Original Article

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Comparable mid-term survival in patients undergoing elective fenestrated endovascular aneurysm repair and endovascular aneurysm repair for abdominal aortic aneurysm

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Abstract

Objective: To evaluate mid-term survival in patients undergoing elective fenestrated endovascular aneurysm repair and standard endovascular aneurysm repair for abdominal aortic aneurysm.

Methods: Consecutive patients treated from 2007 to 2011 with elective fenestrated endovascular aneurysm repair (n = 81) and endovascular aneurysm repair (n = 201) were evaluated concerning age, cardiovascular medication, comorbidities, and mid-term mortality.

Results: Patients in the elective fenestrated endovascular aneurysm repair group were younger than the endovascular aneurysm repair group (p = 0.006). In comparison with the endovascular aneurysm repair group, a lower proportion of patients in the elective fenestrated endovascular aneurysm repair group had diabetes (p = 0.013) and anemia (p = 0.003), and a higher proportion had arterial hypertension (p = 0.009). When entering age, endovascular aneurysm repair or fenestrated endovascular aneurysm repair operation, diabetes, anemia, and hypertension in a Cox regression model, only age (hazard ratio: 1.07; 95% confidence interval: 1.03–1.11; p < 0.001) was a risk factor for mid-term mortality.

Conclusion: Careful patient selection and medical optimization resulted in comparable mid-term survival in patients undergoing elective fenestrated endovascular aneurysm repair and endovascular aneurysm repair.

Keywords

Abdominal aortic aneurysm, elective fenestrated endovascular aneurysm repair, endovascular aneurysm repair, mid-term mortality

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Introduction

Patients with abdominal aortic aneurysm (AAA) have an increased cardiovascular mortality.1 Careful preoperative patient selection is therefore important,^{2,3} taking into account risk factors for atherosclerosis balanced against the risk of aneurysm rupture.4-7 The Vascular Center in Malmö practices an individual evaluation by a specialist in vascular medicine prior to both elective fenestrated endovascular aneurysm repair (FEVAR) and standard endovascular aneurysm repair (EVAR). The major aims of this assessment are evaluation of eligibility8,9 for surgery from a medical perspective, identification of previously unknown medical illness, and pharmacological optimization, resulting in lower preoperative costs and a pharmacological optimization.¹⁰ The FEVAR method enables surgical treatment in a patient group that, because of comorbidities, may not be suitable for open repair.11-14 In comparison with patients treated with EVAR, however, patients who require FEVAR have a more advanced aneurysm disease, and the FEVAR method is also a more technically demanding procedure that may be associated with a higher risk of perioperative morbidity and mortality. The larger extent of aneurysmal disease in FEVAR patients per se may also perhaps indicate a higher burden of generalized atherosclerosis associated with a decreased midterm survival. Hence, a more stringent preoperative patient selection in the FEVAR group might therefore be motivated. To elucidate these questions, we have evaluated differences

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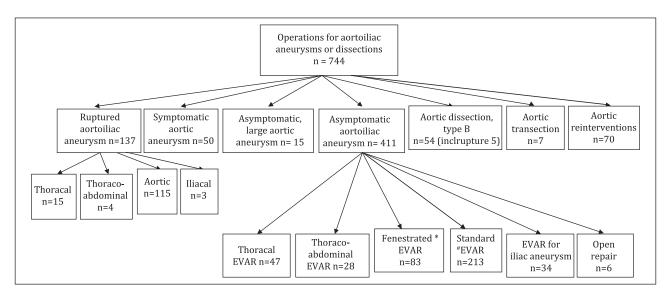


Figure 1. Flow chart over operations for aorto-iliac aneurysms and dissections during the study period. EVAR: endovascular aneurysm repair.

*Two emergency cases.

#Eight pseudoaneurysms in the abdominal aorta, one additional embolization to the inferior mesenteric artery, three not evaluated by a vascular physician prior to EVAR.

in comorbidities, age, medication, and mortality in patients undergoing elective FEVAR and EVAR.

