Editor's Choice – Thirty day Outcomes and Costs of Fenestrated and Branched Stent Grafts versus Open Repair for Complex Aortic Aneurysms

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WHAT THIS PAPER ADDS

The use of fenestrated and branched endovascular repair for complex aortic aneurysms is currently limited by the high unit cost of the custom made devices and the lack of head to head trial evidence of a better outcome compared with open surgical repair. In addition, there has been no economic evaluation of f/b EVAR in the treatment of complex aortic aneurysms. The results of this study are a first step towards helping clinicians decide which patients should benefit from these expensive and innovative devices.

Objective: To compare 30 day outcomes and costs of fenestrated and branched stent grafts (f/b EVAR) and open surgery (OSR) for the treatment of complex abdominal aortic aneurysms (AAA) and thoraco-abdominal aortic aneurysms (TAAA).

Methods: The multicenter prospective registry WINDOW was set up to evaluate f/b EVAR in high risk patients with para/juxtarenal AAA, and infradiaphragmatic and supradiaphragmatic TAAA. A control group of patients treated by OSR was extracted from the national hospital discharge database. The primary endpoint was 30 day mortality. Secondary endpoints included severe complications, length of stay, and costs. Mortality was assessed by survival analysis and uni/multivariate Cox regression analyses using pre- and post-operative characteristics. Bootstrap methods were used to estimate the cost-effectiveness of f/b EVAR versus OSR.

Results: Two hundred and sixty eight cases and 1,678 controls were included. There was no difference in 30 day mortality (6.7% vs. 5.4%, $p = 0.40$), but costs were higher with f/b EVAR (€38,212 vs. €16,497, $p < .001$). After group stratification, mortality was similar with both treatments for para/juxtarenal AAA (4.3% vs. 5.8%, $p = .26$) and supradiaphragmatic TAAA (11.9% vs. 19.7%, $p = .70$), and higher with f/b EVAR for infradiaphragmatic TAAA (11.9% vs. 4.0%, $p = .010$). Costs were higher with f/b EVAR for para/juxtarenal AAA (€34,425 vs. €14,907, $p < .0001$) and infradiaphragmatic TAAA (€37,927 vs. €17,530, $p < .0001$), but not different for supradiaphragmatic TAAA (€54,710 vs. €44,163, $p = .18$).

Conclusion: f/b EVAR does not appear justified for patients with para/juxtarenal AAA and infradiaphragmatic TAAA fit for OSR but may be an attractive option for patients with para/juxtarenal AAA not eligible for surgery and patients with supradiaphragmatic TAAA. Clinical Trial Registration: http://www.clinicaltrials.gov/ct2/show/NCT01168037; identifier: NCT01168037 (WINDOW registry).
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INTRODUCTION

The benefits of standard endovascular (EVAR) over open repair (OSR) for infrarenal abdominal aortic aneurysms (AAA) have been documented both in terms of 30 day mortality and length of stay (LOS) by randomized controlled trials (RCT) and meta-analyses.[1–9] However, standard stent grafts are not adapted to complex aortic aneurysms, including AAAs with short or absent neck and/or involving visceral arteries, and thoraco-abdominal aneurysms (TAAA). Fenestrated and branched stent grafts (f/b EVAR), which

allow revascularization of thoracic, visceral, and renal arteries, have been developed to fill that gap. Initial reports have demonstrated feasibility and efficacy of this technique;[10–12] however, no head to head trial has ever been carried out to compare f/b EVAR with OSR. The very high unit cost of the custom made f/b stent graft also needs to be considered. While several in trial analyses and models have compared the cost-effectiveness of EVAR and OSR in AAA,[2,4,7–9] there has not, to the authors' knowledge, been an economic evaluation of f/b EVAR in the treatment of complex aortic aneurysms. The objective of the present study was to compare outcomes and costs of f/b EVAR with those of OSR for complex AAA or TAAA.

MATERIALS AND METHODS

Study design

WINDOW is a multicenter prospective registry for patients treated with f/b EVAR, which has been described previously.[13] Only 30 day data are available at this stage. A control group of patients treated with OSR was extracted from the national hospital discharge database (Programme de médicalisation des systèmes d'information) for the years 2010–2012. This database records all acute care hospital admissions using diagnostic related groups (DRG), along with other variables such as diagnoses (primary and secondary, using the 10th edition of the International Classification of Diseases [ICD-10]), surgical procedures, and LOS. Record linkage is performed at national level. In addition, a probabilistic analysis of the national hospital discharge database was performed to consolidate the information available in cases' case report forms (CRF) and for comparison purposes.

