Endoluminal Stent Grafts in the Management of Infrarenal Abdominal Aortic Aneurysms: a Realistic Assessment†

S. Sultan, D. Evoy, S. Nicholls, M.-P. Colgan, D. Moore and G. Shanik

Department of Vascular and Endovascular Surgery, St. James’s Hospital, P.O. Box 580, Dublin 8, Ireland

Objectives: transfemoral endoluminal aortic management (TEAM) is technically feasible in the treatment of infrarenal abdominal aortic aneurysms but its advantage over conventional repair is unproved. We report our initial experience, learning curve and technical difficulties encountered during the process of establishing this novel technique in our institute.

Material and Methods: over a 3-year period 400 cases of abdominal aortic aneurysms were reviewed; only 58 cases (15%) were suitable for endovascular repair under our TEAM protocol and 36 (9%) were offered endovascular intervention. They were mainly high-risk patients (85% ASA III and IV) with a mean age of 72 years. Thirty-three bifurcated grafts, two straight tube grafts and one aorto mono-iliac graft were deployed. We oversized the graft by 15–20% to the diameter of the aortic neck and both common iliac arteries.

Results: two cases (6%–95% CI: 1–19%) had on-table conversion because of ruptured common iliac arteries. Perioperatively there were two deaths from multi-organ failure. Transient renal failure occurred in two patients and three patients (9%) suffered a non-fatal myocardial infarction. Sixteen percent of patients had a groin wound problem. The mean hospital stay was 7 days. Five minor endoleaks (15%) were identified and sealed at 30 days. One secondary endoleak was identified at 18 months because of a patent juxta-renal lumbar artery. No secondary cuffs or extensions were used. The technical, clinical, continuous and secondary success rates were 78%, 91%, 89% and 91% respectively with TEAM.

Conclusion: endovascular training, patient selection and learning curve impose an impact on the final outcome. Until a reliable hard point is reached so that endovascular repair could be exercised in routine practice, the use of TEAM must be questioned in high-risk patients, and should be performed under clinical trial conditions using strict selection criteria.

Key Words: TEAM; Endoluminal stent graft; AAA; Technique; Oversizing; Endoleak; Duplex; Complication; Success rate.

Introduction

The feasibility of transfemoral endoluminal aortic management (TEAM) has been reported in many studies but the incidence of complications varying from 20% to 75% is considerable and requires further attention.1–9 With TEAM the incisions are small, no cross-clamping of the aorta is necessary, patient acceptance is high, blood loss and hospital stays are significantly reduced. In spite of all these advantages, TEAM has not lived up to initial expectations when it is compared to standard open repair.9–13

The requirements for technical success of TEAM are a device that is deliverable to the target area with secure fixation to the vessel wall and blood tight seal at all junctions. A serious problem with this procedure is persistent perfusion of the aneurysm sac with resultant endoleak and endotension.5 Early reported series indicated that complications were due to deficiency in design of these devices. Present delivery and stent graft systems have improved and are reasonably standardised.14–17

Sound clinical judgement must be made on the basis of understanding the natural history of aneurysms and the risk of rupture rather than the technical ability of delivering catheter-based technology.18–22 We report our initial experience with TEAM in 36 patients over a period of 40 months. The aim of this report is to critically evaluate our results according to our learning curve with this technique, and assess its application in clinical practice.

Materials and Methods

Between January 1997 and April 2000, 400 cases of abdominal aortic aneurysm were investigated with
Table 1. Types of endovascular grafts employed.

<table>
<thead>
<tr>
<th>Type</th>
<th>Aortic tube</th>
<th>Aorto-bi-iliac</th>
<th>Aorto-mono-iliac</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talent</td>
<td>1</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Gore, Excluder</td>
<td>—</td>
<td>14</td>
<td>—</td>
</tr>
<tr>
<td>AneuRx</td>
<td>—</td>
<td>6</td>
<td>—</td>
</tr>
<tr>
<td>Zenith AAA</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Home-made</td>
<td>1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>33</td>
<td>1</td>
</tr>
</tbody>
</table>

an intention to treat by endovascular intervention if deemed suitable under our TEAM protocol at St James’s Hospital, a tertiary referral university vascular centre. Spiral CT scan with contrast at 3 mm slices was performed, if the aortic neck length was more than 10 mm and the iliac artery diameter was less than 17 mm and greater than 6 mm, the patient was subjected to a calibrated digital subtraction angiogram. A proximal aortic neck diameter of 16–30 mm, an aortic neck angulation of less than 60° and no thrombus at the implantation site were mandatory for inclusion.

