Risk Factors of Early and Late Complications in Patients Undergoing Endovascular Aneurysm Repair

S. Haulon, P. Devos, S. Willoteaux, C. Mounier-Vehier, A. Sokoloff, P. Halna, J. P. Beregi and M. Koussa

Departments of 1Vascular Surgery, 2Vascular Radiology, 3Cardiology and 4Anesthesiology, Hôpital Cardio logique, CHRU, Lille, France, 5Department of Biostatistics, Faculté de Médecine Lille II, Lille, France

Objectives: to identify pre-operative factors that could predict complications following from transluminal repair of abdominal aortic aneurysms (AAA).

Methods: during a 5-year period, 96 consecutive patients underwent elective endovascular treatment of a AAA. In all patients, helical CT and/or Magnetic Resonance Imaging (MRI), and plain abdominal roentgenogram were performed at 1, 3, 6, 12, 18, and 24 months and yearly thereafter. Angiography was performed systematically 1 year after the stent-graft implantation, or earlier if helical CT or MRI diagnosed an increase in the maximal transverse diameter or a high flow endoleak.

Results: early (≤30 days) morbidity (12%) was significantly increased by pre-operative renal insufficiency (p = 0.01). Early mortality (2%) correlated with ASA score (p ≤ 0.01). Median follow-up was 27 months (range 3–66). Mortality (12%) during follow-up was correlated to the pre-operative coronary status (p = 0.01). A type I endoleak was diagnosed in 18 patients (19%). Common iliac artery diameter was correlated with the presence of type I endoleak (p < 0.001). A type II endoleak was diagnosed in 47 (49%) patients. The diagnostic of type II endoleak was significantly increased (p = 0.001) in patients with pre-operative patent IMA associated with more than four patent lumbar arteries.

The anatomic characteristics of the aneurysm were correlated to the additional endovascular procedures during stent-graft implantation (p = 0.01), and to the implantation of a complementary iliac limb extension during follow-up (p = 0.01).

Conclusions: the risk factors determined by this statistical analysis could help surgeons to select more accurately patients suitable for endovascular treatment.

Key Words: Abdominal Aortic Aneurysm (AAA); Endoprosthesis.

Introduction

Technical success and early favourable outcomes reported after endovascular treatment of abdominal aortic aneurysms (AAA) by stent-graft implantation has contributed to the enthusiasm for this method.1 According to early results, the endovascular treatment has emerged as a method of repair which is less invasive compared to open surgery. Initial endovascular experience was limited by AAA morphology.2 New devices have been developed to expand stent-graft implantation indication.3 Data from series with medium and long-term follow-up are progressively reported.4,5 Endoleaks, the persistence of blood flow outside the stent-graft lumen, but within the aneurysm sac, resulting in incomplete exclusion of the aneurysm sac, which remains pressurized, is diagnosed with rates up to >50%.6 This persistent peri-graft blood flow can occur from the proximal and distal (type I endoleaks) or midgraft (type III endoleaks) segments of the stent-graft, or from retrograde flow into the aneurysm sac by feeding vessels arising from the lumbar arteries or from the inferior mesenteric artery (type II endoleaks).7,8 Complications concerning the stent-graft device integrity are also reported. These include structural alteration, limb kinking and thrombosis secondary to the longitudinal shrinkage of the excluded aneurysmal sac or to graft migration. Secondary interventions are frequently necessary to maintain stent-graft patency and aneurysm exclusion.9–12

We prospectively analysed 96 consecutive endovascular procedures for AAA exclusion to determine statistically significant risk factors of complications during stent-graft implantation, early, and late follow-up.
Methods

Patients

Between March 1996 and August 2001, 96 consecutive patients with anatomical variables compatible for endovascular treatment were selected for AAA treatment (AAA maximum diameter or increasing in 6 months) in our institution. This represented 20% of the AAA treated in our institution during this period. The population comprised 95 men and one woman, with a median age of 68 years (range 46–85). Risk factors and American Society of Anesthesiology (ASA) scores are reported in Table 1. All pre-operative data and follow-up events were prospectively entered into a database.

