, Landry GJ, Porter JM. Functional outcome after open repair of abdominal aortic aneurysm. *J Vasc Surg* 2001; 33: 913-920.
4. Dadik A, Lin JW, Gordon TA, *et al*. Results of elective AAA repair in the 1990s: A population-based analysis of 2 335 cases. *J Vasc Surg* 1999; 30: 985-995.
5. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for AAA. *Ann Vasc Surg* 1991; 5: 491-499.
6. Beehquemin J, Bourriez A, D'audiffret A, *et al*. Midterm results of endovascular versus open repair for AAA in patients anatomically suitable for endovascular repair. *Eur J Vasc Endovasc Surg* 2000; 19: 656-661.
7. Blankensteijn JD, De Jong S, Prinssen M, Van der Ham AC, Buth J (DREAM Trial Group). Two year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2005; 352:

2398-2405.

8. Holzenbein TJ, Kretschmer G, Thurnher S, *et al*. Midterm durability of AAA endograft repair: A word of caution. *J Vasc Surg* 2001; 33: s46-s54.

9. Becquemin JP, Kelley L, Zubilewicz T, Desgranges P, Lapeyre M, Kobeiter H. Outcomes of secondary interventions after abdominal aortic aneurysm endovascular repair. *Vasc Surg* 2004; 39: 298-305.

10. Ohki T, Veith FJ, Shaw P, *et al*. Increasing incidence of midterm and long-term complications after endovascular graft repair of AAA: a note of caution based on a 9-year experience. *Ann Surg* 2001; 234: 323-334.

11. May J. Long-term outcome after aortic endovascular repair: The Sydney experience. *Semin Vasc Surg* 2003; 16: 123-128.

12. Parodi JC. Long-term outcome after aortic endovascular repair: The Buenos Aires experience. *Semin Vasc Surg* 2003; 16: 113-122.

13. Matsumura JS, Brewster DC, Maroun MS, Naftel DC. A multicentred controlled clinical trial of open vs endovascular treatment of AAA. *J Vasc Surg* 2003; 37: 262-271.

14. The UK Small Aneurysm Trial Participants. Results for randomized controlled trial of early elective surgery or ultrasonographic surveillance of small abdominal aortic aneurysms. *Lancet* 1998; 352: 1649-1660.

15. Peppelenbosch N, Buth J, Harris PL, Van Marrew NKC, Fransen G. Diameter of AAA and outcome of endovascular aneurysm repair: Does size matter? A report from Eurostar. *J Vasc Surg* 2004; 39: 288-297.

16. Greenhalgh RM, Brown LC, Kwong GP, Powell JT, Thompson SG, EVAR trial participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurism (EVAR trial 1), 30-day operative mortality results: randomized controlled trial. *Lancet* 2004; 364: 818-820.

17. Thomas SM, Gaines PA, Beard JD. Short-term (30 day) outcome of endovascular treatment of AAA results from a prospective registry of endovascular treatment of aneurysms (RETA). *Eur J Vasc Endovasc Surg* 2001; 21: 57-64.

18. Cuypers PWM, Laheij RJF, Buth J. Which factors increase the risk of conversion to open surgery following endovascular aneurysm repair? *Eur J Vasc Endovasc Surg* 2000; 19: 308-312.

19. Torella F (on behalf of the EUROSTAR Collaborators). Effect of improved endograft design on outcome of endovascular aneurysm repair. *J Vasc Surg* 2004; 40: 216-221.