Elective endovascular stent-grafting of abdominal aortic aneurysms
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CHAPTER 6

The influence of aortic cuffs and iliac limb extensions on the outcome of endovascular abdominal aortic aneurysm repair

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Abstract

**Background:** In a proportion of patients with an endovascular abdominal aortic aneurysm repair (EVAR), aortic cuffs or iliac graft limb extensions are required to enhance sealing or to fix the position of the device. This requirement arises when these goals are not primarily obtained with the basic stent-graft configuration. The aim of this study was to assess the influence of the use of endograft extensions during the primary EVAR procedure on the short- and long-term outcome.

**Methods:** The study was based on the data of the EUROSTAR registry. Patient and anatomic characteristics, data regarding the procedure, post-operative complications, and mortality of patients undergoing EVAR were retrieved from the database. Patients were divided in three groups: (1) no extensions, (2) proximal aortic cuffs, and (3) iliac limb extensions. Logistic regression and Cox proportional hazards models were used to compare significant influences of the use of cuffs or extensions on different outcomes relative to control patients, adjusted for patient and anatomic factors.

**Results:** The overall cohort comprised 6668 patients: 4932 (74.0%) without extensions, 259 (3.9%) with an aortic cuff, and 1477 (22.2%) with an iliac endograft extension. Both the 30-day (2.3-3.9%) and the all-cause mortality rate (23-27% at 4 years) were similar in the three study groups. The use of proximal cuffs or iliac extensions did not have an effect on the incidence of endoleaks of any type (24-32% at 4 years). The incidences of device kinking (p=0.0344) and secondary transfemoral interventions (p=0.0053) during follow-up were increased in patients in whom iliac limb extensions were used. In patients with aortic cuffs, no significant associations with altered outcome found were observed.

**Conclusion:** The use of iliac graft limb extensions at EVAR was associated with a higher incidence of kinking and secondary transfemoral interventions, whereas proximal aortic cuffs did not influence outcome.
Introduction

Elective endovascular repair (EVAR) of an abdominal aortic aneurysm (AAA) is an accepted interventional alternative to open aortic repair. Randomized clinical trials demonstrated a lower initial mortality rate compared with open repair. In a considerable number of patients, complete exclusion is not obtained with the basic endograft combination, typically consisting of a body piece and unilateral or bilateral iliac limb endografts. In addition to these two- or three-piece devices, one of the current brands markets a unipiece model. In cases in which aneurysmal disease of the iliac arteries is present, a multi-junctional graft containing one or more graft limb extensions is sometimes needed to reach the external iliac artery for a safe sealing. In other cases, inaccurate preoperative size or length measurements of aneurysm morphology necessitate an endograft extension. Finally, sealing may be incomplete at the site of proximal or distal attachment because of calcifications, resulting in endoleakage. Proximal aortic cuffs or distal iliac graft limb extensions have been demonstrated to be helpful for achieving successful stent grafting. In some patients, multiple graft extensions may be needed to obtain complete aneurysm exclusion. Optimal preoperative imaging may reduce the need for stent-graft extensions. In a study by Velazquez et al, fewer iliac graft limb extensions were required when software-assisted three-dimensional reconstruction based on computed tomography (CT) was used. However, in the day-to-day practice of many centres, these advanced imaging techniques are not the routine.

An endograft that is composed of multiple parts is more complex and presumably has a greater risk of device-related complications. Furthermore, the use of graft extensions prolongs the procedure, and this may be associated with a greater incidence of procedure- or patient-related complications. Most studies concerning endograft extensions describe their application during secondary interventions. Little is known about the relationship between the use of aortic cuffs and iliac extensions during the primary procedure and the effects on long-term outcome. The objective of this study was to assess whether the use of endograft extensions influences the early or late outcomes of EVAR of AAAs.