Anatomic characteristics of the aneurysms

The baseline assessment comprised a helical CT of the abdomen and pelvis, and angiography of the abdominal aorta and the lower limbs, with a calibration catheter.

The anatomic characteristics of the proximal neck, the aneurysm, and the right and left common iliac arteries are reported in Table 2. Based on Eurostar Registry criteria, 12 (13%) patients presented a type A aneurysm, 48 (50%) a type B, 32 (33%) a type C, and 4 (4%) a type D.

<table>
<thead>
<tr>
<th>Arterial hypertension</th>
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</tr>
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<tbody>
<tr>
<td>Diabetes</td>
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<td>6</td>
</tr>
<tr>
<td>Coronary artery disease</td>
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<td>60</td>
</tr>
<tr>
<td>Renal insufficiency (creatinemia &gt; 120 μmol/L)</td>
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<td>18</td>
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<tr>
<td>COPD</td>
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<td>35</td>
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<tr>
<td>Previous laparotomy</td>
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<td>22</td>
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<tr>
<td>Obesity (weight &gt; 110% ideal body weight as per Lorenz)</td>
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<td>25</td>
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<td>ASA 1</td>
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<td>ASA 3</td>
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<tr>
<td>ASA 4</td>
<td>17</td>
<td>18</td>
</tr>
</tbody>
</table>

Table 1. Risk factors and ASA scores in the 96-patient cohort.

Stent-grafts

In 51 cases, a Vanguard® prosthesis (Boston Scientific) was implanted, in 20 cases an AneurRx® prosthesis (Medtronic), in 11 cases a Zenith® prosthesis (Cook), in eight cases a Talent® prosthesis (Medtronic), and in six cases a Stentor® prosthesis (Mintec). The stent-graft was bifurcated in 91 (95%) patients, tubular in four (4%) patients, and degressive in one patient.

The stent-grafts were implanted by a conventional transfemoral approach. Stent-grafts diameters were determined by oversizing the CT scan proximal aortic neck and iliac arteries diameters by 10–15%. In 14 (15%) patients, a common and/or external iliac angioplasty±stenting was performed (defined as additional endovascular procedure during stent-graft implantation).

Follow-up

In all patients, helical CT and/or Magnetic Resonance Imaging (MRI), and plain abdominal roentgenogram (PAR) were performed at 1, 3, 6, 12, 18, and 24 months and yearly thereafter. MRI was not performed in the 12 patients with a Zenith® prosthesis (Cook). Helical CT and MRI were performed together to compare both exams specificity and sensitivity for endoleak detection.

An angiography was scheduled systematically 12 months after the implantation of the stent-graft, or earlier if helical CT or MRI diagnosed:

An increase of the aneurysm MTD, considered to be significant when it was greater than the inter-observer variability (> 2 mm).

A type I endoleak.

Table 2. Pre-operative anatomic characteristics of the aneurysms.

Hypertension was defined as a history of high blood pressure (exceeding 140/90 mm Hg) or the need for antihypertensive medication.

Coronary artery disease as documented coronary stenosis >50% or a history of angina, myocardial infarction, or coronary artery angioplasty or bypass.

COPD (chronic obstructive pulmonary disease) as the need for pharmacologic therapy for the treatment of chronic pulmonary compromise or an forced expiratory volume in 1 s (FEV1) less than 75% of predicted value.

ASA, patient status according to the criteria of the American Society of Anesthesiology.
Helical CT, MRI, and angiography techniques were described in a previous report.\(^{15}\) Angiograms were performed in a dedicated numeric vascular suite (Philips V3000, Best, Holland, or Toshiba, Tokyo, Japan). MRI examinations were performed on a 1.5 Tesla Vision (Siemens, Erlanghen, Germany). Helical CT scans were performed on a Somatom Plus 4A (Siemens, Erlanghen, Germany) scanner.

