Analysis of Outcome after using High-risk Criteria Selection to Surgery Versus Endovascular Repair in the Modern Era of Abdominal Aortic Aneurysm Treatment

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KEYWORDS
Aortic aneurysm; Abdominal; Endovascular; Surgery; Mortality; Morbidity; Risk factors; Survival; High-risk

Abstract

Introduction: The concept of high-risk patients suggests that such patients will experience a higher rate of postoperative complications and worse short- and long-term outcomes, and should therefore benefit from the use of endovascular techniques for aortic abdominal aneurysm (AAA) repair. The primary goal of this study was to assess the relevance of the different high-risk criteria, defined by the French health agency Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) in a single-centre continuous series. Secondary goals were to retrospectively compare the incidence of postoperative complications and short- and long-term survival in three groups of patients.

Materials and methods: Between January 1999 and December 2006, details of all the patients undergoing elective surgery for AAA in our hospital were recorded into a prospective registry (n = 626). Three groups were considered according to the level of risk and type of repair defined by the AFSSAPS: endovascular aortic aneurysm repair (EVAR) high-risk (HR) (at least one high-risk factor and EVAR, n = 138), open HR (at least one high-risk factor and open repair, n = 134) and open low-risk (LR) (no high-risk factors and open repair, n = 344). None of the low-risk patients were treated using an endovascular approach. The demographics, preoperative risk factors, intra-, postoperative data and short- and long-term survival were compared between the groups. Interrelations among the set of high-risk criteria for mortality were calculated using multiple correspondence analysis (MCA).

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Introduction

Since the first experiences of endovascular aortic aneurysm repair (EVAR) reported by Volodos et al. and Parodi et al., this treatment option has gained widespread acceptance and application as an alternative to conventional open repair (OR) of abdominal aortic aneurysm (AAA).1–4 EVAR was developed to provide a less-invasive treatment. In France, in 2001, the ad hoc health agency Agence Francaise de Sécurité Sanitaire des Produits de Santé (AFSSAPS), defined different high-risk criteria to limit the use of EVAR, which was deemed less safe given the state of knowledge at the time (Table 1).5 EVAR could only be offered if at least one of the following criteria were met:

- age 80 years or above;
- non-revascularisable coronary artery disease;
- symptomatic heart failure;
- inoperable aortic valve stenosis;
- left ventricle ejection fraction equal to 40% or less;
- evidenced severe chronic obstructive pulmonary disease;
- chronic renal insufficiency; and
- hostile abdomen (without specification but including ascitis and other signs of portal hypertension).

Today, the guidelines are still applied in France, although some recent publications showed the benefits of EVAR in a broader population, including younger patients and those in good enough health for standard open surgical repair.5,9 Recently, two major randomised controlled trials reported a significantly lower perioperative mortality rate for EVAR than for open surgery.5,9 This has since been emphasised by population-based observational studies using large databases in the USA.3 The development of endograft technology has led to a situation in which EVAR is overtaking open repair, at least in some countries, and even in low-risk patients.10,11

Objectives

To retrospectively compare lengths of hospital stay, the incidence of postoperative complications and short- and long-term survival, and to assess the relevance of the different AFSSAPS high-risk criteria with regard to the choice of treatment in a continuous single-centre series of AAA.

Materials and methods

A prospective database collecting all of the AAAs treated in our department of vascular surgery was approved by the ethics committee of our teaching hospital and initiated in 1999. Using data from this database, we retrospectively studied a continuous series of consecutive patients who had undergone elective surgery for AAA from January 1999 to December 2006 (n = 626). Three groups were formed, according to their AFSSAPS risks and type of repair:

- EVAR high-risk (HR): at least one high-risk factor and endovascular repair (n = 148);
- open HR: at least one high-risk factor and open repair (n = 134); and
- open low-risk (LR): no high-risk factors and open repair (n = 344).

Patients who presented with ruptured AAA in the same period (n = 65, 15 EVAR and 50 open repairs) were excluded from the study in order to eliminate bias. In accordance with the AFSSAPS rules, none of the low-risk patients received endovascular treatment. The leading operating surgeon was responsible for selecting EVAR or open repair for each patient. Patients in the open high-risk group underwent open repair because of morphological contraindications for endografting or because of the surgeon’s or the patient’s choice. Each patient underwent a preoperative computerised tomography (CT) scan (cuts \( \leq 5 \) mm) and a preoperative multiplanar contrast angiography using a catheter with radio-opaque markers to measure various lengths and to assess pelvic anatomy. Preoperative angiography has not been used since 2003 because the information provided by the CT scan alone has been judged sufficient since then.5

All of the patients were treated in the operating room under general anaesthesia. Open repair was done with a retroperitoneal approach in all cases. Radiology imaging was performed with a C-arm fluoroscopic unit with digital imaging and road-mapping capability (Phillips, the Netherlands).