The protocol was approved by the institutional review board of Hôtel Dieu Hospital (Paris), and all cases signed a written consent to participate in the registry. The French Data Protection Authority granted access to control data.

Study population

Selection criteria of patients with complex AAA or TAAA treated by f/b EVAR have been described previously.[13] Briefly, patients were included if they were considered at high risk for open surgery and had an AAA >50 mm in men (45 mm in women), with or without thoracic aortic aneurysm >55 mm (50 mm in women), and with an infrarenal neck <10 mm in length or aneurysm extending to the suprarenal aorta. Patients were divided into three groups according to type of aneurysm: para/juxtarenal AAA, infradiaphragmatic TAAA, and supradiaphragmatic TAAA. Control participants were extracted by combining primary diagnosis and procedure codes and were then assigned to their anatomical groups based on those same criteria (see Appendix 2, supplementary material). Emergent and ruptured aneurysms as well as aortic dissections were excluded from both groups.

Comorbidities at baseline were drawn from the CRF and the discharge database for cases, and from the discharge database for controls. To reduce discrepancies caused by the different recording methods, data from the discharge database were used for both cases and controls when comparing baseline characteristics between treatment groups. The Charlson index[14] was calculated to assess patient severity at inclusion. This was preferred to other indexes — including the Medicare score[15] — because it could be scored using hospital discharge data and has been validated for use with a claims database, including the French hospital discharge database.[16,17]

Study endpoints

The primary clinical endpoint was 30 day all cause mortality. Secondary endpoints included major complications (myocardial infarction, stroke, permanent hemodialysis, major amputation, paraplegia, and bowel infarction) as well as vascular repeat interventions, LOS (both in hospital and in the intensive care unit), re-admissions within 30 days (identified using record linkage and each patient's national anonymized identification number), and costs. Endpoints were recorded in the CRF and checked against the discharge database for cases and retrieved from the discharge database for controls.

Economic evaluation

Only hospital (acute) resources were considered. Procedure costs for f/b EVAR were obtained with a bottom up micro-costing approach that identified all relevant cost components of the procedure and valued each of those components for all individual patients[18] using the following variables: duration of the procedure, staff present, medical devices used, and type of operating theatre. Graft components and other supplies for each patient were recorded in the CRF or retrieved from the surgical ward databases. The prices of the medical devices used during the procedure were obtained from each center and are in 2012€ (Appendix 3, supplementary material). Hospitalization costs were estimated by adjusting the 2012 average national cost of each patient's DRG with their actual LOS and resources used during their hospitalization (intensive care, blood transfusion, hemodialysis, etc.). This average cost was drawn from the national hospital cost study, which is undertaken yearly by the Ministry of Health and records actual costs for all patients admitted to a sample of hospitals based on a combination of itemized resources and activity based costing. This allowed exclusion of items relative to surgery from patients' hospital costs so as to not count this twice.

For controls, procedure costs were not estimated with a micro-costing as there was no access to individual patients and therefore this could not be performed. Those costs are included in controls' hospital costs, which — like cases — were taken from the national hospital cost study and adjusted with LOS and other resources used to ensure comparability between the two groups. No tariffs were used at any point in the cost computation as this is not recommended.

Finally, transfers to another acute care hospital and repeat admissions within 30 days of the initial intervention were also included in cost computations using the same methodology.

A cost-effectiveness analysis was conducted to assess incremental costs per incremental death averted with f/b EVAR versus OSR.

Statistical analysis

The primary goal of the study was to test the null hypothesis that 30 day survival was identical with f/b EVAR and OSR. Proposed sample sizes of 200 (f/b EVAR) and 600 (OSR), with a total number of required events of 20 and a 0.05 level two sided log-rank test for equality of survival curves, had 95% power to detect the difference between the OSR group proportion at time t of 0.900 and the fenestrated stent grafts group proportion at time t of 0.970 (hazard ratio of 3.459).