Fifty-eight cases (15%) were suitable for endovascular repair, but only 36 (9%) were offered endovascular intervention. The reasons for exclusion from TEAM were as follows: 11 patients were under 60 years of age, four patients were on long-term anticoagulation, three patients were excluded as funds were not available for a suprarenal spare-spring endograft, and four patients died from other comorbid medical problems while awaiting construction of endografts. There were 25 males and 11 females, with a median age of 72 (61–85) years. Patient risk was classified according to the American Society of Anaesthesiology (ASA) into ASA I 5%, ASA II 10%, ASA III 40%, ASA IV 44%. Seventy-five percent of the patients had a general anaesthetic while the remaining 25% had an epidural catheter, which was removed after 2 h in the recovery room.

Vertical and transverse groin incisions were performed in 20 and 17 cases, respectively. Five adjunctive procedures were necessary to gain access to the aorta: three iliac artery angioplasties; two of which progressed to iliolumbar endarterectomies, and two iliac artery delooping and reductions. In 15 patients aortic neck length was less than 15 mm and we used suprarenal spare springs. Table 1 illustrates the types and configuration of endografts employed.

Duplex and contrast spiral CT scans were performed at 1, 3 and 6 months and 6-monthly thereafter. The CT scans were measured at fixed length from the lowest renal artery at 30 mm and 50 mm in all cases.

Criteria for success as defined by Ahn et al. and according to the reporting standards for endovascular AAA repair were used and defined as follows: Technical success includes uneventful access, deployment and patency of the endoluminal graft without any obstruction or endoleak, without death or the need for standard aortic reconstruction during the first 30 days following the procedure. Clinical success is similar to technical success, although a small endoleak that spontaneously seals within 6 months is not considered a failure of the procedure. Continuing success is defined as the maintenance of technical and clinical success in addition to absence of aneurysmal expansion of 0.5 cm or greater. Secondary success is defined as obtaining or maintaining successful treatment by additional endovascular procedure.

Results

All grafts were successfully deployed to the targeted areas. In two cases (6%–95% CI: 1–19%) the renal and hypogastric arteries were partially covered by the endograft. One case resulted in renal failure and death at 32 days from multi-organ failure. The second was completely asymptomatic. On-table conversion was required in two cases (6%–95% CI: 1–19%) patients, in both of whom Talent grafts were employed. Rupture of a calcified common iliac artery to accommodate the endograft was the cause of failure in both instances, in spite of 17-mm common iliac artery diameter. Four patients (11%) had proximal migration of the graft, which was corrected immediately by aortic cuffs. In subsequent graft deployment, the systolic blood pressure was lowered to 80 mmHg. Proximal and distal balloon angioplasties were required after deployment of the graft in 26 and 25 patients, respectively. The main iliac limb of a Zenith AAA graft collapsed. Endovascular thrombectomy and angioplasty successfully managed this problem. Iliofemoral segment dissection occurred in three cases, necessitating repair after deployment of the graft.

Fever (38–39.5°), leucocytosis, elevated ESR (46–96) and C-reactive proteins (4–34 mg/dl) were present in
Table 2. Overview of results.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Median operative time</td>
<td>168 minutes (70–360)</td>
</tr>
<tr>
<td>Median operative blood loss</td>
<td>250 ml (50–2500)</td>
</tr>
<tr>
<td>Median blood transfusion</td>
<td>3 units (2–14)</td>
</tr>
<tr>
<td>Median screening time</td>
<td>28 min (22–100)</td>
</tr>
<tr>
<td>Mean hospital stay</td>
<td>7 days</td>
</tr>
<tr>
<td>Mean ICU stay</td>
<td>One day</td>
</tr>
<tr>
<td>Morbidity</td>
<td>19%</td>
</tr>
<tr>
<td>Mortality</td>
<td>6%</td>
</tr>
</tbody>
</table>

68% of patients had aorta bi-iliac grafts and one patient had an aorta uni-iliac graft. Eighteen patients who were suitable for endovascular repair and excluded because of their young age (below 60 years), had standard surgery by a straight tube graft with no groin incisions. Ninety-four percent of the patients were ASA III or less, mean operative time was 2 h with a mean hospital stay of 8 days. Morbidity was low and no patient died. However, since age and patient risk according to ASA classification were significantly lower than that of the 36 patients treated with TEAM, no direct comparison has been made.