Methods

Patients

The Vascular Center Malmö-Lund is a tertiary referral center for patients with vascular disease. Patient data were retrieved from the prospective database for endovascular interventions and from patient records. This study comprised consecutive patients undergoing elective FEVAR for complex (juxtarenal) nonruptured AAA (Zenith® stent grafts; Cook Europe A/S, Bjaeverskov, Denmark) (n = 81), and standard EVAR (Zenith stent grafts; Cook Europe A/S) for infrarenal nonruptured AAA (n = 201), between February 2007 and May 2011 (Figure 1). Necks < 8 mm in length, conical in shape (>15%) diameter change/10 mm) or heavily thrombus lined were common indications for FEVAR. The fenestrated stent graft is a modular stent graft with fenestrations, sometimes with a scallop, located on the most proximal tubular portion of the stent graft. Fenestrations were designed to match the locations of the target visceral artery ostia. The target visceral arteries were catheterized through the fenestrations after partial deployment of the proximal tubular graft using access from the contralateral common femoral artery. The stent graft repair was then completed by extension with a bifurcated main body stent graft overlapping into the tubular stent graft and extension stent graft limbs into the iliac arteries bilaterally. 15 During the study period, target visceral arteries were routinely stent grafted through the fenestrations and scallops. Prior to operation, a specialist in vascular medicine evaluated patient eligibility for surgical intervention in both groups in accordance with recommendations from the European Society of Cardiology, 16 concerning hypertension, cardiopulmonary, and renal function deficits. Antiatherosclerotic and antihypertensive medication was evaluated and optimized in each patient. Simvastatin was provided 40 mg once daily to reach recommended target values.¹⁷ Metoprolol was given 50 mg once daily in the absence of contraindications such as bradycardia, atrioventricular (AV) block, or severe obstructive pulmonary disease. Echocardiography, spirometry, cardiopulmonary exercise testing, or stress echocardiography were performed in selected cases according to recommendations. 16 Two out of 83 (2.4%) FEVAR patients were excluded from analysis because preoperative evaluation was impossible due to emergency operation, and 23 of 224 (10.3%) EVAR patients were excluded from the comparative analysis because preoperative evaluation had not been performed. The Research Ethics Committee, University of Lund, granted an ethical approval of this study (2012/638).

Electrocardiography

Preoperative electrocardiography (ECG) at rest was performed to evaluate signs of atrial fibrillation and myocardial ischemia. Myocardial ischemia on ECG was defined as presence of pathological Q/QS patterns, deep or moderate T-wave inversion, ST-segment depression, or complete left bundle branch block. 18,19

Echocardiography

As part of the preoperative evaluation, transthoracic echocardiographic examinations were carried out with Sonos 2500 or Sonos 5500 (Philips, Eindhoven, the Netherlands).

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Left ventricular ejection fraction (EF) was assessed visually by qualified personal. 20,21 EF was graded either as normal (\geq 55%), mildly (45%–50%), moderately (35%–40%), or severely reduced (<35%). 20,21

Evaluation of renal function

Glomerular filtration rate (GFR) was calculated in accordance with the Cockroft–Gault formula taking into account serum creatinine, age, weight, and gender.²² The National Kidney Foundation guidelines were used, grading GFR levels for different stages of chronic kidney disease:^{23,24} Stage I defined as GFR > 90 mL/min/1.73 m² (normal or increased GFR), stage II as GFR 60–89 mL/min/1.73 m² (minute decrease in GFR), stage III as GFR 30–59 mL/min/1.73 m² (moderate decrease in GFR), stage IV as GFR 15–29 mL/min/1.73 m² (substantial decrease in GFR), and stage V as GFR < 15 mL/min/1.73 m² (end-stage renal disease in need of dialysis).