Analyses were performed for the entire population and for the three prospectively defined groups. Dichotomous variables were compared using the chi-square test or the Fisher exact test while continuous variables, described by mean and standard deviation (SD), were assessed with a Student t test. Kaplan–Meier survival analyses were carried out and the log-rank test was calculated. Univariate and multivariate analyses were also performed on 30 day mortality using a Cox model. Variables were included in the multivariate model if they were significant in the univariate analysis ($p < .2$). The final model was identified using a descending stepwise method with a 0.05 significance level. Age, sex, group, and Charlson index were forced. Hazard ratios (HR) and their 95% confidence intervals (95% CI) were calculated. Multiple sensitivity analyses were performed to test the model (presented in Appendix 4, supplementary material, along with their results).

A concordance analysis using the Kappa test was performed to compare the data present in the CRF and in the national discharge database for cases. Finally, bootstrap methods were used to examine the distribution of the incremental cost and incremental effectiveness across the cost-effectiveness plane for the three subgroups.

Analyses were performed using Excel (2010, Microsoft) and SAS (9.3, SAS corp. NC) software.

RESULTS

Patient characteristics

Three hundred and twenty five patients were assessed for eligibility for the WINDOW registry. There were 10 deaths before intervention: rupture while waiting for the custom made device in four patients, other causes in five, unknown in one. They were excluded from the final analysis, which included 268 patients effectively treated by f/b EVAR as it was not possible to identify controls who had similarly died before their scheduled surgery. Control participants treated with OSR (1,678) were collected from the national discharge database during the same period of time. Cases were significantly older than controls: 71.6 (8.5) versus 69.2 (8.9)

years ($p < .001$). There was no difference in Charlson index, but all comorbidities were more frequent in cases when comparing CRF with the national discharge database. However, when the national discharge database was used for both cases and controls, only dyslipidemia, hypertension, chronic pulmonary disease, and congestive heart failure were significantly more common in f/b EVAR cases, while peripheral arterial occlusive disease was more common in controls (Table 1). On average 6.2 (2.4) devices were implanted in patients treated by f/b EVAR.

Costs

The costs of the initial hospitalization were estimated at €37,708 (23,196) on average for a patient treated with f/b EVAR vs. €16,255 (16,660) for a patient treated with OSR ($p < .001$). The cost of medical devices used in f/b EVAR

Table 1. Patient characteristics at baseline, using data from the national discharge database for both cases and controls.

	f/b EVAR (n = 268[a])	OSR (n = 1,678)	p[b]
Age, y, mean (SD)	71.6 (8.5)	69.2 (8.9)	<.001
Men, n (%)	250 (93.3)	1,539 (91.7)	.38
Type of aneurysm, n (%)			
Para/juxtarenal AAA	184 (68.6)	1,382 (82.4)	<.001
Infradiaphragmatic TAAA	42 (15.7)	225 (13.4)	
Supradiaphragmatic TAAA	42 (15.7)	71 (4.2)	
Comorbidities, n (%)			
Hypertension	161 (61.5)	858 (51.1)	.002
Hyperlipidemia	111 (42.4)	579 (34.5)	.013
Diabetes	38 (14.5)	210 (12.5)	.37
Coronary artery occlusive disease	24 (9.2)	138 (8.2)	.61
History of stroke	7 (2.7)	35 (2.1)	.54
Peripheral arterial occlusive disease	21 (8.0)	243 (14.5)	.005
Cardiac insufficiency	19 (7.3)	53 (3.2)	.001
Arrhythmia	19 (7.3)	139 (8.3)	.57
Chronic pulmonary disease	61 (23.3)	241 (14.4)	<.001
Chronic renal disease	23 (8.8)	104 (6.2)	.12
Charlson index, n (%)[c]			
0	115 (43.9)	751 (44.8)	.22
1	60 (22.9)	461 (27.5)	
2	47 (17.9)	249 (14.8)	
3	21 (8.0)	136 (8.1)	
4	11 (4.2)	56 (3.3)	
≥ 5	8 (3.1)	25 (1.5)	
Missing	6 (2.2)	0 (0.0)	

y = years.
[a] n = 262 for comorbidities (six patients could not be found in the discharge database).
[b] Chi-square test for dichotomous variables and Student t test for continuous variables.
[c] Charlson index: includes myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, rheumatologic disease, peptic ulcer disease, mild liver disease, diabetes without chronic complications, diabetes with chronic complications, hemiplegia or paraplegia, renal disease, any malignancy, moderate or severe liver disease, metastatic solid tumor, HIV/AIDS.[14]

accounted for the difference, as it amounted to €21,905 (3,337). There was no difference in readmission costs: €5,985 (5,969) for f/b EVAR cases vs. €4,570 (4,886) for controls, $p = .248$. Total costs at 30 days (or at patient discharge) were €38,212 (23,252) per case and €16,497 (16,695) per control ($p < .001$).