Materials and methods

Perioperative data of 6668 patients from 167 centres in 19 countries were retrieved from the European collaborators on stent-graft techniques for AAA repair (EUROSTAR) registry. This voluntary registry was founded in 1996 with the objective of collecting data on EVAR of AAAs. Several commercially available stent-grafts were used, including 47 Anaconda (Sulzer...
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Vascutek Ltd, Inchinnan, Scotland), 924 AneuRx (Medtronic Corp, Santa Rosa, Calif), 915 Excluder (Gore Inc, Flagstaff, Ariz), 71 EVT (Guidant Inc, Menlo Park, Calif), 84 Fortron (Cordis/Johnson & Johnson, Fort Lauderdale, Fla), 127 Lifepath (Edwards Lifesciences, Irvine, Calif), 123 Powerlink (Endologix, Irvine, Calif), 1855 Talent (Medtronic) and 2522 Zenith (Cook Inc, Bloomington, Indiana). Vanguard and Stentor stent-grafts were initially enrolled into the EUROSTAR registry but have been excluded from recent analyses together with EVT devices enrolled before June 1, 1998. The purpose of this was to obtain study outcomes representative of the current situation. Eligible patients with EVAR of a non-ruptured, asymptomatic AAA were prospectively enrolled into the registry on an intention-to-treat basis to prevent selection bias. Informed consent was obtained. From 2002, most patient data were entered online into the EUROSTAR database at the Website http://www.eurostar-online.org (KIKI Medical, Nancy, France). Alternatively, contributing physicians could complete a printed standardized case record form (CRF) for submission to the data registry centre by fax or mail. In this study, the 3-year follow-up was 74% complete for all patients expected to have a 3-year follow-up.

Sex, age, American Society of Anaesthesiologist class, risk factors according to the Society for Vascular Surgery/International Society for Cardiovascular Surgery guidelines, aneurysm morphology assessed by enhanced (CT) and angiography, procedural technical details, and postoperative outcomes (including mortality, endoleaks, complications, secondary interventions, and ruptures) were recorded. All patients had a maximum aneurysm diameter of at least 40 mm, and patients with missing operative data were excluded from the analysis. Furthermore, patients without any follow-up were excluded from the current analysis. Follow-up findings at clinical examination and CT assessment and, in a small proportion, angiography, magnetic resonance imaging, or duplex ultrasonography were recorded at 1, 3, 6, 12, 18, and 24 months after surgery and annually thereafter. Patients who underwent operation up to December 2005 were enrolled in the current study.

Study group assignment was based on the use of aortic cuffs or iliac graft limb extensions only during the primary stent-graft procedure. The first cohort consisted of patients without any graft extension. The second cohort of patients had a proximal aortic cuff, and the third cohort included patients who had an iliac graft limb extension device. Some patients required both a proximal aortic cuff and an iliac limb extension. In this analysis, these patients were assigned to the cohort of proximal aortic cuffs. Postoperative outcome was compared between these three groups. Early procedural and clinical outcome events included 30-day mortality, rupture, and conversion rate. Cardiac, neurologic, gastroenterologic, and renal complications were assessed, combined, and indicated as systemic complications. Late postop-
operative outcome events involved device migration, stenosis, thrombosis, kinking (a collapse of the stent-graft caused by excessive bending), endoleaks, aneurysm rupture, aneurysmal growth (defined as an 8-mm increase from the preoperative measurement), the need for secondary interventions (subdivided into transfemoral, extra-anatomic, and conversion to open aortic repair), and all-cause and aneurysm-related mortality. Aneurysm-related mortality was defined as death within 30 days of the initial or any secondary aortic intervention or that associated with aneurysm rupture or endograft infection. 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.12

Chi-square tests, Mann-Whitney tests, and multivariate logistic regression were performed for procedural outcomes, and Kaplan-Meier life tables and Cox proportional hazards models were used for late outcomes of proximal aortic cuffs and iliac limb extensions compared with endografts without any additional extension. Resulting P values were adjusted for confounding variables, including patient-related (age, sex, and risk factors), anatomic (dimensions, angulations, iliac aneurysmal disease, and occlusive disease), procedural (type of stent-graft), and physician-related (team experience) factors. A P value <0.05 implied statistical significance. Statistical analysis was performed with the SAS system (version 8.02; SAS Institute, Cary, North Carolina).