Spirometry

Spirometry was performed in accordance with the European Respiratory Society standards.²⁵ The majority of the spirometries were performed at the Vascular Center in Malmö. The spirometer (Microlab 3000 or EasyOne; Microlab 3000, CareFusion, Hoechberg, Germany, and EasyOne, ndd Medical Technologies, Inc., Andover, MA, USA) was utilized under the supervision of a physiotherapist, measuring forced expiratory volume in 1 s (FEV1) and forced vital capacity (FVC). FEV₁% was defined as the percentage of measured-to-predicted normal FEV1, and FVC% as measured-to-predicted normal FVC.26-28 The Global Initiative for Chronic Obstructive Lung Diseases (GOLD) guidelines were used to evaluate the presence and severity of chronic obstructive pulmonary disease (COPD).²⁹ COPD was defined as present if FEV₁/FVC < 70% (age < 65 years) or $FEV_1/FVC < 65\%$ (age ≥ 65 years). Stage 1 (mild) was defined as FEV₁ \geq 80%, stage 2 (moderate) as FEV₁ \geq 50% to <80%, stage 3 (severe) as $FEV_1 \ge 30\%$ to <50%, and stage 4 (very severe) as FEV₁ < 30% of predicted value.

Follow-up

All patients were monitored from operation until 1 May 2013 or until death. Median time of follow-up was 40 months (interquartile range (IQR): 28–61 months) in the FEVAR group and 43 months (IQR: 30–55 months) in the EVAR group. The Swedish Population Registry was used to retrieve mortality data.

Other definitions

Cerebrovascular disease was defined as either a history of stroke (bleeding or infarction) or transient ischemic attack (TIA). Ischemic heart disease was defined as previous myocardial infarction, angina pectoris, coronary artery bypass grafting, or percutaneous coronary angioplasty. Diabetes mellitus was defined as ongoing antidiabetic treatment (diet, oral hypoglycemic agents, or insulin), and anemia as hemoglobin < 134 g/L in men and <117 g/L in women. The maximal AAA diameter was defined as the shortest transverse diameter of the AAA at its widest portion. Hypertension was defined as ongoing antihypertensive medication and uncontrolled hypertension as systolic blood pressure > 140 mm Hg or diastolic blood pressure > 90 mm Hg (systolic blood pressure > 130 mm Hg or diastolic blood pressure > 80 mm Hg in patients with diabetes mellitus). Active smoking was defined as current tobacco consumption or tobacco consumption < 1 year before surgery.

Statistical methods

SPSS 17.0 software (SPSS, Inc., Chicago, IL) was used for data managing and statistical analysis. Differences in proportions were evaluated using the chi-square test or Kendall tau-b test. Mann–Whitney U tests were used when comparing groups using continuous variables. Survival curves for groups 1 and 2 were constructed according to the Kaplan–Meier method and Life table analysis. Log rank test was used in the overall comparison of survival curves. A multivariate Cox regression analysis was performed for identification of independent variables associated with mid-term mortality and expressed as hazard ratio (HR) with 95% confidence interval (CI). P < 0.05 was considered as significant.

Results

Comparison of patient characteristics between groups

Patients in the FEVAR group (median age: 72 years (IQR: 67–75 years)) were significantly younger than the EVAR group (75 years (IQR: 69–78 years), p = 0.006). There was no significant difference between the two groups concerning gender, smoking, or age of 80 years and above (Table 1).

Maximal aneurysm size was equal in the two groups (p = 0.15). The percentages of fenestrations for renal and superior mesenteric arteries and scallops for the celiac trunk in the FEVAR patients are shown in Table 2.

A larger proportion of patients in the FEVAR group (n = 76 (94%)) had hypertension in comparison with the EVAR group (n = 164 (82%); p = 0.009). A larger proportion of the patients in the EVAR group (14%, n = 28) suffered from diabetes mellitus in comparison with the FEVAR group (n = 3 (4%); p = 0.013, Table 1).

There was no difference between the groups in renal function (p = 0.47). A higher percentage of the patients in the EVAR group suffered from anemia, in comparison with the FEVAR group ($n = 71 \ (35\%)$ vs. $n = 14 \ (17\%)$; p = 0.003, Table 2).

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Table 1. Patient variables and comorbidities in patients undergoing FEVAR and EVAR.

Variable	FEVAR N (%)	EVAR N (%)	p-value	
Age ≥ 80 years	9 (11)	38 (19)	0.11	
Women	18 (22)	30 (15)	0.14	
Arterial hypertension	76 (94)	164 (82)	0.01	
Active smoking	38 (47)	74/199 (37)	0.28	
Diabetes mellitus	3 (4)	28 (14)	0.01	
Ischemic heart disease	46 (57)	93 (46)	0.11	
Cerebrovascular disease	14 (17)	34 (17)	0.94	
Peripheral arterial occlusive disease	11 (14)	34 (17)	0.49	
All patients	81	201		

EVAR: endovascular aneurysm repair; FEVAR: fenestrated endovascular aneurysm repair.