While costs were significantly higher for cases in para/juxtarenal AAA and infradiaphragmatic TAAA, there was no significant difference in costs between f/b EVAR and OSR in supradiaphragmatic TAAA (Table 2). Overall, patients with supradiaphragmatic TAAA had higher costs than patients with para/juxtarenal AAA and infradiaphragmatic TAAA in both treatment groups.

Mortality

At 30 days, 18 patients treated with f/b EVAR (6.7%) and 90 patients treated with OSR (5.4%) had died ($p = .40$). Kaplan–Meier survival analysis at 30 days found no difference in survival rates between cases and controls (93.3% vs. 94.6%, $p = .48$). There was no difference in survival for patients with para/juxtarenal AAA (95.7% vs. 94.2%, $p = .26$) and supradiaphragmatic TAAA (88.1% vs. 79.6%, $p = .70$), while cases with infradiaphragmatic TAAA had a worse survival than controls (88.1% vs. 95.0%, $p = .010$).

Univariate Cox regression analysis found a significant association between 30 day mortality and age, type of aneurysm, and all complications except amputations. Multivariate analysis confirmed the absence of a significant impact of treatment on 30 day mortality (HR 0.97, 95% CI 0.57–1.66) and a significant association with age, type of aneurysm, and some of the complications (Table 3, sensitivity analyses in Appendix 4, supplementary material).

Economic evaluation

f/b EVAR had a higher cost than OSR for a similar clinical outcome and was therefore dominated. The bootstrap analysis per group (Fig. 1) showed little uncertainty surrounding this result in para/juxtarenal AAA and infradiaphragmatic TAAA, with f/b EVAR being less effective in patients

Table 3. Multivariate Cox regression analysis (final model[a]).

	Hazard ratio	95% confidence interval	p
Mean age at intervention	1.06	1.04–1.09	<.001
Sex			
Male	1	–	.61
Female	1.19	0.61–2.30	
Treatment			
OSR	1	–	.92
f/b EVAR	0.97	0.57–1.66	
Type of aneurysm			
Para/juxtarenal AAA	1	–	<.001
Infradiaphragmatic TAAA	0.82	0.47–1.44	
Supradiaphragmatic TAAA	2.80	1.62–4.84	
Charlson index			
0	1	–	.60
1	0.86	0.54–1.37	
2	1.04	0.60–1.78	
3	1.13	0.63–2.04	
4	0.18	0.02–1.35	
≥ 5	0.91	0.31–2.64	
Complications			
Myocardial infarction	5.52	2.36–12.9	<.001
Severe ischemic colitis and bowel infarction	5.39	3.16–9.21	<.001
Permanent hemodialysis	2.16	1.40–3.34	<.001
Re-intervention	2.28	1.43–3.64	<.001

[a] Variables were included in the multivariate model if they were under the 0.2 significance level of the univariate analysis. The variables in the final model were identified using a descending stepwise method with a 0.05 significance level. Age, sex, group (=type of aneurysm), and Charlson index were forced.

with infradiaphragmatic TAAA. Only supradiaphragmatic TAAA could potentially benefit from f/b EVAR and be cost-effective; however, high uncertainty surrounded this result.

Complications

Based on data recorded in the CRF, permanent hemodialysis was more frequent after OSR (5.6% vs. 20.8%, $p < .001$) and spinal cord ischemia was more frequent after f/b EVAR

Table 2. Hospitalization costs per type of aneurysm (in 2012 €).

	f/b EVAR Mean (SD)	p[a]	OSR Mean (SD)	p[a]	f/b EVAR vs. OSR p[b]
Initial hospitalization					
Para/juxtarenal AAA	33,919 (21,906)	<.001	14,661 (12,822)	<.001	<.0001
Infradiaphragmatic TAAA	37,517 (11,981)		17,239 (12,873)		<.0001
Supradiaphragmatic TAAA	54,121 (29,069)		44,158 (45,089)		.2026
30 day re-admissions					
Para/juxtarenal AAA	5,686 (6,856)	.794	4,487 (4,831)	.566	.4064
Infradiaphragmatic TAAA	5,327 (2,943)		5,444 (5,416)		.9723
Supradiaphragmatic TAAA	8,237 (1,968)		337 (–)		.0737
Total costs at 30 days[c]					
Para/juxtarenal AAA	34,425 (22,021)	<.001	14,907 (12,889)	<.001	<.0001
Infradiaphragmatic TAAA	37,927 (11,994)		17,530 (12,953)		<.0001
Supradiaphragmatic TAAA	54,710 (28,919)		44,163 (45,090)		.1771

[a] ANOVA test.
[b] Student t test.
[c] Or at patient's discharge.

