Elective endovascular stent-grafting of abdominal aortic aneurysms

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Endovascular repair of abdominal aortic aneurysms with concomitant common iliac artery aneurysm

Roel Hobo, Johannes E.M. Sybrandy, Peter L. Harris, and Jacob Buth

*J Endovasc Ther 2008;15:11-21.*
Abstract

**Background:** To compare outcomes following endovascular repair in abdominal aortic aneurysm (AAA) patients with and without concomitant iliac artery aneurysm disease.

**Methods:** Data on patient characteristics and risk factors, aneurysm morphology, interventional details, complications, and mortality were retrieved from the EUROSTAR registry database for the period from October 1996 to November 2006. AAA patients without concomitant iliac aneurysm disease (group I, n=6286) were compared with 1268 patients with aneurysmal iliac vessels (group II) regarding mortality, device-related complications, and need for secondary interventions. Logistic regression and Cox proportional hazards model were performed to assess independent associations with outcome parameters in the study groups.

**Results:** Group II had more patients classified as ASA III or IV (55.1% versus 50.3% in group I; p=0.002); they were more frequently unfit for open aortic repair (30.3% versus 23.4%; p<0.0001) and had larger-diameter aneurysms (62.3 versus 60.7 mm; p<0.0001) and infrarenal necks (24.5 versus 24.1 mm; p<0.001). In addition, group II patients had a higher rate of internal iliac artery occlusion (11.4% versus 5.2%; p<0.0001) and more significant angulation of the aortic neck (30.8% versus 24.3%; p<0.0001) and iliac artery (48.3% versus 41.9%; p<0.0001). Group II patients had higher 5-year cumulative incidences of distal type I endoleaks (9.1% versus 4.3%; p<0.0001), iliac limb occlusion (5.9% versus 4.4%; p=0.040), secondary transfemoral intervention (17.6% versus 8.9%; p=0.019), and aneurysm rupture (4.5% versus 1.7%; p=0.042).

**Conclusion:** Although aneurysm-related mortality and mortality from other causes were similar in both study groups, concomitant iliac artery aneurysms in AAA patients were associated with an increased incidence of distal type I endoleak, iliac limb occlusion, and aneurysm rupture. Therefore, caution is warranted, and efforts should be made to avoid procedural mishaps.
Introduction

Elective endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAA) has become an important interventional alternative to open aortic repair, with a lower procedure-related mortality rate demonstrated by randomized clinical trials. In ~15% to 40% of the patients, the aneurysm extends into at least one of the common iliac arteries (CIA). Involvement of a CIA frequently complicates the procedure and may exert a higher risk for complications. Therefore, EVAR in AAA patients with co-existing iliac aneurysms may require special technical expertise. Most studies of concomitant iliac aneurysm disease focus on technical and anatomical problems and strategies to overcome these difficulties. However, whether the midterm success rate in these patients differs from EVAR without device extension into the external iliac arteries was not addressed in most of the previous studies. Therefore, we assessed whether the simultaneous exclusion of concomitant CIA aneurysms influences outcome of EVAR in terms of mortality, device-related complications, and need for secondary interventions.

Methods

Database and Population Characteristics

Perioperative data on 7554 patients (7043 men; mean age 72.4 years, range 41-100) from 177 centres in 19 countries were retrieved from the database of the European collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair (EUROSTAR) registry. This voluntary multicentre registry was established in October 1996 with the objective of collecting data on endovascular repair of AAA patients. Patients with a non-ruptured, asymptomatic AAA (maximum diameter ≥50 mm) selected for elective endovascular surgery were prospectively enrolled into the registry on an intention-to-treat basis to prevent selection bias. Informed consent was obtained. The EUROSTAR database closed enrollment in November 2006.

Patients received commercially available CE-approved stent-grafts: Anaconda (Sulzer Vascutek Ltd, Inchinnan, Scotland; 74 patients), AneuRx (Medtronic Vascular, Santa Rosa, Calif; 670 patients), EVT (Guidant Inc, Menlo Park, Calif; 65 patients), Excluder (W.L. Gore & Associates, Inc, Flagstaff, Ariz; 1011 patients), Fortron (Cordis, a Johnson & Johnson company, Miami Lakes, Fla; 90 patients), Lifepath (Edwards Lifesciences, Irvine, Calif; 114 patients), Powerlink (Endologix, Irvine, Calif; 126 patients), Talent (Medtronic Vascular; 2209 patients), and Zenith (Cook
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Inc, Bloomington, Indiana; 3131 patients). Patients with Vanguard or Stentor stent-grafts, devices that have long been withdrawn from the market, were excluded from the analysis to reflect the current EVAR situation.