Comparison of patient medication between groups

At admission, there were no significant differences between the two groups regarding the proportions of patients with ongoing treatment with antiplatelet drugs, lipid-lowering agents, and vitamin K antagonists (Table 3).

Comparison of reinterventions between groups

There was no significant difference between the FEVAR and EVAR groups concerning reintervention rate (16/81 (20%) and 28/201 (14%); p = 0.22) or in the number of reinterventions performed per patient (p = 0.14).

Comparison of mortality between groups

There was no significant difference between the FEVAR and EVAR groups in crude 30-day (2/81 (2.5%) and 3/200 (1.5%); p = 0.56), 1-year (3/81 (3.7%) and 9/200 (4.5%); p = 0.77), and 2-year mortality (8/81 (9.9%) and 19/200 (9.5%); p = 0.92). Mid-term mortality at end of study was 16/81 (19.8%) in the FEVAR group and 48/200 (24.0%) in the EVAR group (p = 0.47, Figure 2). When entering age, FEVAR or EVAR operation, diabetes mellitus, anemia, and hypertension in a Cox regression model, only age (HR: 1.07, 95% CI: 1.03–1.11; p < 0.001) was found as an independent risk factor for mid-term mortality.

Discussion

The fact that risk of AAA rupture increases with maximal aneurysm diameter has to be weighed against the perioperative risk of surgery and mid-term outcome after endovascular therapy.^{5,30} Because of the increased burden of overall cardiovascular morbidity in patients suffering from aortic

Table 2. Results of investigation prior to FEVAR and EVAR.

Variable	FEVAR	EVAR	p-value	
	N (%)	N (%)		
Maximal aortic aneurys	sm diameter (m	m)		
40–54	12 (15)	29 (14)		
55–64	48 (59)	98 (49)		
≥65	21 (26)	74 (37)	0.15	
Number of stent graft	fenestrations			
Right renal artery	77 (95)	_		
Left renal artery	74 (91)	_		
Superior	16 (20)	_		
mesenteric artery				
Truncus coeliacus (scallops)	5 (6)	_	-	
Electrocardiographic (E	ECG) findings			
Ischemia	41 (51)	77/190 (41)	0.10	
Atrial fibrillation	4 (5)	18/197 (9.6)	0.24	
Echocardiographic find	ings			
Ejection fraction stag	ging			
Normal	40/58 (69)	96/125 (77)		
Slightly	9/58 (16)	16/125 (13)		
decreased				
Moderately decreased	4/58 (7)	7/125 (6)		
Very decreased	5/58 (9)	6/125 (5)	0.25	
Spirometric findings				
COPD by definition	15/33 (45)	59/121 (49)	0.78	
Stages of chronic kidne	ey disease			
Stage I	16 (20)	46/198 (23)		
Stage II	33 (41)	72/198 (36)		
Stage III	29 (36)	70/198 (35)		
Stage IV	2 (2)	6/198 (3.0)		
Stage V	I (I)	4/198 (2.0)	0.93	
Stage ≥ 3 chronic	32 (40)	80/198 (40)	0.85	
kidney disease	(/	` /		
Anemia	14 (17)	71 (35)	0.003	
All patients	81	201		

EVAR: endovascular aneurysm repair; FEVAR: fenestrated endovascular aneurysm repair; COPD: chronic obstructive pulmonary disease.

Table 3. Medication at admission in patients undergoing FEVAR and EVAR.

Variable	FEVAR N (%)	EVAR N (%)	p-value
Any antiplatelet drug	69 (85)	174 (87)	0.76
Lipid-lowering agent	77 (95)	183 (91)	0.26
Vitamin K antagonist	9 (11)	17 (8.5)	0.49
All patients	81	201	

EVAR: endovascular aneurysm repair; FEVAR: fenestrated endovascular aneurysm repair.