Figure 1. Bootstrap methods assessing the cost-effectiveness of f/b EVAR versus OSR in each group. Green, para/juxtarenal abdominal aortic aneurysm; red, infradiaphragmatic thoraco-abdominal aortic aneurysm; blue, supradiaphragmatic thoraco-abdominal aortic aneurysm.

(4.1% vs. 1.0%, $p < .001$). However, 63.6% of patients treated with f/b EVAR recovered, leading to a low rate of permanent paraplegia (1.5%) (Table 4). Using the national discharge database for both f/b EVAR cases and controls, however, led to different results: whereas spinal cord ischemia was still more frequent after f/b EVAR, patients treated with f/b EVAR also presented more myocardial infarctions (3.1% vs. 1.2%, $p = .019$), strokes (4.2% vs. 0.7%, $p < .001$), and re-interventions (15.3% vs. 10.3%, $p = .017$), while there was no difference in the occurrence of renal failure (13.4% vs. 17.2%, $p = .120$). Appendix 5 (supplementary material) compares the rate of complications per type of aneurysm using both data sources, and Appendix 6 (supplementary material) shows the concordance analysis of the two sources.

Length of stay and 30 day readmissions

Total initial LOS (including transfers to another acute care hospital) was 13.9 (15.6) days for f/b EVAR patients and 16.2 (14.3) days for OSR patients ($p = .020$). There was no difference in LOS in ICU: 3.6 (13.5) days after f/b EVAR vs. 4.0 (10.2) after OSR ($p = .55$). A significant positive association was found between type of aneurysm and LOS (total and in ICU) in both f/b EVAR cases and controls, and a significantly higher total LOS for controls versus f/b EVAR cases in patients with para/juxtarenal AAA and infradiaphragmatic TAAA. More f/b EVAR cases than controls were readmitted within 30 days of the intervention (9.1% vs. 5.6%, $p = .035$), although there was no difference in their LOS (total or ICU). After excluding hemodialysis sessions, it was found that there were more re-admissions for a circulatory

Table 4. Post-operative complications, n (%).

Complications	Using CRF for cases and national discharge database for controls			Using national discharge database for cases and controls		
	f/b EVAR ($n = 268$)	OSR ($n = 1,678$)	p^a	f/b EVAR ($n = 262$)	OSR ($n = 1,678$)	p^a
Major amputation	1 (0.4)	4 (0.2)	.69	1 (0.4)	4 (0.2)	.67
Myocardial infarction	4 (1.5)	20 (1.2)	.68	8 (3.1)	20 (1.2)	.019
Stroke	5 (1.9)	12 (0.7)	.060	11 (4.2)	12 (0.7)	$<.001$
Paraplegia	11 (4.1)	16 (1.0)	$<.001$	8 (3.1)	16 (1.0)	.004
Incl. permanent paraplegia	4 (1.5)	NA	NA	NA	NA	NA
Mechanical ventilation $\geq$ 7 days	14 (5.2)	124 (7.4)	.20	18 (6.9)	124 (7.4)	.76
Severe ischemic colitis and bowel infarction	6 (2.2)	51 (3.0)	.47	7 (2.8)	51 (3.0)	.75
Permanent hemodialysis	15 (5.6)	289 (17.2)	$<.001$	35 (13.4)	289 (17.2)	.120
Re-intervention	34 (12.7)	173 (10.3)	.24	40 (15.3)	173 (10.3)	.017

[a] Chi-square test (or the Fisher exact test depending on the number of observations).

system disease in the f/b EVAR group (44.0% vs. 15.7%) and more readmissions for a respiratory system disease in the OSR group (13.3% vs. 0%). In addition, more controls than cases were transferred to a long-term care or rehabilitation facility at discharge (5.0% vs. 15.4%, $p < .001$). This was also true for patients with para/juxtarenal AAA (2.2% vs. 15.8%, $p < .001$); however, there was no difference for patients with infra- or supradiaphragmatic TAAA.