Data Retrieval

Gender, age, American Society of Anesthesiologists (ASA) class, risk factors according to the Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) guidelines, aneurysm morphology assessed by contrast-enhanced computed tomography (CT) and angiography, procedural technical details, and postoperative outcome regarding mortality, endoleaks, complications, secondary interventions, and ruptures were registered. Patients in whom no AAA classification (Fig. 1) was given were excluded from the current study. Findings at clinical examination and CT assessment, angiography, magnetic resonance imaging (MRI), or duplex ultrasound during follow-up were recorded at 1, 3, 6, 12, 18, and 24 months and annually thereafter.

Two study groups were distinguished according to AAA classification. Patients with an aneurysm that had an anatomical class A, B, or C (EUROSTAR classification, Fig. 1) were assigned to group I (6286 patients, 83.2%). Patients with an aneurysm that had a uni- or bilateral CIA/AAA classification (D or E) were assigned to group II (1268 patients, 16.8%). Preoperative patient characteristics and risk factors and postoperative outcome were compared between study groups. The early adverse events that were analyzed included device migration, endoleaks at the completion angiogram [categorized into proximal or distal type I, perfusion from side branches (type II), and midgraft (type III)], paraplegia, bowel ischemia, and systemic complications. In addition, secondary interventions (subdivided into transfemoral, extra-anatomical, and transabdominal) were assessed. Postoperative 30-day mortality, aneurysm rupture, and conversion to open repair were compared between the study groups. The late
adverse events involved device migration, kinking, endoleak (categorized as indicated above), iliac limb occlusion, intermittent claudication or buttoc k claudication, and aneurysm growth (defined as an 8 mm increase from the preoperative measurement). Furthermore, secondary interventions (categorized into transfemoral, extra-anatomical, or conversion to open repair), aneurysm rupture, all-cause mortality, and AAA-related death (defined as within 30 days of the initial or any secondary intervention or associated with rupture or endograft infection) were investigated. Reporting was in accordance with the guidelines of the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery.17

Statistical Analysis

Analyses were performed using chi-square tests, Mann-Whitney tests, and multivariate logistic regression for procedural outcome. Kaplan-Meier life tables and Cox proportional hazards model were used to evaluate late outcome comparing patients in groups I and II. The resulting p values were
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stepwise adjusted for patient (age, gender, risk factors), anatomical (dimensions, angulation, occlusive disease), procedural (type of stent-graft, adjunctive procedures), and physician-related (team experience) factors. p<0.05 was considered statistically significant. All analyses were performed using SAS statistical software (version 8.02; SAS Institute, Cary, North Carolina).

Results

Concomitant iliac aneurysms were less frequently observed in women (4.7% in group II versus 7.2% in group I; p=0.001; Table 1). Patients in group II with uni- or bilateral CIA/AAA classification D or E were more frequently classified as ASA III or IV (55.1% versus 50.3%; p=0.002) and unfit for open aortic repair (30.3% versus 23.4%; p<0.0001) than control patients. Of all SVS/ISCVS risk scores, current smoking (25.2% versus 22.0%; p=0.012), hypertension (33.0% versus 29.7%; p=0.022), and cardiac (37.9% versus 30.7%; p<0.0001), renal (6.2% versus 4.6%; p=0.016), and pulmonary diseases (25.4% versus 19.8%; p<0.0001) were more frequently observed in group II compared with group I.

Table 2: Aneurysm Anatomy of 7554 AAA Patients Undergoing Endovascular Aneurysm Repair.