Discussion

Comorbid medical conditions and anaesthetic risk may influence outcome. The learning curve is important in determining the results, as technical outcome may improve as experience with endovascular treatment increases. Endoluminal repair was achieved in 34 of the 36 patients. The two primary conversions (6%) occurred because of rupture of the common iliac artery in spite of 17-mm diameter. These conversions occurred in patients 33 and 35, respectively. Calcification of the arterial wall and large delivery system may contribute to such a catastrophe. If arterial calcification is evident on X-ray, we do not oversize the endograft limb but select a low profile delivery system. Supraceliac control of the aorta as described by May was the technique used to salvage both patients. In a study by Schunn et al., the early conversion to open surgical repair was 7.4%, which highlights the importance of having these procedures done in operative endovascular suites. All conversion procedures expose the patient to an increased risk and are best avoided by careful case selection, appropriate preoperative investigations, accurate sizing of the endoprosthesis, thoughtful planning and good procedural technique. Misguided efforts aimed at avoiding surgical conversion will have an adverse impact on patient care.
Management of AAAs

by deferring a needed open repair or reserving surgical repair to those patients with aneurysm rupture.19–22 Forty-four percent of the patients in this study were ASA IV and compassionate cases with complex anatomy; angulation, calcification, tortuosity, presence of thrombus and aneurysmal or occlusive disease of the iliac and the femoral systems necessitated adjuvant endovascular and surgical procedures. These manoeuvres increased the complexity of the procedure and the risk of complications. Of note is the groin complication in the two cases who had delooping procedures. The 16% groin complication rate is similar to that reported by Cohnert et al. but our incidence of systemic complications was higher.23 We used both vertical and transverse groin incisions, mobilising the fat, lymph nodes and the lymphatics medially. The femoral sheath was exposed longitudinally. Lymphatics crossing the field were ligated using the Titanium clips. In spite of these precautions lymphocelecs occurred in 9% of cases. The incidence of limb ischaemia due to distal embolisation during open repair of AAA has been estimated to be 3.3% and for small bowel ischaemia has been estimated to be 0.4%. Neither occurred in our endovascular group. We believe that distal embolisation was prevented by clamping the outflow tract prior to manipulation of the AAA sac. Lipsitz et al. reported that the incidence of renal micro-embolisation syndrome in the surgical open repair of AAA is 2%.2 In our endovascular group the incidence of renal failure was 6%, but one of the patients had critical renal impairment preoperatively. This patient had partial covering of his left renal artery by the endograft. Selective lower renal artery canulation abolished the occurrence of such a problem in short aortic neck in subsequent cases. We covered one hypogastric vessel intentionally to treat an on table distal endoleak; the patient was completely asymptomatic.

Endografts do not heal sufficiently to provide firm fixation in human aorto-iliac segment and stent graft fixation relies on mechanical attachment.14 The principles required to keep the endograft in position are the outward radial forces of the stents, columnar strength of the fully supported endograft, and suprarenal spare-springs or hooks penetrating the aortic wall.15 We have applied these principles to the chosen endograft design for each patient. Matsumura and Broeders found a significant increase in the median diameter of the distal aortic neck and this concurs with the results of Malina who found an median increase of 2 mm at the proximal neck at 12 months.10–12 It is either a continuation of the aneurysmal process or an effect of the outward force generated by the endovascular stent on the aortic wall. We oversized the graft size by 15–20% to the diameter of the aortic neck and both common iliac arteries, because the outward forces of the endograft stent will decline when the inner aortic circumference approaches the maximal stent circumference over a period of time.23

Five cases (15%) of type I endoleaks were apparent on spiral CT scans at 48 h but disappeared by 30 days. The absence of an endoleak after successful endovascular aneurysm repair does not guarantee continued long-term success and the development of a new endoleak months after successful repair demonstrates a problem that needs further investigation. A secondary endoleak rate of 3% is low in comparison to other reported series. This patient was on long-term anticoagulation because of aortic and mitral valve replacement. After TEAM the antegrade flow through the lumbar artery stops and most probably thrombosis of both the vessel and the aneurysmal sac occurs. Fibrinolysis of the fresh thrombus mass in the lumbar artery and in the aneurysmal sac may occur by endogenous t-PA within the thrombus. If this is the case, the risk for development of a late endoleak might disappear because thrombi would become resistant to thrombolysis after several months.1 Darling et al. reported that the only risk factor for persistence of endoleak was long-term anticoagulation.27

Change in the aneurysm size, whether by expansion or shrinkage, was not noticeable on follow-up CT scans. We believe, based on our findings, that shrinkage of the AAA sac after complete exclusion by an endograft is a rare finding. Endovascular intervention of abdominal aortic aneurysm highlights the crucial issue of vascular surgeons being trained on catheter-based techniques. Our morbidity and mortality of TEAM for the compassionate cases and high-risk cases are high, and adding to this equation the initial experience and learning curve may explain the complications encountered.

The use of TEAM must be questioned in high-risk patients, and should be performed under clinical trial conditions, until it is found to be safe and reliable in routine clinical practice.


Accepted 27 November 2000