DISCUSSION

The results of this study suggest that f/b EVAR is not a cost-effective option for para/juxtarenal AAA or infradiaphragmatic TAAA. Therefore, OSR should be preferred whenever patients are eligible, although f/b EVAR may be a valuable treatment in high risk patients with para/juxtarenal aneurysms, with a mortality rate close to the mortality of OSR in low risk patients. For infradiaphragmatic TAAA, the poorer results of f/b EVAR may be explained by several factors, including a higher risk for surgery, technical issues related to anatomy, and the need for four fenestrations which increases the complexity of the procedure. For supradiaphragmatic TAAA, no difference was found in mortality and costs between f/b EVAR and OSR, suggesting that f/b EVAR may become a preferred option even in low risk patients, but the study was not sufficiently powered to make a stronger case for those patients.

The efficacy of infrarenal EVAR has been evaluated in several comparative studies, which have found a relatively low mortality — between 1.1% and 1.8%.[3,4,6,19] Repair of complex aortic aneurysms presents a bigger challenge. For such aneurysms, no study has compared f/b EVAR and OSR in a head to head trial, although a recent retrospective comparison of 30 day outcomes suggests that f/b EVAR is associated with reduced 30 day mortality and morbidity compared with OSR.[20] However, this study concerned only "eligible high volume hospitals," and the definition of complex aortic aneurysm was limited to involvement of visceral arteries. Moreover, comparison with results of the present study is rendered difficult by the lack of data on morphologic characteristics of the AAA and differences in case mix and co-morbid conditions. Cohort studies[12,21] also reported a slightly lower mortality than the present study (4.1% and 5.7% 30 day mortality vs. 6.7%), but the present study included a higher proportion of more risky extensive aneurysms.

LOS was shorter in patients treated by f/b EVAR (13.9 vs. 16.2 days, $p = .020$), as is also the case in studies comparing EVAR and OSR for infrarenal AAA. The LOS in the present study is higher than that reported in the literature — between 3.7 and 12.0 days after f/b EVAR,[7,22—25] and between 9.9 and 16.1 days after OSR.[7,9,26,27] LOS in ICU was also higher (3—4 days vs. only 1 day in the literature). The difference may be because, in this study, transfers to other acute care institutions were included in the LOS calculation. Excluding transfers resulted in a LOS of 12.3 days for f/b EVAR and 15.2 days for OSR, which is within the range reported in the literature, albeit not that of the more recent American College of Surgeons registry.[20]

Finally, f/b EVAR was predictably more costly than EVAR because of the cost of custom made stent grafts. The OSR cost in the present study was lower than previously reported, with the usual costs ranging from €18,242 to €27,930 [2,4,9] and up to €39,345,[7] compared with €16,255 in the present study. This may be a result of differences in DRG cost calculations. To the authors' knowledge, the cost of f/b EVAR treatment has been assessed only once, by the Ontario Health Technology Advisory Committee,[28] which found a cost of €27,747 for the initial hospitalization (€10,000 less than figures in the present study). This difference may be explained by the shorter LOS (6 days on average after f/b EVAR vs. close to 14 days in the present study), as the cost of the devices was similar in Canada and France (€20,317 vs. €21,905).

There are some limitations to the present findings. The study is not a traditional head to head RCT; as a result, patients undergoing f/b EVAR were on average 2 years older and sicker than those undergoing OSR. The present risk adjustment used age and Charlson index but other comorbidities may not be accounted for. A RCT was not chosen for several reasons: (1) the relatively low number of patients, even at a nationwide level, that would meet its inclusion criteria; (2) discrepancies between the number of centers currently performing OSR for complex AAA and TAAA and the low number of centers having already fulfilled the learning curve for f/b EVAR; (3) difficulties to convince patients to enter a protocol aimed at comparing a very invasive technique to a lighter one. The weakness of this choice is that clinical outcomes and costs were not measured in an identical way in both arms, the f/b EVAR cases' CRF being more thorough and complete than the controls' data present in the national discharge database. The discrepancies between the two data sources can be observed in the poor results of the concordance analysis, especially where comorbidities are concerned. It also explains the differences between what is reported here vs. what is present in the earlier article by Marzelle et al.,[13] as the latter reported CRF data while we mainly used the national discharge database. Although researchers are increasingly using discharge databases worldwide, these usually are not designed for research purposes. As such, the data available for a given patient are subject to coding incentives and more likely to contain comorbidities and complications that impact on reimbursement. In addition, using two different data sources meant only variables that were recorded in both could be included. As a result body mass index or aneurysm diameter could not be included in analyses despite potentially influencing mortality. Also, a nationwide database was compared with only eight centers performing f/b EVAR, but while a comparison limited to the same centers may appear more robust, it proved impossible to do because f/b EVAR centers had switched massively to endovascular repair and could not provide a sufficiently large control group. Finally, the discharge database records only hospital deaths, therefore mortality in the control arm may have been underestimated as deaths occurring at home or in another type of institution