Follow-up was organised according to the AFSSAPS recommendations: contrast-enhanced CT scan and abdominal plain X-ray before hospital discharge and at 6, 12, 18 and 24 months and then yearly. In the case of renal insufficiency, CT was replaced with magnetic resonance angiography (MRA) or CT without contrast plus a duplex scan.

Results: The distribution of high-risk criteria was similar in both high-risk groups, except for age, heart failure and hostile abdomen, which were significantly more frequent in EVAR HR. Operation time, blood loss and length of stay in an intensive care unit and hospital were significantly lower in the EVAR HR group. The 30-day mortality and survival rates at 5 years were 5.4 and 59.4% for EVAR HR, 3.7 and 70.4% for open HR and 2.3 and 83.7% for open LR, respectively, with no significant difference between the three groups for the mortality, but a significant higher survival at 5 years for the open LR versus both high-risk groups.

Conclusion: The high-risk AFSSAPS criteria were not predictive of postoperative mortality and should not be used to determine the choice of treatment technique. Other criteria therefore need to be established to determine whether open or EVAR repair should be used.

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Primary study outcomes focussed on operative mortality (less than 30 days or during hospital stay if >30 days) and mortality at 5 years in the three groups. The demographics (cardiovascular risk factors, past medical history and AFS-SAPS high-risk), morphological features (proximal neck length and diameter, aneurysm greatest diameter and common iliac artery diameter), operative data (operative time, blood loss, length of stay in the intensive care unit (ICU)), length of hospital stay, postoperative complication rate, postoperative death rate and long-term survival were analysed and compared in the three groups.

### Statistical analysis
Cumulative event rates were determined with the Kaplan–Meier (KM) survival analysis. The probability difference
Discussion}

The first aim of our study was to compare the postoperative mortality rate among the three groups, and surprisingly, there was no statistical difference. The mortality rate for

Results

The analysis of the three groups — EVAR HR, open HR and open LR — are presented in Tables 1—3 and Figs. 1 and 2. Table 1 shows the demographics, including cardiovascular risk factors, past medical history and the different AFSSAPS high-risk criteria. With regard to cardiovascular risk factors, the distribution among the three groups showed fewer males in the open HR group (85.8%; p < 0.01; df 2) and less dyslipidaemia in the EVAR HR group (46.6%, p < 0.01; df 2). Approximately half of patients (range 43–52%) in each group presented with three or more cardiovascular risk factors. Regarding past medical history, there were significantly more cancers (23.6%, p < 0.01, df 2) and cardiac disease (67.5%, p < 0.01, df 2) in the EVAR HR group. The distribution of high-risk criteria was similar in both high-risk groups (EVAR HR and open HR), except for a higher number of patients above 80 years of age (54.5%, p < 0.01, df 1) in the open HR group, and significantly more previous heart failure (29.1%, p < 0.01; df 1) and hostile abdomen (25.6%, p < 0.01, df 1), in the endovascular group (EVAR HR). A significant difference in the presence of AFSSAPS criteria was noted between the EVAR HR and open HR group (p < 0.01, df 3). While more patients with a single AFSSAPS high-risk factor presented in the open HR (81 versus 57%), more patients with two (32 versus 16%) and three risk factors (10 versus 3%) were noted in the EVAR HR group. No difference was noted in the small number of patients with four or more AFSSAPS risk factors. The operative data presented in Table 2 show that the EVAR HR patients had a significantly lower intraoperative blood loss (311 ml, p < 0.01, df 2) and a shorter operation time (146 min, p < 0.01, df 2), mean intensive care unit stay (11 days, 95% confidence interval (CI) 0–1 days, p < 0.01, df 2) and a mean hospitalisation (8 ± 7 days, 95% CI 7–9 days, p < 0.01, df 2), compared with the two open repair groups. There was no significant difference between the two open repair groups with regard to operative data. The postoperative complications were analysed and are presented with the causes of death in Table 3. No significant difference was noticed among the groups, despite a relatively high mortality rate of 5.4% in the EVAR HR group, which will be discussed later.