<table>
<thead>
<tr>
<th>Measurements</th>
<th>Group I (n= 6286)</th>
<th>Group II (n=1268)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrarenal neck diameter, mm</td>
<td>24.1± 3.3</td>
<td>24.5± 3.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Infrarenal neck length, mm</td>
<td>26.8±11.5</td>
<td>27.7±12.6</td>
<td>NS</td>
</tr>
<tr>
<td>Maximum aneurysm diameter, mm</td>
<td>60.7±10.4</td>
<td>62.3±11.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Common iliac artery, mm</td>
<td>14.8±4.7</td>
<td>25.9±13.2</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Oclusion

| Common or external iliac artery   | 109 (1.7%)       | 23 (1.8%)        | NS     |
| Hypogastric artery               | 329 (5.2%)       | 144 (11.4%)      | <0.0001|

Angulation

| Aortic neck                      | 1529 (24.3%)     | 390 (30.8%)      | <0.0001|
| Aneurysm                         | 776 (11.7%)      | 160 (10.9%)      | NS     |
| Iliac artery                     | 2632 (41.9%)     | 612 (48.3%)      | <0.0001|

Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages). NS: not significant. *Univariate analysis.
Patients in group II had a larger maximum aneurysm diameter (62.3 versus 60.7 mm; p<0.0001) and a larger infrarenal neck diameter (24.5 versus 24.1 mm; p<0.001) than patients in group I (Table 2). In agreement with the selection criteria for the study groups, patients in group II had a larger CIA diameter (25.9 versus 14.8 mm; p<0.0001). Patients in group II more frequently had occlusion of at least one of the hypogastric arteries (11.4% versus 5.2%; p<0.0001). Significant angulation of the aortic neck (30.8% versus 24.3%; p<0.0001) and iliac artery (48.3% versus 41.9%; p<0.0001) was more frequently observed in group II aneurysms compared with group I aneurysms.

Table 3: Early Adverse Events, Reinterventions, and Mortality

<table>
<thead>
<tr>
<th></th>
<th>Group I (n= 6286)</th>
<th>Group II (n=1268)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device migration</td>
<td>79 (1.3%)</td>
<td>20 (1.6%)</td>
<td>NS</td>
</tr>
<tr>
<td>Endoleaks at the completion</td>
<td>1022 (16.3%)</td>
<td>224 (17.7%)</td>
<td>NS</td>
</tr>
<tr>
<td>CTA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal anastomotic</td>
<td>188 (3.0%)</td>
<td>44 (3.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Distal anastomotic</td>
<td>66 (1.1%)</td>
<td>36 (2.8%)</td>
<td>&lt;0.0001/</td>
</tr>
<tr>
<td>Perfusion from side branches</td>
<td>642 (10.3%)</td>
<td>108 (8.5%)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Midgraft prosthetic</td>
<td>99 (1.6%)</td>
<td>34 (2.7%)</td>
<td>0.006/</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.025*</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>4 (0.1%)</td>
<td>1 (0.1%)</td>
<td>NS</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>21 (0.3%)</td>
<td>3 (0.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Systemic complications</td>
<td>666 (10.8%)</td>
<td>156 (12.6%)</td>
<td>NS</td>
</tr>
<tr>
<td>Secondary intervention†</td>
<td>163 (2.6%)</td>
<td>49 (3.9%)</td>
<td>0.012/</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.026*</td>
</tr>
<tr>
<td>Transfemoral</td>
<td>72 (1.2%)</td>
<td>23 (1.8%)</td>
<td>NS</td>
</tr>
<tr>
<td>Extra-anatomical</td>
<td>31 (0.5%)</td>
<td>12 (1.0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Transabdominal</td>
<td>67 (1.1%)</td>
<td>15 (1.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Major events at 30 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rupture</td>
<td>4 (0.1%)</td>
<td>1 (0.1%)</td>
<td>NS</td>
</tr>
<tr>
<td>Conversion</td>
<td>56 (0.9%)</td>
<td>12 (1.0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Mortality</td>
<td>146 (2.3%)</td>
<td>35 (2.8%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Categorical data are given as counts (percentages). NS: not significant. *Univariate/multivariate analysis. †Secondary intervention predischarge or within the first postoperative month.
The incidences of distal type I endoleak (2.8% versus 1.1%; p<0.0001) and midgraft prosthetic endoleak (2.7% versus 1.6%; p=0.025) at the completion angiogram were increased in patients with concomitant iliac aneurysms compared with control patients (Table 3). The incidences of device migration, paraplegia, bowel ischemia, and systemic complications were not significantly different among the study groups. Predischarge postoperative interventions were more frequently performed in group II patients compared with group I (3.9% versus 2.6%; p=0.026). In the first 30 days following the primary procedure, aneurysm rupture was observed
in 4 (0.1%) patients in group I compared with 1 (0.1%) patient in group II. Fifty-six (0.9%) conversions to open repair and 146 (2.3%) deaths were observed in patients with AAA classification A, B, or C as opposed to 12 (1.0%) conversions and 35 (2.8%) deaths in patients with AAA classification D or E, all not significantly different between the 2 study groups.