The following parameters were determined:

- Aneurysm MTD on helical CT.
- Endoleaks and graft patency on helical CT, MRI and angiograms.
- Stent-graft limb kink (\(>60^\circ\)) on PAR.

**Statistical analysis**

Quantitative values were expressed as median with range values in brackets, qualitative ones as frequencies.

Comparison of means have been performed with the \(t\)-test or Wilcoxon test according to the sample size and the assumption of normality. Comparisons of frequencies have been performed using a Chi-square or Fisher exact test.

Logistic regression was performed to identify pre-operative risk factors. Decision trees were performed with the CHAID (Chi-square Automatic Interaction Detection) method in order to determine sub-groups of patients with low or high risk of type II endoleak. This non linear method was complementary with the logistic linear regression method.

Mortality and freedom of type II endoleak cumulative rates were assessed by lifetable methods. A value of \(p<0.05\) was considered as statistically significant.

**Results**

**Peri-operative period**

Severe renal failure (creatinemia > 250\(\mu\)mol/L) \((n=5)\), cardiac failure \((n=2)\), myocardial infarction \((n=1)\), anemia \((n=1)\), respiratory insufficiency \((n=1)\), and sigmoiditis \((n=1)\) were observed in 11 patients (morbidity: 12%). Early morbidity was significantly increased by pre-operative renal insufficiency (creatinemia > 120\(\mu\)mol/L). Post-operative renal failure was always transient, and never required dialysis. It was not correlated to the amount of periprocedural contrast media. Results are summarized in Table 3.

During early follow-up (<30 days), 2 patients died, one from cardiac failure, and the other from myocardial infarction. Early mortality (2%) was correlated to the ASA score.

**Follow-up**

Median follow-up was 27 months (range 3–66). No patient was lost to follow-up. Three patients were followed up at another institution.

During follow-up, 11 patients (12%) died (Table 4), from myocardial infarction \((n=5)\), respiratory failure \((n=3)\), lung cancer \((n=2)\), and pulmonary embolism \((n=1)\). Mortality during follow-up was correlated to the pre-operative coronary status and respiratory status (Table 3). The cumulative survival rates at 12, 24, and 36 months were respectively 98, 97, and 91% (Fig. 1).

Helical CT or MRI diagnosed 18 type I endoleaks (19%) during follow-up (Table 4), always confirmed by angiography. In 11 cases, it was a primary

<table>
<thead>
<tr>
<th>Event</th>
<th>Risk factors</th>
<th>Statistical method</th>
<th>(p) value</th>
</tr>
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<tbody>
<tr>
<td>Early morbidity</td>
<td>Renal insufficiency</td>
<td>Fisher exact</td>
<td>0.0035</td>
</tr>
<tr>
<td>Early mortality</td>
<td>ASA score</td>
<td>Fisher exact</td>
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<tr>
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<td>Coronary status</td>
<td>Chi square</td>
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<td></td>
<td>Respiratory status</td>
<td>Fisher exact</td>
<td>0.03</td>
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<td>Type I endoleak</td>
<td>CIA diameter</td>
<td>Wilcoxon</td>
<td>0.0004</td>
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<td>Distal type I endoleak</td>
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<td>Wilcoxon</td>
<td>0.0361</td>
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<td>Type II endoleak</td>
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<td>Patent IMA+</td>
<td>Chi square</td>
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<td>Additional procedures during stent-graft</td>
<td>CIA angulation</td>
<td>Wilcoxon</td>
<td>0.0181</td>
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<tr>
<td>implantation</td>
<td>AAA anatomic characteristics</td>
<td>Fisher exact</td>
<td>0.01</td>
</tr>
<tr>
<td>Secondary iliac limb extension during</td>
<td>AAA anatomic characteristics</td>
<td>Fisher exact</td>
<td>0.0149</td>
</tr>
<tr>
<td>follow-up</td>
<td></td>
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</tbody>
</table>

