Are Fenestrated Grafts Really Necessary: What Is a Short Infrarenal Neck and How Does It Affect the Results of EVAR? A EUROSTAR Study

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Purpose

The applicability of endovascular abdominal aortic aneurysm repair (EVAR) depends on the anatomy of the abdominal aorta and the iliac segment.[1] Adverse anatomy of the iliac arteries usually can be overcome by one or another adjunctive procedure. The main cause for unsuitability of a patient for endovascular treatment of an abdominal aortic aneurysm (AAA) involves the anatomy of the infrarenal neck, in particular the length.[1–4] The risks associated with the use of EVAR in short necks include the occurrence of type I endoleaks, migration of the endografts, thrombosis of the renal arteries, embolization in the renal arteries, and intra-abdominal hemorrhage from excessive manipulation or overdilatation.[5,6]

An infrarenal neck of at least 15 mm is generally accepted as a safe sealing zone for endografts. In case of associated adverse factors regarding the neck such as angulation, mural thrombus or a reversed conical shape, the threshold is 15 mm. With the improvement of endovascular devices and growing experience, the applicability of EVAR to patients with short infrarenal necks increased. The aim of the present assessment is to determine the influence of limited infrarenal neck length on outcome after EVAR with two current stent grafts (Talent and Zenith). The role of fenestrated stent grafts, which are anticipated to improve results in patients with short necks, will be discussed. The patient series that was assessed was retrieved from the European Collaborators Registry on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR). Data collection and follow-up methods have been reported previously.

Results

Between January 1999 and April 2005, 3,897 patients were enrolled in the EUROSTAR registry; 1,580 patients were treated with a Talent and 2,317with a Zenith device. The study cohort was subdivided in three groups according to the proximal neck length. Group A consisted of 3,164 patients with a neck longer than 15 mm, group B of 525 patients with an infrarenal neck of 11 to 15 mm, and group C of 208 patients with a neck ? 10 mm.

Results at 30 Days

A proximal endoleak at completion angiography or within the first postoperative month occurred 3 to 4 times more frequently in patients with ? 10 mm aortic neck length (2.4%, 3.2%, and 10.6% in groups A, B, and C, respectively; $p < .0001$). Type II endoleaks occurred less frequently in group C ($p = .02$). Arterial complications were more frequent in group C (7.2% versus 3.4%, $p = .05$). Systemic complications had a higher prevalence in combined groups B and C (15% versus 11%, $p = .04$). Death at one month had a higher incidence in the combined groups B and C (4.6% versus 2.5%, $p = .04$). Conversion to open surgery was rarely performed. The frequency was similar in the three study groups (0.8, 0.6, and 1.0% in groups A, B, and C, respectively; ns).

Results at Follow-Up

The mean follow-up for the overall study group and the subgroups A, B, and C was 15, 14, and 16 months (ns). Aneurysm-related death was comparable (ns with adjusted analysis) in groups B and C compared with group A (5.5, 4.3, and 3.0%). No differences between subgroups were observed in the rates of conversion to open repair. The rupture rates in the entire group was 0.4%. However, only 1 patient (0.2%) had a post-EVAR rupture in group B and none in group C compared to 12 (0.4%) of the patients with a > 15 mm (group A).

Proximal type I endoleak, which is one of the major adverse outcome events in this assessment, occurred significantly more frequently in patients with shorter necks (8.5% and 10.3% after 48 months in groups B and C, as opposed to 3.2% in group A, $p = .005$, Table 1). Other adverse events, which occurred more frequently in the categories with shorter necks, were combined systemic complications ($p = .01$) and all-cause death (early and late combined, $p = .02$).