The mean length of follow-up was 18.6 months (range 0-108). The 5-year cumulative incidence of distal type I endoleak was higher in group II patients than in group I (9.1% versus 4.3%; p<0.0001; Table 4 and Fig. 2). Iliac limb occlusion was more frequently reported in patients with aortoiliac aneurysms than in patients with aortic aneurysms (5.9% versus 4.4%; p=0.040; Fig. 3).

Secondary interventions were more frequently performed in group II patients (23.0% versus 15.6% at 5 years; p=0.018). These reinterventions consisted primarily of transfemoral procedures (17.6% versus 8.9%; p=0.019; Fig. 4), which were performed in 30.3% of patients with a distal type I endoleak and in 27.9% of patients with iliac limb occlusion compared with 3.2% in all other patients (p<0.0001 and p<0.0001, respectively). Femorofemoral crossover grafts were needed in a minority of patients in both study groups (1.8% versus 1.6% at 5 years; p=NS). There was 1 lower extremity amputation due to iliac limb occlusion in a patient without concomitant iliac aneurysm disease.

![Figure 2. Freedom from distal type I endoleak.](image-url)
Figure 3. Freedom from iliac limb occlusion.

Figure 4. Freedom from transfemoral secondary intervention.
Concomitant common iliac artery aneurysm

Figure 5. Freedom from aneurysm rupture.

Figure 6. Survival.
The 5-year cumulative incidence of aneurysm rupture was significantly higher in group II than in group I (4.5% versus 1.7%; \( p = 0.042 \); Fig. 5). The excess rupture rate in group II was attributable to distal attachment site endoleak (odds ratio 9.68; 95% CI 4.60 to 20.39; \( p < 0.0001 \)). The 5-year cumulative mortality rate in group I patients was 26.8% and 36.0% in group II patients, which was not significantly different after adjusting for confounding factors (Fig. 6). No other independent outcome measures associated with concomitant iliac aneurysm disease were observed.

Discussion

The proportion (17%) of AAA patients with concomitant iliac aneurysms in the EUROSTAR database was comparable to previous studies.\(^5\)\(^-\)\(^9\) Endovascular repair of these aneurysms frequently consists of embolization of the hypogastric artery to prevent retrograde flow and extension of the endograft into the external iliac artery. Although, hypogastric embolization is considered a safe procedure,\(^18\) symptoms of pelvic ischemia, such as buttock claudication and erectile dysfunction, have been reported by several investigators, especially in patients with bilateral hypogastric embolization.\(^19\)\(^-\)\(^25\) Although this was rarely observed in our study, bowel ischemia may be a severe and often lethal complication.\(^24\) Pelvic flow should be preserved at least unilaterally.\(^22\) Delle et al.\(^12\) suggested a lower risk for ischemic complications by unilaterally extending the endograft into the hypogastric artery combined with a crossover bypass. Branched iliac devices combined with aortic bifurcated stent-grafts to preserve hypogastric artery flow are being investigated in specialized centres and may provide a new solution in the treatment of CIA aneurysms.\(^13\)\(^,\)\(^26\) In the present study, branched iliac devices have not been considered, and the consequences of hypogastric inflow obliteration and stenting to the external iliac artery are assessed. In the group with concomitant iliac aneurysm disease, we found a significantly higher incidence of limb occlusion, which is the most frequent cause of lower extremity ischemia\(^24\) after aortoiliac stent-graft treatment. However, in the present series, claudication or buttock claudication was not a prominent symptom, and its higher incidence in group II was not significant.