Results

The study group consisted of 6668 patients out of a total of 10,146 enrolled into the EUROSTAR database, with a mean age of 72.4 years (range, 43-100 years). Patients were enrolled between October 1996 and December 2005, and the mean follow-up period was 21.3 months (range, 0-108 months). Three groups were distinguished: group 1 (4932 patients; 74.0%), who did not require any additional endograft extension; group 2 (259 patients; 3.9%), who had an aortic cuff; and group 3 (1477 patients; 22.2%), who had an iliac graft limb extension. Patients with iliac graft limb extensions were older than the control group (72.9 vs 72.2 years; p=0.0037), had more frequent hyperlipemia (47.1% vs 43.5%; p=0.0143) and renal co-morbidities (21.0% vs 17.6%; p=0.0036), and were more frequently unfit for open repair (27.9% vs 24.8%; p=0.0174) compared with the control group (Table I). Patients with aortic cuffs had less frequent hypertension observed (56.4% vs 64.4%; p=0.0089), and a higher proportion was female (9.7% vs 6.4%; p=0.0384).
Aortic cuffs were more frequently used in patients with larger aneurysms (61.1 vs 58.0 mm diameter; p<0.0001) and with a shorter (25.4 vs 27.0 mm; p=0.0058) and more angulated (44.0% vs 19.9%; p<0.0001) infrarenal neck length (Table II). Iliac limb extensions were also used in aneurysms with a larger diameter (60.6 vs 58.0 mm; p<0.0001). In this group, infrarenal necks were longer (28.0 vs 27.0 mm; p=0.0012) and wider (24.1 vs 23.9 mm; p=0.0058) compared with those in patients without extensions. Aortic cuffs were more frequently used in AneuRx (7.0%), Lifepath (10.2%), and Endologix (36.6%) and less frequently in Zenith (1.4%) devices compared with the entire cohort. Iliac limb extensions were more frequently used in AneuRx (32.5%), Talent (27.0%), and Lifepath (40.2%) and less frequently in Zenith (14.1%), EVT (1.4%), and Endologix (9.8%) devices.
Coexisting common iliac aneurysm was more frequent in patients with iliac device limb extensions (18.8% vs 8.0%; p<0.0001). In addition, occlusion of the hypogastric artery during the procedure by stent-graft covering occurred more frequently in group 3 (10.7% vs 5.1%; p<0.0001) compared with the control group. In group 2, patients also had more frequent hypogastric device overlapping during the procedure (8.1% vs 5.1%; p=0.0367). Severe angulation (≥60°) of the aortic neck and the iliac arteries was significantly more frequently observed in patients with both types of endograft extensions (groups 2 and 3).
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Table 3. Early postoperative outcome.

<table>
<thead>
<tr>
<th>Thirty-day rate</th>
<th>Group 1 (controls; n = 4932)</th>
<th>Group 2 (proximal aortic cuff, n = 259)</th>
<th>p-value</th>
<th>Group 3 (iliac extensions; n = 1477)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic complications</td>
<td>569 (11.6%)</td>
<td>38 (14.7%)</td>
<td>0.2855</td>
<td>169 (11.5%)</td>
<td>0.1850</td>
</tr>
<tr>
<td>Rupture of the aneurysm</td>
<td>2 (0.04%)</td>
<td>-</td>
<td>0.9824</td>
<td>2 (0.14%)</td>
<td>0.3350</td>
</tr>
<tr>
<td>Conversion to open aortic repair</td>
<td>59 (1.2%)</td>
<td>2 (0.8%)</td>
<td>0.7539</td>
<td>7 (0.5%)</td>
<td>0.0278*</td>
</tr>
<tr>
<td>Mortality</td>
<td>126 (2.6%)</td>
<td>6 (2.3%)</td>
<td>0.5513</td>
<td>58 (3.9%)</td>
<td>0.3437</td>
</tr>
<tr>
<td>Hospital stay, d (range)</td>
<td>5.7 (0-165)</td>
<td>6.2 (0-82)</td>
<td>0.6891</td>
<td>6.0 (0-86)</td>
<td>&lt;0.0001*</td>
</tr>
</tbody>
</table>