The Kaplan—Meier analysis highlighted the fact that open repair low-risk patients showed a significantly higher 60-month cumulative survival of 84% than did the high-risk EVAR HR (59%; p < 0.001) or high-risk open repair patients (70%; p = 0.002), with no significant difference between the two latter groups (p = 0.252).

Fig. 2 shows the MCAs that were used to jointly examine the relationship between high-risk criteria and mortality at different time points. Renal insufficiency seemed to correlate with early mortality (postoperative, at 12 and 24 months). ‘Age over 80’ appeared to correlate with late mortality (at 48 and 60 months).

Discussion

The first aim of our study was to compare the postoperative mortality rate among the three groups, and surprisingly, there was no statistical difference. The mortality rate for
EVAR of 5.4% in our series is clearly one of the highest rates reported in this setting, ranging from 0 to 5.3%.15–20 The causes of death are presented in Table 3. Four patients out of eight presented an acute ischaemic event (three myocardial infarctions and one intestinal infarction), which may be explained by our former policy of stopping anti-platelet drugs 1 week before any type of operation. After 2003, we decided to maintain anti-platelet drugs, and thereafter, no other postoperative ischaemic events have occurred. Although the 30-day mortality rate in the EVAR HR group (5.4%) was high, the difference between the groups was not significant. Surprisingly, in the open HR group the mortality rate was low at 3.7%. According to the AFSSAPS criteria, these patients were considered high-risk as they were supposedly unfit for open surgery. The post-operative course showed that these patients were in fact good candidates for open surgery, even though they presented with high-risk criteria.

A major limit of this study is the way the groups were formed. As we followed the AFSSAPS recommendations, no low-risk patients received EVAR. The open HR group contained patients with AAAs that were morphologically different: some aortas were unsuitable for endografting, while others were favourably shaped, but in patients who were unwilling to be treated with an endovascular graft, or for whom the referring surgeon did not recommend endovascular treatment. However, the series was continuous and reflected real-life clinical practice in a vascular department in a French teaching hospital. The three groups were comparable in term of hypertension, smoking, diabetes mellitus, number of cardiovascular risk factors per patient, rate of peripheral arterial occlusive disease, history of stroke and transient ischaemic attack.

Regarding the distribution of AFSSAPS high-risk criteria, the number of octogenarians was even higher in open HR group, which emphasises the fact that age does not necessarily reflect the state of the arteries. As previously reported, age should not be a critical criterion when deciding whether or not to repair an AAA.21 Conversely, octogenarians seem to have higher life expectancy after AAA repair, as showed in Fig. 2, (green zone, dotted lines); plots correspond to death rates at 48 and 60 months. This surprising finding is in keeping with the publication of Mani et al., who recently reported the long-term outcomes from the Swedish Vascular Registry and showed that relative 5-year survival after elective AAA repair was better for octogenarians than for patients <80 years of age.22 Another remarkable difference between the two high-risk groups concerns the rate of heart failure and hostile abdomen in the EVAR HR group, which was significantly higher than in the open HR group. Both these conditions discourage the surgeon from proposing open repair to patients, even though these conditions do not correlate with early death after surgery as shown in Fig. 2. Renal insufficiency, however, does correlate with a high rate of postoperative complications and early death (postoperative, at 12 and 24 months) as shown in Fig. 2 (red zone, dashed lines) and has to be considered a high-risk factor regardless of the type of AAA treatment.

