SAJS
Vascular Surgery

Repair of abdominal aortic aneurysms with aorto-uni-iliac stentgraft and femoro-femoral bypass

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Summary

Objectives. Endovascular repair (EVAR) is accepted as effective treatment for abdominal aortic aneurysms (AAAs) and has become the standard of care in many instances. The standard bifurcated stentgraft (BFG) is often not possible in patients with unfavourable aneurysm morphology. The aorto-uni-iliac (AUI) graft configuration with femoro-femoral bypass (FFBP) is a promising alternative which may extend the scope of EVAR for AAAs. The aim of this study was to evaluate the feasibility, efficacy and durability of AUI with FFBP.

Design. The results of a single institution and a single surgeon were prospectively collected from January 2002 to August 2010. All patients were followed up at 1, 3, 6 and 12 months and then annually.

Results. There were 33 patients (27 males) with a mean age of 71.7 years (range 46 - 84). Open surgery posed an unacceptably high risk to all patients owing to advanced age and/or American Society of Anesthesiologists (ASA) classification 3/4. Ineligibility for BFG was due to unfavourable anatomy or a combination of factors in most cases (31 patients). Two patients had anastomotic aneurysms after previous open surgery.

The technical success rate was 100%. One severe intra-operative complication occurred (perforated iliac artery). Two patients (ASA 4) died within 30 days (peri-operative mortality rate 6.1%). Seven patients (21.1%) developed postoperative wound complications. Eight patients died during follow-up of non-aneurysm-related conditions. Twenty-three patients are alive, with mean follow-up of 24.4 months and a survival rate of 69.7%. Two complications occurred during long-term follow-up, namely 1 case of graft sepsis and 1 of FFBP occlusion.

Conclusion. AUI with FFBP is a safe, effective and durable alternative in high-risk patients with AAAs where standard open repair is contraindicated and BFG repair is not possible owing to unfavourable aneurysm morphology.

S Afr J Surg 2012;50(2):33-36.

Three randomised controlled trials have shown a significant reduction in peri-operative mortality when comparing endovascular aneurysm repair (EVAR) with standard open surgery (1.7% v. 4.7% in the EVAR Trial 1; 1.2 v. 4.6% in the Dream Trial; 0.5 v. 3% in the OVER Trial[1-3]). EVAR has therefore become the standard of care in many centres.

There are, however, patients who require EVAR because open surgery poses an unacceptably high risk to them, but unfavourable anatomy precludes the use of the standard bifurcated stentgraft (BFG). It is estimated that approximately 50% of patients are not ideal candidates for EVAR because of anatomical constraints.[4] The aorto-uni-iliac (AUI) configuration with a femoro-femoral bypass graft (FFBP) appears to be a good alternative in these patients, and can improve patient eligibility by a further 20%.[4-8]

There are still limited data available for long-term follow-up of these patients (>60 months). In this study we look at the feasibility, efficacy and durability of AUI with FFBP in this group of patients over the mid- to long term.

Methods

Design

The results of a single surgeon in a single institution were prospectively collected from January 2002 to August 2010.

Patient selection

All patients who underwent elective AUI with FFBP for abdominal aortic aneurysms (AAAs) in this period were included in the study. The primary indications for EVAR in these patients were AAAs greater than 5.5 cm, symptomatic aneurysms or rapidly increasing aneurysm size (>10 mm per year). We included in the study only patients in whom open surgery posed a high risk and who therefore could not be considered for standard open aneurysm repair. The primary indication for AUI was unfavourable aneurysm morphology.

Device specification

The Talent™ and Endurant™ stentgrafts (Medtronic) were used in all the patients. These devices are self-expanding Nitonol M-shaped stents covered with a multifilament polyester material. A 6 mm or 8 mm standard polyester graft was used for the FFBP.

Patient assessment and procedure

Contrast computed tomography (CT) angiography was performed pre-operatively to evaluate the anatomy of the vessels and to plan the procedure. Aneurysm size, infra-renal neck diameter and length were noted, as well as diameter and length of the common iliac arteries.

All procedures were done by the same surgeon in a fully equipped hybrid theatre. All patients received general anaesthesia

with central venous catheters and arterial lines for invasive monitoring. Pre-operative prophylactic antibiotics were given. The patients all underwent on-table digital subtraction angiography at the time of the procedure, which was done according to the standard method which has been described previously.[9]

Postoperatively all patients were observed in a high-care unit. Routine venous thromboprophylaxis was given. Mobilisation was started on day 1. Patients were discharged on antiplatelet therapy consisting of aspirin and clopidogrel.

After discharge patients were followed up at 1, 3, 6 and 12 months and then annually according to our EVAR protocol. Duplex Doppler ultrasound was done routinely to evaluate patients for endoleaks (enlargement of the aneurysm sack and flow in the aneurysm). Patients were then referred for a CT angiogram if any abnormalities were detected.

We considered a procedure to be successful if the aneurysm was fully excluded from the circulation, with the graft being patent.