* P < 0.05

The incidence of postoperative systemic morbidity after EVAR was comparable in all groups of patients. The hospital stay was longer (6.0 vs 5.7 days; p<0.0001) in group 3 compared with group 1 (Table 3). The all-cause mortality rate was similar in all patient groups. Aneurysm-related mortality was not higher in patients with iliac limb extensions than in patients without any extensions (6.0% vs 4.2% after 4 years; p=0.0694; Fig 1). The use of an aortic cuff or iliac limb extension was not associated with an increased risk of late rupture of the aneurysm. Thirty-nine patients experienced a late rupture after a mean of 25.1 months (the 3-year cumulative rate of rupture was 0.9% in the entire cohort). The late conversion rate was comparable in the three study groups (4.9%, 8.9% and 5.1% after 4 years in groups 1, 2, and 3, respectively).

Endoleaks, irrespective of type, did not correlate with the use of any type of endograft extensions. Kinking of the stent-graft was more frequently observed in patients who had iliac endograft extensions (p=0.0344). Secondary transfemoral interventions were more frequently required in group 3 than in the control group (p=0.0053; Table 4). The cumulative incidence of transfemoral intervention after 4 years is 8.0%, 11.2%, and 12.6% in groups 1, 2, and 3, respectively (Fig 2). Stent-graft migration, stenosis, and thrombosis were not associated with the use of iliac graft extensions.
Figure 1. Freedom from aneurysm-related mortality. No significant differences were observed among the three groups.

Figure 2. Freedom from secondary transfemoral interventions. Significant differences were observed between patients with iliac limb extensions and patients without extensions (p=0.0053).
Among the findings of this study were a substantial increase in late device kinking and secondary transfemoral interventions in patients with an iliac device limb extension during the primary operation. The use of aortic cuffs yielded a comparable difference from patients without extensions, although none of these differences reached significance, perhaps because of a small-