### Table 3: Details of postoperative complications death. HR: high-risk; LR: low-risk.

<table>
<thead>
<tr>
<th>Population: N (%)</th>
<th>EVAR HR</th>
<th>Open HR</th>
<th>Open LR</th>
</tr>
</thead>
<tbody>
<tr>
<td>148 (24%)</td>
<td>134 (21%)</td>
<td>344 (55%)</td>
<td></td>
</tr>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>44 (29.7)</td>
<td>50 (37.3)</td>
<td>119 (34.6)</td>
<td></td>
</tr>
<tr>
<td>a. Postoperative complications: p = 0.273</td>
<td>df = 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with complications (N and %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>2 (5)</td>
<td>15 (30)</td>
<td>24 (20)</td>
</tr>
<tr>
<td>Wound</td>
<td>12 (27)</td>
<td>16 (32)</td>
<td>18 (15)</td>
</tr>
<tr>
<td>Digestive</td>
<td>2 (5)</td>
<td>8 (16)</td>
<td>8 (7)</td>
</tr>
<tr>
<td>Neurologic</td>
<td>2 (5)</td>
<td>2 (4)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Prosthesis</td>
<td>4 (9)</td>
<td>3 (6)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>5 (11)</td>
<td>20 (40)</td>
<td>29 (24)</td>
</tr>
<tr>
<td>Renal</td>
<td>9 (20)</td>
<td>11 (22)</td>
<td>29 (24)</td>
</tr>
<tr>
<td>Urinary</td>
<td>2 (5)</td>
<td>2 (4)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Vascular</td>
<td>22 (50)</td>
<td>35 (70)</td>
<td>44 (37)</td>
</tr>
<tr>
<td>Total complications (n)</td>
<td>60</td>
<td>112</td>
<td>159</td>
</tr>
<tr>
<td>Complications per patient</td>
<td>1. 4</td>
<td>2.2</td>
<td>1.3</td>
</tr>
<tr>
<td>b. Causes of postoperative death: p = 0.242</td>
<td>df = 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of deaths (% in each group)</td>
<td>8 (5.4)</td>
<td>5 (3.7)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Myocardial infarction (n)</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Intestinal ischemia (n)</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Sepsis (n)</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonary embolism (n)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Multiple organ failure (n)</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total (n)</td>
<td>8</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

1 Fisher’s Exact test.
Figure 1  Kaplan–Meier survival analysis of the EVAR high-risk (green), open repair high-risk (pink) and open repair low-risk (blue) groups. The Log-Rank test includes the curves only until 60 months. The further curves until 84 months are for information only, as the number of patients at risk was less than 20% of the original population at 72 months already. The 95% CI is indicated by horizontal bars every 12 months. The standard error did not exceed 10% until 84 months (SE max = 6.3%) in all three groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of patients</th>
<th>0 months</th>
<th>12 months</th>
<th>24 months</th>
<th>36 months</th>
<th>48 months</th>
<th>60 months</th>
<th>72 months</th>
<th>84 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR HR</td>
<td>147</td>
<td>112</td>
<td>93</td>
<td>60</td>
<td>40</td>
<td>22</td>
<td>14</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>OPEN HR</td>
<td>134</td>
<td>113</td>
<td>81</td>
<td>62</td>
<td>47</td>
<td>19</td>
<td>10</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>OPEN LowR</td>
<td>344</td>
<td>297</td>
<td>256</td>
<td>212</td>
<td>157</td>
<td>100</td>
<td>75</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

Figure 2  Multiple correspondence analysis (MCA); the original variables are represented in a space defined by factorial axes, which are characterized by a percentage of inertia (i.e. the amount of total variability explained by the axis itself). The distance between points indicates the dissimilarities between categories, while categories that plot close to each other are statistically related and are similar with regard to the pattern of relative frequencies. COPD, chronic obstructive pulmonary disease.
Though our series is neither prospective nor randomised, the findings contrast with the results of the ‘EVAR 2’ trial, but match results in other published series that included high-risk patients. Nevertheless, the high-risk population analysed in this series had a lower life expectancy compared to low-risk patients. We did not assess here the quality of life and the potential drawbacks of the life-long follow-up required by endovascular repair. The ideal candidates for endovascular repair are still to be defined. Data from the EVAR trials suggest that the healthiest patients are the ones most likely to benefit from the procedure, and that they are also the most likely to tolerate open surgical procedures with acceptable rates of postoperative complications and death.

Conclusion

In our single-centre continuous series, the high-risk criteria as defined by the French health agency AFSSAPS predicted neither complications nor postoperative mortality. They cannot be decisive in the choice of treatment. The sum of these risks, however, seems to be predictive of complications or mortality, but gives no indication of the type of treatment that is most likely to be successful for a given patient. Each high-risk criterion should be weighted independently to assess its relevance as a factor of morbidity.

Conflict of interest/funding

None.

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The authors would like to thank Mr. Ph Bastable, from the Department of Clinical Research, (Département de Recherche Clinique et d’Innovation), for English language revision.

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16 Buth J, van Marrewijk CJ, Harris PL, Hop WC, Riambau V, Laheij RJ. Conventional and endovascular abdominal aortic aneurysm repair: long-term outcome analysis in this series had a lower life expectancy compared to low-risk patients. We did not assess here the quality of life and the potential drawbacks of the life-long follow-up required by endovascular repair. The ideal candidates for endovascular repair are still to be defined. Data from the EVAR trials suggest that the healthiest patients are the ones most likely to benefit from the procedure, and that they are also the most likely to tolerate open surgical procedures with acceptable rates of postoperative complications and death.

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