were not recorded, although the concordance was high and mortality rate for OSR was close to that reported in EVAR vs. OSR trials: 5.4% in the present study vs. 4.3—4.7% in others[3,4,6] and up to 10% in TAAA.[29] This suggests that using the discharge database had only a limited impact on the 30 day mortality evaluation.

Endovascular technology is a rapidly evolving field. Since the start of the current study, new devices from different companies have been developed, which will probably decrease the cost of the stent grafts and reduce the waiting time for patients (and thus the risk of rupture).[30] Parallel grafts such as chimney grafts using a combination of a standard stent graft with standard covered stents are also being developed, with the advantages of being readily applicable and much cheaper.[31]

CONCLUSION

f/b EVAR does not appear to be justified for patients with para/juxtarenal AAA and infradiaphragmatic TAAA fit for OSR. However, it offers an attractive option for patients with para/juxtarenal AAA at high risk for surgery and for patients with supradiaphragmatic TAAA, including patients fit for open surgery. Durability of these devices needs to be assessed by longer-term follow up.

CONFLICT OF INTEREST

None

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ejvs.2015.04.012.

REFERENCES

1　Lederle FA, Freischlag JA, Kyriakides TC, Padberg Jr FT, Matsumura JS, Kohler TR, et al. Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial. *JAMA J Am Med Assoc* 2009;**302**(14):1535—42.

2　Hayes PD, Sadat U, Walsh SR, Noorani A, Tang TY, Bowden DJ, et al. Cost-effectiveness analysis of endovascular versus open surgical repair of acute abdominal aortic aneurysms based on worldwide experience. *J Endovasc Ther Off J Int Soc Endovasc Spec* 2010;**17**(2):174—82.

3　Greenhalgh RM, Brown LC, Kwong GPS, Powell JT, Thompson SG. EVAR trial participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30 day operative mortality results: randomised controlled trial. *Lancet* 2004;**364**(9437):843—8.

4　United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D, et al. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med* 2010;**362**(20):1863—71.

5　Becquemin J-P, Pillet J-C, Lescalie F, Sapoval M, Goueffic Y, Lermusiaux P, et al. A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients. *J Vasc Surg* 2011;**53**(5):1167—73.

6　Stather PW, Sidloff D, Dattani N, Choke E, Bown MJ, Sayers RD. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2013;**100**(7):863—72.

7　Lederle FA, Stroupe KT. Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group. Cost-effectiveness at two years in the VA Open versus Endovascular Repair Trial. *Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg* 2012;**44**(6):543—8.

8　Sultan S, Hynes N. Clinical efficacy and cost per quality-adjusted life years of pararenal endovascular aortic aneurysm repair compared with open surgical repair. *J Endovasc Ther Off J Int Soc Endovasc Spec* 2011;**18**(2):181—96.

9　Tarride J-E, Blackhouse G, De Rose G, Novick T, Bowen JM, Hopkins R, et al. Cost-effectiveness analysis of elective endovascular repair compared with open surgical repair of abdominal aortic aneurysms for patients at a high surgical risk: a 1-year patient-level analysis conducted in Ontario, Canada. *J Vasc Surg* 2008;**48**(4):779—87.

10　Semmens JB, Lawrence-Brown MMD, Hartley DE, Allen YB, Green R, Nadkarni S. Outcomes of fenestrated endografts in the treatment of abdominal aortic aneurysm in Western Australia (1997—2004). *J Endovasc Ther Off J Int Soc Endovasc Spec* 2006;**13**(3):320—9.