ASA score: patient status according to the criteria of the American Society of Anesthesiology; CIA: common iliac artery, AAA: abdominal aortic aneurysm, IMA: inferior mesenteric artery.
(or early <30 days) endoleak, proximal (proximal aortic neck) in three cases, and distal (iliac limb) in eight cases. In seven cases, it was a secondary or late (>30 days) endoleak, proximal in four cases, and distal in three cases. A secondary stent-graft implantation (proximal or distal) was performed in 9 patients to treat the type I endoleak and is scheduled in 6 other patients. The endoleak sealed spontaneously in three patients.

The common iliac arteries diameters were correlated with the presence of type I endoleaks and distal type I endoleak (Table 3). A type II endoleak was diagnosed by CT scan and/or MRI in 47 (49%) patients (Table 4). CT scan alone diagnosed a type II endoleak in 22 (23%) patients.

In 8/47 patients (17%), the type II endoleak sealed spontaneously during follow-up. In 18 patients, the MTD shrunk despite the type II endoleak and no complementary treatment was performed. In 21 (22%) patients, presenting no aneurysm shrinkage 6 months after the endoleak detection, an endovascular embolization was performed.

A patent pre-operative IMA increased significantly the incidence of type II endoleak (Table 3). A type II endoleak was diagnosed in 62% of patients with a pre-operative patent IMA, and diagnosed in 29% of patients without a pre-operative patent IMA. The number of pre-operative patent lumbar arteries increased also significantly the diagnostic of type II endoleak. A type II endoleak was diagnosed in 82% of patients with patent pre-operative IMA associated with more than four patent lumbar arteries, and in 29% of patients without a pre-operative patent IMA (Fig. 2). A logistic regression analysis demonstrated that pre-operative patent IMA or lumbar arteries had adjusted odds ratio respectively of 3.7 (95% CI: 1.5–9.2)

Table 4. Number of endoleaks and deaths during follow-up.

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Sample size</th>
<th>Type I endoleaks</th>
<th>Type II endoleaks</th>
<th>Deaths</th>
</tr>
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<tr>
<td>0–12</td>
<td>91</td>
<td>13</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>12–24</td>
<td>77</td>
<td>2</td>
<td>18</td>
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<td>24–36</td>
<td>54</td>
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<td>4</td>
</tr>
<tr>
<td>&gt;36</td>
<td>21</td>
<td>1</td>
<td>4</td>
<td>6</td>
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</table>

![Fig. 1. Cumulative survival rates assessed by lifetable methods.](image1)

![Fig. 2. Type II endoleaks (T2) diagnosed by CT scan and/or MRI during follow-up. Patent/thrombosed IMA: pre-operative angiographic status of the inferior mesenteric artery. Patent lumbar arteries: number (≤ or > 4) of patent lumbar arteries on the pre-operative angiography.](image2)
and 3.1 (95% CI: 1.1–9.3) for type II endoleak detection. The cumulative freedom of type II endoleak rates at 12, 24, and 36 months were respectively 96, 77 and 46% (Fig. 3).

A type III endoleak was diagnosed in 6 (6%) patients. It was always treated by secondary implantation of a covered stent.

A kink of an iliac limb of the stent-graft was diagnosed on PAR and CT scan in 34 (35%) patients and was responsible for iliac limb thrombosis in eight (8%) patients. A femoro-femoral cross over bypass was performed in two patients, and an in situ thrombolysis associated with complementary balloon expandable stent implantation in the remaining six patients. Angulations of the iliac artery increased significantly additional endovascular procedures during stent-graft implantation (Table 3). The MTD at the end of follow-up, compared to the pre-operative MTD, decreased in 48 (50%) patients, remained unchanged in 47 (49%) patients, and increased in one patient. The pre-operative MTD of the AAA increased significantly additional endovascular procedures during stent-graft implantation. The anatomic characteristics of the aneurysm was also correlated to the additional endovascular procedures during stent-graft implantation (50% in type D aneurysms, 17% in type A aneurysms), and to the implantation of a complementary iliac limb extension during follow-up (75% in type D aneurysms, 17% in type A aneurysms).