Sanchez et al.\(^27\) reported a perioperative mortality rate of 2.5% for isolated iliac aneurysms treated by endovascular techniques, which was comparable to the mortality in patients undergoing EVAR for aortic aneurysm. According to the same author group, the endoleak rate was 5%, which was less than the 15% to 20% incidence that was found in a meta-analysis of AAA stent-grafting.\(^28\) In a more recent study, Boules et al.\(^29\) also found EVAR of isolated CIA aneurysm to appear safe and effective, with initial
results similar to those after EVAR of AAAs. However, combined CIA and infrarenal aortic aneurysms may predispose for a higher risk of complications. Parlani et al.\textsuperscript{7} studied the influence of CIA aneurysm presence on the outcome of endovascular AAA repair. In a group of 336 AAA patients of whom 59 (18\%) had concomitant iliac aneurysm disease, these authors did not find any difference in early or late outcome between the study groups. In our study, we found a strong association (p<0.0001) of distal type I endoleaks with concomitant iliac aneurysms, which was sustained for several years after the initial intervention. The increased incidence of these endoleaks may be attributed to a more caudal deployment of the device with a less robust fixation in the external iliac artery. A higher prevalence of angulated iliac arteries in patients with aortoiliac aneurysms supports this supposition. It is more difficult to achieve an adequate distal seal and fixation in tortuous or diseased arteries than in healthy vessels. The exact length of the distal seal zone and the degree of oversizing could not be investigated in the current series. The risk of a type I endoleak is aneurysm rupture,\textsuperscript{30,31} so prophylactic secondary intervention is strongly indicated. In the current series, both iliac limb occlusions and distal type I endoleaks were repaired by secondary interventions, mainly via the transfemoral approach. Nonetheless, a higher incidence of aneurysm rupture was observed in AAA patients with concomitant iliac aneurysm disease, which could frequently be attributed to distal type I endoleak. However, stent-graft migration, which was similar in both study groups, was not significantly associated with distal type I endoleak.

Despite an increase in device-related complications and aneurysm rupture, aneurysm-related mortality was not significantly different between the study groups. AAA-related mortality may be underestimated because the cause of death is unknown or controversial in a considerable number of patients. Furthermore, many device-related complications are not fatal and can be successfully managed. In addition, death from other causes, such as cardiovascular diseases or malignancies, is considerable in AAA patients, who frequently suffer from comorbidities.

AAA patients with concomitant iliac aneurysms demonstrated a higher prevalence of infrarenal aortic neck angulation. In a previous EUROSTAR report, an association of infrarenal neck angulation to proximal type I endoleak was observed.\textsuperscript{32} However, no difference in the incidence of proximal type I endoleaks was seen between the 2 groups in the current study. Before discharge, type III endoleaks were more frequently found in the group of patients with coexistent iliac aneurysms than in the control group. These junction leaks are known to be associated with modular devices, and concomitant iliac artery aneurysms more frequently require an additional distal component. Therefore, an increased rate of type III endoleaks is not surprising. However, following the perioperative period, the incidences of
type III endoleaks were comparable in both study groups, indicating that concomitant CIA aneurysm disease was not a risk factor for type III endoleak beyond the perioperative period.

Patients with aortoiliac aneurysms had a higher prevalence of comorbidities, indicated by risk classification (higher ASA class, more frequently unfit for open repair) as well as specific risk factors (higher cardiac, renal, and pulmonary risk classification). This may be explained by the shared etiology of iliac aneurysms and comorbidities and by a higher frequency of conservative or expectative treatment of physically low-risk patients with complex aneurysm morphology.

The AAA diameter was also larger in group II patients. Aneurysm diameter was demonstrated as being representative of more advanced aneurysm disease, which is also likely to be associated with coexistent iliac artery aneurysms. Adjusted for these factors, the overall and aneurysm-related mortality rates were similar for the study groups. These findings indicate that EVAR of AAA with concomitant CIA aneurysms can be regarded as a safe procedure.

Limitations of our study included disadvantages that apply to registries in general; the data are incomplete and subject to interobserver variability due to the participation of many surgeons and interventional radiologists. Owing to its large size, this series should provide a realistic reflection of current EVAR practice.

Conclusion

The findings of our study revealed a higher incidence of distal type I endoleak, an increased need for secondary transfemoral interventions, and a higher incidence of aneurysm rupture but similar mortality following EVAR in AAA patients with concomitant CIA aneurysm disease compared with EVAR of simple AAA. Whereas endovascular repair can be safely performed in patients with aortoiliac aneurysm, caution is warranted regarding various complications, and efforts should be made to avoid procedural mishaps.
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