Results

We treated 33 patients with AUI and FFBP between 2002 and 2010. There were 27 males. The mean age was 71.7 years with a range of 46 - 84 years. Five patients had an American Society of Anesthesiologists (ASA) classification of 2, 19 had a classification of 3 and 9 had a classification of 4. Table 1 summarises the co-morbidities of our patients.

The mean aneurysm diameter was 67.1 mm (range 40 - 85 mm). In most cases the indication for AUI was anatomical constraints or a combination of factors (31 patients, Table 2). Two patients had false aneurysms at the anastomosis site of previous aorto-bifemoral bypass grafts.

Placement of the AUI stent graft was successful in all patients (technical success rate 100%). The mean operative time was 148 minutes (range 40 - 237 minutes) and the mean fluoroscopy time was 20.85 minutes (range 7.55 - 42.32 minutes). The mean intensive care unit stay was 2 days and the mean hospital stay 5.5 days.

One serious intra-operative complication occurred. A very tortuous and severely calcified common iliac artery was perforated during placement of the occluder of the contralateral common iliac artery. This was managed by a flank incision and suturing of the artery. The patient did well postoperatively.

Short-term follow-up (<30 days)

Two patients died in the peri-operative period. Both were males with an ASA classification of 4. They both had large aneurysms with high risk of rupture, and we felt that treatment was indicated. One patient developed acute respiratory distress syndrome and multi-organ failure, and the other died of an acute myocardial infarction.

Seven patients developed wound complications (1 lymphocele and 6 superficial wound breakdowns), all of which required debridement and antibiotic therapy. All these patients did well subsequently.

Mid- and long-term follow-up

During long-term follow-up 8 patients died of non-aneurysm-related causes. Three patients died of different forms of malignant disease and the rest all died of cardiac-related illness. Twenty-three patients are alive and well with mean follow-up of 24.4 months (range 1 - 90 months) and a survival rate of 69.7% (Fig. 1). Long-term follow-up data (>60 months) are available on 1 patient.

One patient developed graft sepsis during long-term follow-up. He was managed with a bypass to the popliteal artery and did well. One patient developed an occlusion of his FFBP 3 years after the initial procedure, which was subsequently revised. The primary patency rate of the FFBP in this series is 97%, and the secondary patency rate is 100%.

Table 1. Co-morbidities

Disease	Patients (*n* (%))
Coronary artery disease	19 (57)
Recent acute myocardial infarction	2 (6)
Arterial hypertension	13 (39)
Current smoker	11 (33)
Ex-smoker	13 (39)
Diabetes mellitus	1 (3)
Hyperlipidaemia	7 (21)
Chronic renal insufficiency	5 (15)
Chronic obstructive airway disease	13 (39)
Cerebrovascular incident	3 (9)
Other*	17 (51)

*Includes cardiac failure, gastric cancer, prostate cancer, previous coronary artery bypass or percutaneous transluminal arterial angioplasty and stent, morbid obesity, peptic ulcer disease and cardiac pacemaker.

Table 2. Indications for AUI

Anatomical characteristics	Patients (*n* (%))
Contralateral iliac stenosis/occlusion	14 (42)
Ectatic/aneurysmal common iliac artery	7 (21)
Narrow bifurcation	9 (27)
Tortuosity and calcified vessels	11 (33)
False aneurysms at previous anastomosis	2 (6)
Dissection	2 (6)

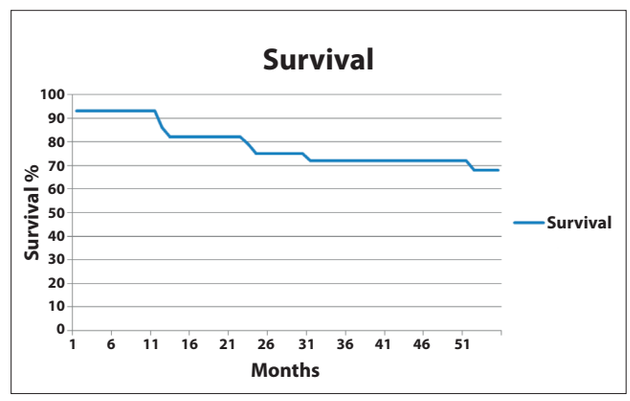

Fig. 1. Long-term graft survival.