Table 1. Complications during Follow-Up

	Group A*		Group B*		Group C*			
Major Complication	Failure after n48 mo	(%)	Failure after n48 mo	(%)	Failure after n48 mo	(%)	Hazard Rate	95% CI	Adjusted† p Value
Findings at assessment									
Proximal endoleak	59	3.2	18	8.5	10	10.3	1.54	1.14-2.08	.005
Midgraft endoleak	92	5.5	12	3.4	1	0.7	0.61	0.38-0.98	.040
Distal endoleak	64	3.8	5	1.2	6	6.5	0.88	0.57-1.35	NS
Reinj sidebranches	302	15.2	41	13.8	14	12.0	0.83	0.67-1.03	NS
Kinking stent graft	37	2.6	2	3.6	0–		0.27	0.08-1.00	NS (.050)
Stenosis	94	4.9	13	3.4	7	4.5	0.95	0.67-1.34	NS
Graft migration	27	2.5	6	2.7	2	1.9	1.09	0.62-1.92	NS
Systemic compl.	180	10.4	37	14.4	22	20.5	1.31	1.07-1.60	.010
Sec. intervention									
Transfemoral	103	6.5	12	5.1	8	11.0	0.93	0.67-1.30	NS
Transabdominal	21	1.9	5	4.5	1	0.7	1.07	0.55-2.10	NS
Extra-anatomic	30	1.0	7	2.3	2	0.9	1.06	0.61-1.82	NS
AAA growth ? 8mm	153	19.8	24	18.8	9	13.9	0.95	0.73-1.25	NS
Death 265	20.3	61	24.7	31	33.4		1.22	1.04-1.43	.016
Conversion	45	3.2	7	3.0	3	6.2	1.02	0.62-1.67	NS

CI = confidence interval; NS = not significant.
*Group A had neck ? 15 mm; group B had neck 1-15 mm; group C had neck < 10 mm.
†ASA, hypertension, renal and pulmonary impairment, unfitness for open surgery or anesthesia, maximal aneurysmal diameter, and infrarenal neck diameter.

Discussion

The proportion of patients with AAAs for whom treatment by EVAR is considered suitable has risen from a reported 20% in the early experience of this technique,[7] to 45 to 80%.[8–10] Adverse anatomy of the infrarenal neck of the aneurysm is the predominant reason for exclusion from EVAR candidacy. It is generally considered that at least 15 mm of nonaneurysmal vessel proximal to the aneurysm is needed for secure graft fixation. More recently this threshold has been relieved to a minimum of 10 mm by some device companies, provided that the neck is not angulated, has no thrombus, and has a cylindrical configuration. Several of these prerequisites have been challenged. In selected patients

with high-risk for open procedures, necks wider than 30 mm and with some thrombus had comparable results with other patients.[11,12] In the present report, we discuss the outcome in patients with shorter necks than the recommended 15 or 10 mm.

Patients in groups B and C had poorer physiologic characteristics than patients with suitable necks (group A) as indicated by a higher incidence of ASA > 3, manifest hypertension, poor pulmonary function, renal impairment, and most importantly a higher 30-day mortality. The lack of an adjusted overall (early and late) higher aneurysm-related mortality is convincing evidence that short necks in high-risk patients can be safely treated by EVAR.

Procedural outcome favors adhering to the accepted guidelines of a neck length of 15 mm. The risk of type I proximal endoleak is significant. In 11% in group C a proximal type I endoleak was observed, which was over four times as high as in group A at one month. At 4-years of follow-up the proximal endoleak rate was three times as high. Also the overall all-cause death rate was higher in short neck patients. However, the adjusted aneurysm-related death rate was not significantly worse. Fourteen patients had neck lengths of 5 mm or less. Fenestrated endografts enjoy an immense interest at the present time, as they may present a noninvasive solution to improve the durability of EVAR in patients with short necks. However, the efficacy of fenestrated grafts needs to be demonstrated in larger series and indications for its use delineated. Despite reported excellent early results one may ask whether comparable outcome might have been obtained at least in a proportion of these patients by using a regular stent graft. In the present series recorded in the EUROSTAR series, necks < 10 mm did well after regular endograft implantation. Fenestrated endografts do require an infrarenal neck. Complete absence of an infrarenal neck or true suprarenal aneurysms require branch vessel technology, which fall outside the present discussion.

Two recent reports with considerable detail will be used for comparison.[13,14] In the first, of all 18 patients, 17 had a neck length ? 6 and 11 ? 8 mm. In the second study, 24 patients had a neck length < 10 mm and 12 had 10 to 15 mm. The type I proximal endoleak rate after 1 month (mean follow-up time 9 months in both studies) was 1 of 18 (5%) in the first and 1 of 32 (3%) in the second study. This is a lower rate than in the present EUROSTAR recorded short neck cohort in which an 11% endoleak rate was observed at 1 month. On the other hand, regular stent-graft use is simpler and less demanding for the high-risk patients who are included in this category. In addition, regular endografts involve no issues of ongoing risks from the site of stented visceral vessels.

Conclusion

The advantage of fenestrated endografts in patients with short infrarenal necks needs to be demonstrated in a comparative study, in which patients with short necks treated by regular stent grafts constitute the control group.

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