### Table 4. Late adverse events, reinterventions, and mortality

<table>
<thead>
<tr>
<th>Four-year cumulative incidence</th>
<th>Group 1 (controls; n = 4932)</th>
<th>Group 2 (proximal aortic cuff; n = 259)</th>
<th>p-value</th>
<th>Group 3 (iliac extensions; n = 1477)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any endoleak</td>
<td>24.2%</td>
<td>32.8%</td>
<td>0.7670</td>
<td>25.9%</td>
<td>0.2444</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>8.1%</td>
<td>17.8%</td>
<td>0.3713</td>
<td>8.1%</td>
<td>0.8347</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>16.5%</td>
<td>17.2%</td>
<td>0.8752</td>
<td>17.4%</td>
<td>0.3477</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>5.8%</td>
<td>7.8%</td>
<td>0.6455</td>
<td>8.8%</td>
<td>0.1845</td>
</tr>
<tr>
<td>Device migration</td>
<td>7.4%</td>
<td>5.4%</td>
<td>0.9010</td>
<td>10.2%</td>
<td>0.0590</td>
</tr>
<tr>
<td>Stenosis/thrombosis</td>
<td>4.3%</td>
<td>5.6%</td>
<td>0.6114</td>
<td>4.2%</td>
<td>0.1201</td>
</tr>
<tr>
<td>Kinking</td>
<td>1.9%</td>
<td>6.6%</td>
<td>0.1137</td>
<td>4.7%</td>
<td>0.0344*</td>
</tr>
<tr>
<td>Aneurysmal growth (≥8 mm)</td>
<td>12.2%</td>
<td>12.1%</td>
<td>0.1636</td>
<td>12.5%</td>
<td>0.0716</td>
</tr>
<tr>
<td>Any secondary intervention</td>
<td>12.6%</td>
<td>20.0%</td>
<td>0.1823</td>
<td>17.3%</td>
<td>0.0036*</td>
</tr>
<tr>
<td>Transfemoral intervention</td>
<td>8.0%</td>
<td>11.2%</td>
<td>0.5717</td>
<td>12.6%</td>
<td>0.0053*</td>
</tr>
<tr>
<td>Extra-anatomic intervention</td>
<td>1.3%</td>
<td>4.8%</td>
<td>0.1751</td>
<td>1.9%</td>
<td>0.7850</td>
</tr>
<tr>
<td>Conversion to open repair</td>
<td>4.9%</td>
<td>8.9%</td>
<td>0.2927</td>
<td>5.1%</td>
<td>0.9402</td>
</tr>
<tr>
<td>Rupture of the aneurysm</td>
<td>1.4%</td>
<td>0.6%</td>
<td>0.9313</td>
<td>3.0%</td>
<td>0.0652</td>
</tr>
<tr>
<td>Mortality</td>
<td>23.1%</td>
<td>27.2%</td>
<td>0.0889</td>
<td>24.9%</td>
<td>0.1234</td>
</tr>
<tr>
<td>AAA-related mortality</td>
<td>4.4%</td>
<td>4.2%</td>
<td>0.9093</td>
<td>6.0%</td>
<td>0.0694</td>
</tr>
</tbody>
</table>

AAA, Abdominal aortic aneurysm. *P < 0.05

### Discussion

Among the findings of this study were a substantial increase in late device kinking and secondary transfemoral interventions in patients with an iliac device limb extension during the primary operation. The use of aortic cuffs yielded a comparable difference from patients without extensions, although none of these differences reached significance, perhaps because of a small-
er size of group 2. Endograft extensions were not associated with an increased incidence of postoperative systemic complications or an increased 30-day or long-term mortality. These observations may be reassuring when the use of extensions seems appropriate.

Some patients in the current study required both an aortic cuff and an iliac limb extension, and this category was considered in the proximal cuff category. To categorize the patients in this way was chosen after a preliminary analysis demonstrated that a number of main outcome parameters (mortality, device-related complications, and need for secondary interventions) in patients with both types of device extensions were closer in agreement with the group in which aortic cuffs were used than in those with iliac limb extensions. Because of this, we included these patients in group 2, in which an aortic cuff was used. Both groups with endograft extensions included patients who had multiple device extensions. However, for practical reasons, we did not further subdivide the patient categories.

In general, the use of a device extension results into an additional graft junction, which has the potential to increase the risk of a type III endoleak.6,7 In this study, there was a trend toward an increased incidence of type III endoleaks in patients with endograft extensions. However, this difference did not reach the level of significance in either group 2 or 3. Although there was a large increase in the incidence of type I endoleaks for aortic cuffs, this also did not reach statistical significance. It has been reported previously that type I and III endoleaks are associated with a significantly increased risk of aneurysm rupture13,14; this emphasizes the need for a prompt repair by reintervention, most notably by a secondary device extension.15

In the long term, the use of iliac endograft extensions was associated with an increased incidence of secondary transfemoral procedures. These secondary interventions were due to the occurrence of an endoleak of either type, endograft migration, stenosis, or thrombosis. The incidence of each of these different device-related complications was not related to the use of extensions. The incidence of device limb kinking was increased in patients with iliac limb extension. However, device kinking was not associated with an increased rate of secondary transfemoral procedures. The all-cause mortality was similar in all patient groups. Although aneurysm-related mortality was significantly higher in patients with iliac limb extensions in univariate analysis, this difference disappeared in multivariate analysis. AAA diameter, neck length, patient age, and fitness were all associated with aneurysm-related mortality in this group of patients.