Discussion

There remains little doubt that EVAR has definite short-term advantages over open surgery as far as morbidity and mortality are concerned.[10-12]

In the USA EVAR has surpassed open repair as the preferred treatment for AAA with the annual number of EVARs doubling from 2001 to 2006, while the annual number of open repairs decreased by more than 50% during the same period.[13] EVAR is also increasingly being used in young patients at low risk.[13,14] This trend is often fuelled by patient preference, as was shown by a survey in which patients preferred EVAR to open repair after being fully informed about both procedures, including short- and long-term expectations.[15]

Approximately 50% of patients are not good candidates for the standard BFG because of anatomical constraints.[4] The literature reports an increase in eligibility for EVAR by 18% with the advent of AUI.[6] During the same time period our vascular unit at Unitas did 320 standard EVARs compared with 33 AUIs (10.3%) and another 22 AUIs were done in patients with ruptured AAAs. The AUI configuration was first described by May *et al.*,[16] Parodi[17] and Marin *et al.*[18]

Placement of the AUI stentgraft is technically less demanding than that of the standard BFG, which can be difficult and even impossible if anatomical constraints are severe. When placing an AUI, only one common iliac artery is stented. The absence of a contralateral limb ensures a smaller profile, which enables easier cannulation of smaller vessels. This also makes the device more pliable, enabling navigation of more difficult anatomy and making it possible to obtain a good seal in a less favourable aneurysm neck. The contralateral common iliac artery is occluded to prevent back-bleeding. Perfusion of the contralateral limb is ensured by doing an FFBG (Fig. 2).

When the AUI graft first came into use there was initial resistance to it because of the necessity of using an extra-anatomical bypass for these patients. The initial reports of FFBP were on patients with peripheral arterial occlusive disease, and 5-year patency rates were between 35% and 92%.[19-24] It has, however, been shown that poor run-off is the major risk factor for graft occlusion in these patients.

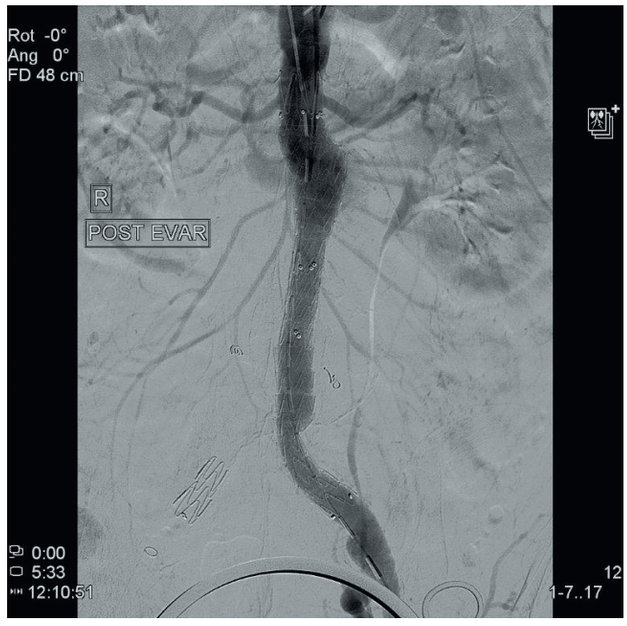

Fig. 2. Post-EVAR digital subtraction angiogram with contralateral common iliac artery occluded.

Patients with aneurysmal disease usually do not present with distal occlusive disease, and the initial reports are more encouraging in this group. In a recent paper, Lazardis *et al.*[6] reported a patency rate of 98.11% over a mean follow-up of 34.9 months. Others have reported similar figures, with patency rates between 91% and 99%.[4-6] Our experience in this study confirmed these figures, with an overall patency rate of 97%.

Although we have long-term (>5 years) follow-up data for only 1 patient in this series, the mid-term follow-up is very promising. When we compare our data with the literature, the mid- to long-term results are comparable to standard BFG in this group of patients. We currently have a long-term survival rate of 69.7% at 2 years (Fig. 1), with no aneurysm- or procedure-related deaths.

The 6.1% 30-day mortality in this series is high compared with elective EVAR in the literature (0.5 - 4.6% for elective patients). A previous report from our institution showed a peri-operative mortality rate of 4% for high-risk patients (ASA 3).[25] The 2 patients who died in the peri-operative period were both ASA 4, comparable to the patient population of the EVAR trial 2, where a peri-operative mortality of 9% was reported.[26]

During the peri-operative period of 30 days, 7 patients developed wound complications requiring secondary wound debridement. There were no endoleaks in this series. Another 2 patients developed graft-related complications. One patient presented with groin sepsis 1 year after EVAR and another with occlusion of the FFBP 3 years after the initial procedure. Both grafts were replaced and the patients subsequently did well. There was no limb loss in this series.

Many authors consider AUI with FFBP to be the procedure of choice for repair of ruptured AAAs.[27-29] We have previously reported our own results with ruptured AAAS, showing good medium-term results with no endoleaks or FFBP occlusion.[30] The good results reported after AUI with FFBP in patients with ruptured AAAs also support the use of this procedure in elective patients with less-than-favourable anatomy for standard BFG EVAR.

Conclusion

AUI with FFBP is a safe and effective procedure. It allows us to treat patients to whom open surgery poses an unacceptably high risk and who do not qualify for standard EVAR with a BFG because of anatomical constraints. Although long-term data for this procedure are starting to be available, they are still very limited. Mid-term data suggest that AUI is safe and effective, but more long-term follow-up is needed.

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