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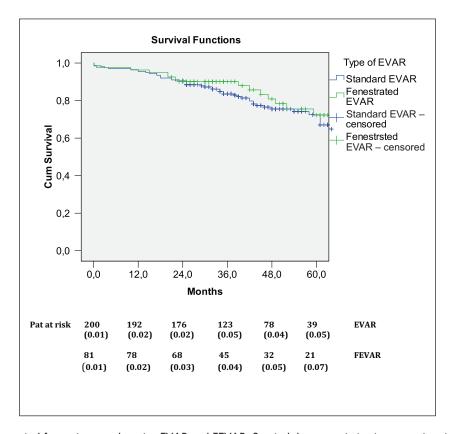


Figure 2. Long-term survival for patients undergoing EVAR and FEVAR. Survival data are missing in one patient in the EVAR group. Numbers below axis denote the patients at risk at respective time point. Standard error of cumulative proportion of patient survival at end of interval is shown within parenthesis. The tick marks indicate censored data. EVAR: endovascular aneurysm repair; FEVAR: fenestrated endovascular aneurysm repair.

aneurysm, careful patient selection and medical optimization prior to elective FEVAR and EVAR is of utmost importance.^{3–5} This highlights the importance of current recommendations on control of cardiovascular risk factors in AAA patients, both before and after interventional treatment.³¹ The present study demonstrated important differences in comorbidities and patient characteristics between the two groups. In comparison with the EVAR group, patients in the FEVAR group were younger and suffered to a lesser extent from diabetes mellitus and anemia. On the contrary, the FEVAR group had a higher proportion of patients with hypertension. The apparently more fit patients in the FEVAR group seems to reflect a more strict preoperative patient selection in the FEVAR group caused by a perceived increased risk of postoperative morbidity and mortality.

FEVAR enables surgical treatment in a patient group that, because of comorbidities, may not be suited for open repair. 11-13 It has been shown that FEVAR for juxtarenal aneurysms and EVAR for infrarenal aneurysms are associated with reduced short-term mortality in comparison with open repair. 14,32,33 In the present study, comparable short- and mid-term survival was found in the FEVAR and EVAR groups. This might, again, be explained by the more stringent patient selection in the FEVAR group. In addition, there

was no difference in reintervention rate between the EVAR and FEVAR groups. Crude 2-year mortality data in the FEVAR patients in the present study was 10%. This is in concordance with a previous prospective study including 38 patients undergoing FEVAR, with median time of follow-up of 25 months, in which all-cause mortality was 13%. ³⁴ Crude 30-day mortality in the EVAR group presented is in concordance with the results of previous large randomized trials. ^{33,35-37} According to the Kaplan–Meier curve presented in this study, mid-term mortality in the EVAR group was similar to the mortality in previous large randomized trials. ^{33,35-38}

This study demonstrated a high cardiovascular medication coverage in both the FEVAR and the EVAR groups at admission. There was no significant difference between the groups regarding the number of patients with ongoing treatment with antiplatelet drugs, lipid-lowering agents, or vitamin K antagonists. Pharmacological optimization is considered an essential part of the preoperative evaluation in AAA patients and is at our unit performed by a specialist in vascular medicine. Such preoperative individual assessment prior to elective AAA repair has been shown to uncover a substantial proportion of patients with suboptimal cardiovascular medication and furthermore to decrease postoperative

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short- and mid-term morbidity due to better cardiopulmonary medication. 5,6,10,39

Besides its retrospective design, one limitation of the study was that the percentage of patients turned down for both FEVAR and EVAR, and the reasons why during the study period were unknown. Such information would have strengthened this study. Another study limitation was that patients were postoperatively referred to general health care physicians. Therefore, we do not know to what extent the optimized cardiovascular medication in each patient at discharge was maintained, a factor that might well influence postoperative mortality.

Conclusion

Mid-term survival in patients with juxtarenal aneurysmal disease undergoing elective FEVAR was comparable to patients undergoing elective standard EVAR. This might be explained by careful patient selection and medical optimization.

Declaration of conflicting interests

No conflicts of interest exist for any of the authors.

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