**Discussion**

Early post-perative morbidity and mortality were significantly influenced by the patients’ pre-operative status, especially the presence of multiple system disease. As for conventional open surgery, renal insufficiency was a significant risk factor of early morbidity. No correlation between post-operative renal failure and the amount of periprocedural contrast media was demonstrated, probably because we used very low doses, especially in patients with pre-operative renal insufficiency. Endovascular treatment is nonetheless probably the first choice treatment in high risk patients, with favourable AAA anatomic morphology, but the peri-operative management of such patients requires adapted protocols and post-operative surveillance in intensive care unit.

Mortality during follow-up (median 27 months) was also significantly influenced by the pre-operative patient’s status, especially by the coronary status, and the respiratory status. It has been already reported that the long term mortality rate of patients undergoing surgical repair of AAA is significantly higher compared with an aged match population. A major reason for that is the high incidence of risk factors in the AAA population.

This study confirmed that the most frequent endoleaks seems to be type II endoleaks. A higher rate of type II endoleaks (50%) was observed compared to other series. This high rate of type II endoleaks may be explained by our specific follow-up using magnetic resonance in addition to helical CT. This exam is considered as the most sensitive for type II endoleaks location. We would report a 23% rate of type II endoleaks if we considered only those diagnosed by CT scan. Pre-operative patency of the IMA and the number of patent lumbar arteries influenced significantly the diagnosis of type II endoleaks, especially when associated with > 4 pre-operative patent lumbar arteries ($p = 0.001$).

The rate of type I endoleak we reported (19%) is also higher than other series. As these are high flow endoleaks, they can be diagnosed by a routine imaging follow-up, performed either by duplex scan, helical CT, or MRI. Therefore the frequent use of MRI during follow-up did not influence this high rate. Follow-up did influence detection of type I endoleaks, because 7/18 (39%) were secondary endoleaks. The rate of primary type I endoleaks was 12%, which we attribute to the sizing errors incurred at the beginning of our experience. The secondary endoleaks resulted from migration and deformation of the prosthesis due to the aneurysmal retraction, or from the aneurysmal evolution of the aortic neck and the iliac arteries.

The diameter of the implantation site of the stent-graft on the iliac arteries influenced significantly during follow-up the diagnostic of type I endoleak. This result advocate the necessity of implanting the distal end of the iliac limbs as far as possible, in healthy iliac arteries.
arteries segments, ideally just above the iliac bifurcation. The implantation zone can be the external iliac artery when necessary, after embolization of the internal iliac artery, if the contralateral internal iliac artery remains patent. We recommend, as for the proximal neck, oversizing the stent-graft’s iliac limbs by > 10%. Manufacturers now provide extensions with diameters up to 22 mm to exclude efficiently ectasic iliac arteries. The combination of extensive and oversize stent-grafting will probably decrease distal type I endoleaks by device migration or aneurysm evolution, by limiting AAA longitudinal shrinkage and anticipating artery diameter changes.

The pre-operative anatomic characteristics of the AAA is a major factor influencing adverse events during follow-up. The aneurysm propagation, according to the Eurostar Registry criteria, had equivalent influence on peri and post-operative complications.

The results of our study should be interpreted cautiously because nearly 60% of the devices employed are first generation devices no more commercially available. A comparison of the results between the first and second generation devices will be interesting when sufficient follow-up of second generation devices will be available.

The data from our series confirms the important number of adverse events after endovascular exclusion of AAA. To prevent AAA rupture, a close life time follow-up is necessary, especially in patients presenting risk factors for secondary procedures.

References


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