11　Verhoeven ELG, Vourliotakis G, Bos WTGJ, Tielliu IFJ, Zeebregts CJ, Prins TR, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single centre experience. *Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg* 2010;**39**(5):529—36.

12　British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry. Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. *Circulation* 2012;**125**(22):2707—15.

13　Marzelle J, Presles E, Becquemin JP. WINDOWS trial participants. Results and factors affecting early outcome of fenestrated and/or branched stent grafts for aortic aneurysms: a multicenter prospective study. *Ann Surg* 2015;**261**(1):197—206.

14　Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;**40**(5):373—83.

15　Giles KA, Schermerhorn ML, O'Malley AJ, Cotterill P, Jhaveri A, Pomposelli FB, et al. Risk prediction for peri-operative mortality of endovascular vs open repair of abdominal aortic aneurysms using the Medicare population. *J Vasc Surg* 2009;**50**(2):256—62.

16　Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi J-C, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care* 2005;**43**(11):1130—9.

17　Quan H, Li B, Couris CM, Fushimi K, Graham P, Hider P, et al. Updating and validating the Charlson comorbidity index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. *Am J Epidemiol* 2011;**173**(6):676—82.

18　Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the economic evaluation of health care programmes. Édition: 3*. Oxford; New York: OUP Oxford; 2005. p. 400.

19 Sun Z, Mwipatayi BP, Semmens JB, Lawrence-Brown MMD. Short to midterm outcomes of fenestrated endovascular grafts in the treatment of abdominal aortic aneurysms: a systematic review. *J Endovasc Ther Off J Int Soc Endovasc Spec* 2006;**13**(6): 747—53.

20 Tsilimparis N, Perez S, Dayama A, Ricotta JJ. Endovascular repair with fenestrated-branched stent grafts improves 30 day outcomes for complex aortic aneurysms compared with open repair. *Ann Vasc Surg* 2013;**27**(3):267—73.

21 Chisci E, Kristmundsson T, de Donato G, Resch T, Setacci F, Sonesson B, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. *J Endovasc Ther Off J Int Soc Endovasc Spec* 2009;**16**(2):137—46.

22 Haulon S, Greenberg RK, Pfaff K, Francis C, Koussa M, West K. Branched grafting for aortoiliac aneurysms. *Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg* 2007;**33**(5):567—74.

23 Roselli EE, Greenberg RK, Pfaff K, Francis C, Svensson LG, Lytle BW. Endovascular treatment of thoracoabdominal aortic aneurysms. *J Thorac Cardiovasc Surg* 2007;**133**(6):1474—82.

24 Ziegler P, Avgerinos ED, Umscheid T, Perdikides T, Stelter WJ. Fenestrated endografting for aortic aneurysm repair: a 7-year experience. *J Endovasc Ther Off J Int Soc Endovasc Spec* 2007;**14**(5):609—18.

25 Greenberg RK, Sternbergh 3rd WC, Makaroun M, Ohki T, Chuter T, Bharadwaj P, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. *J Vasc Surg* 2009;**50**(4): 730—7.

26 Wilt TJ, Lederle FA, Macdonald R, Jonk YC, Rector TS, Kane RL. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. *Evid Rep Technol Assess* 2006;**144**: 1—113.

27 Chambers D, Epstein D, Walker S, Fayter D, Paton F, Wright K, et al. Endovascular stents for abdominal aortic aneurysms: a systematic review and economic model. *Health Technol Assess Winch Engl* 2009;**13**(48):1—189. 215—318, iii.

28 Ontario Health Technology Advisory Committee. *Fenestrated endovascular grafts for the repair of juxtarenal aortic aneurysms: an evidence based analysis*. 2009.

29 Bensley RP, Curran T, Hurks R, Lo RC, Wyers MC, Hamdan AD, et al. Open repair of intact thoracoabdominal aortic aneurysms in the American College of Surgeons National Surgical Quality Improvement Program. *J Vasc Surg* 2013;**58**(4):894—900.

30 Kitagawa A, Greenberg RK, Eagleton MJ, Mastracci TM. Zenith p-branch standard fenestrated endovascular graft for juxtarenal abdominal aortic aneurysms. *J Vasc Surg* 2013;**58**(2):291—300.

31 Coscas R, Kobeiter H, Desgranges P, Becquemin J-P. Technical aspects, current indications, and results of chimney grafts for juxtarenal aortic aneurysms. *J Vasc Surg* 2011;**53**(6): 1520—7.