Device kinking and secondary transfemoral interventions were the only long-term adverse outcomes that were increased in patients with an iliac graft limb extension. The same morphologic factors that necessitate the use of iliac limb extensions may also be responsible for these adverse
effects. Although aortic cuffs demonstrated an influence on kinking or re-intervention similar to that of iliac limb extensions, this correlation was not significant, probably because of group size and fewer follow-up data. With regard to treatment cost, extensions and cuffs increase the expense of the procedure. Having said this, the adverse clinical effects of endograft extensions seemed quite small, and when the need arises, they should be used.

Coexisting iliac aneurysm is observed in approximately 20 to 40% of AAA patients. These patients more frequently require distal extension of the endograft. Iliac graft limb extensions were used when the basic endograft combination was not long enough to exclude the entire aneurysm or when adequate distal sealing was not obtained. In this series, 34% of the patients had some aneurysmal involvement of the iliac arteries, and of this group, 53% (18% of the total population) had extensive aneurysmatic iliac arteries. In 45% of these cases, an iliac endograft extension was deemed necessary. The hypogastric artery was understandably significantly more frequently overlapped and occluded in patients requiring an endograft extension. In most patients, the overlapping was combined with a coil embolization to prevent backflow from the hypogastric artery.

Increased anatomic risk in group 3 also included a larger infrarenal neck and AAA diameter and more angulation of the aortic neck and iliac arteries. It is more difficult to achieve good attachment of the device in tortuous or diseased arteries than in patent or healthy arteries. According to Greenberg et al, patients at both clinical and anatomic risk constitute a particularly appropriate indication for endovascular therapy even when extensions or additional procedures are necessary. One may conclude that the use of aortic or iliac graft limb extensions allows EVAR in aneurysms with a more complex anatomy and widens the indication for EVAR.

In the present series, an aortic cuff or iliac graft limb extension was used in as many as 35% of the patients during the initial procedure. Elkouri et al performed 9 aortic and 39 iliac extensions in their initial 100 patients. Velazquez et al reported a 16% use of aortic cuffs and up to 62% iliac extensions. Studies regarding endovascular extensions are limited and mostly concern extensions during secondary interventions. However, Biebl et al found that proximal cuffs were an effective intraoperative adjunct to achieve proximal seal with similar postoperative survival, type I endoleak rate, and need for secondary interventions compared with patients without proximal aortic cuffs. The only adverse outcome in the category with aortic cuffs was an increased incidence of late endograft migration, which could not be confirmed in the current EUROSTAR study. Alas, the use of iliac graft limb extensions was not investigated by Biebl et al. Weaknesses of the current study included a large interobserver variability and an incomplete dataset, which are commonly seen in multicentre registries.
However, the large number of patients increased the reliability by reducing the effect of variability.

The reasons for the use of extensions were not registered in the EUROSTAR database and could not be analyzed on a patient-to-patient basis, and this is a shortcoming of this analysis. It was also impossible to distinguish between deliberately planned and unplanned extensions. However, this study enabled us to investigate statistical associations of the use of device extensions compared with basic stent-graft combinations. To assess specific technical queries regarding the use of extensions, such as fixation and length of overlapping with the primary stent, additional and more detailed studies will be more suitable.

In conclusion, despite an increased incidence of device kinking and secondary interventions in patients treated with iliac graft extensions, it is encouraging to find that EVAR with the use of additional extensions provides satisfactory procedural results. However, single devices are potentially less vulnerable to late failure, and cuff or limb extensions should only be used when there is a clear indication for them. Extensions may be avoided by accurate preoperative or intraoperative assessment of the aortoiliac anatomic configuration.
References


Aortic cuffs and iliac limb extensions


