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A Study of the Cost-effectiveness of Fenestrated/branched EVAR Compared with Open Surgery for Patients with Complex Aortic Aneurysms at 2 Years

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WHAT THIS PAPER ADDS

Fenestrated and branched (f/b) grafts are an attractive option for complex aortic aneurysms. Their use is currently limited by the high unit cost of the devices and the lack of head to head trial evidence of a better outcome than open surgical repair. In addition, there has been no mid-term economic evaluation of f/b EVAR in the treatment of complex aortic aneurysms. The results at 2 years of this study may help clinicians better decide which patients should benefit from these expensive and innovative devices.

Objectives: The aim was to assess the cost-effectiveness of fenestrated and branched stent grafts (f/b EVAR) compared with open surgical repair (OSR) in thoraco-abdominal or complex abdominal aortic aneurysms (TAAA/AAA) at 2 years.

Methods: Two matched cohorts of patients with TAAA or complex AAA were compared after a follow-up of two years. Patients included in the WINDOW French multicentre prospective registry were treated by f/b EVAR, and OSR patients were extracted from the French national hospital discharge database. All cause mortality was assessed along with readmissions and hospital costs. The association between treatment and 2 year mortality was assessed by uni/multivariate Cox regression analyses using pre- and post-operative characteristics. Incremental cost-effectiveness ratios (ICER) were estimated for para/juxtarenal AAA, and infra- and supra-diaphragmatic TAAA.

Results: A total of 268 high risk patients were treated by f/b EVAR and 1678 average or low risk patients were treated with OSR during the same period. Mortality did not significantly differ between the groups (14.9% vs. 11.8%, $p = .150$) and multivariate Cox regressions did not find an association between 2 year mortality and treatment. Similar proportions of patients were readmitted at least once (69.7% with f/b EVAR vs. 64.2% with OSR, $p = .096$) but f/b EVAR patients had more readmissions on average (2.2 vs. 1.7, $p = .001$). Two year hospital costs were higher in the f/b EVAR group (€46,039 vs. €22,779, $p < .001$). At 2 years, f/b EVAR was dominated (more expensive and less effective), except in the supra-diaphragmatic TAAA subgroup with an ICER of €42,195,800 per death averted.

Conclusions: f/b EVAR in high risk patients offers similar 2 year mortality to OSR performed in lower risk patients but at a higher cost. The cost is mainly driven by the cost of the stent graft, which is not compensated for by lower healthcare resource consumption. Further studies are necessary to evaluate the cost-effectiveness in low risk f/b EVAR patients who may experience fewer complications.

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INTRODUCTION

While endovascular repair has become the preferred surgical therapy to treat abdominal aortic aneurysm (AAA)[1–5] although some authors question its long-term benefits,[6] it was initially limited to aneurysms with a neck long enough to accommodate the stent graft. New technologies have made it more widely available and extended the indication for the technique to complex aortic aneurysms: AAAs with a short or

[†] See Supplementary Material, Appendix 1.

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absent neck and/or involving visceral arteries and thoracoabdominal aortic aneurysms (TAAAs). Several studies have demonstrated the feasibility and efficacy of fenestrated and branched stent grafts (f/b EVAR) in different types of AAA.[7–9] Medium-term and a few long-term results are encouraging[10–14] but mitigated by the high cost of the stent and frequent need for repeat interventions.[14,15] In addition, no RCT has ever compared f/b EVAR with open surgical repair (OSR), and no medium- or long-term economic evaluation of f/b EVAR in the treatment of complex aortic aneurysms has been published. In a previous article it was reported that f/b EVAR in high risk patients versus open surgery in normal risk patients was not cost-effective at 30 days.[16] The objective of the present study is to assess the cost-effectiveness of f/b EVAR at 2 years, comparing its outcomes and costs with those of OSR for complex AAA or TAAA.

MATERIALS AND METHODS

Study design

WINDOW (http://www.clinicaltrials.gov/ct2/show/NCT01168037; NCT01168037, WINDOW registry) is a French multicentre prospective registry for patients treated with f/b EVAR which has been described previously.[17] Patients treated by OSR between 2010 and 2012 were extracted from the French national hospital discharge database to use as a comparator. This exhaustive administrative database, meant for reimbursement purposes, records all acute care hospital admissions with diagnostic related groups, diagnoses, surgical procedures, and length of stay (LOS).

The protocol was approved by the Institutional Review Board of Hôtel Dieu Hospital (Paris), and all patients treated by stent grafts signed written consent to participate in the registry. The French Data Protection Authority granted access to the data regarding patients treated by OSR.

Study population

Selection criteria for the WINDOW registry were patients at high risk for open surgery, with an AAA $>$ 50 mm in men (45 in women), with or without thoracic aortic aneurysm greater than 55 mm for men (50 for women), and with an infrarenal neck $<$ 10 mm in length or the extent of the aneurysm to the suprarenal aorta. Emergency and ruptured aneurysms as well as aortic dissections were excluded. Patients were then divided into three groups depending on the type of aneurysm: para/juxtarenal AAA, infra-diaphragmatic TAAA, and supra-diaphragmatic TAAA.

Patients treated by OSR were extracted from the national discharge database by combining primary diagnosis and procedure codes and were then assigned to their anatomical groups. The same inclusion and exclusion criteria as in the registry were applied whenever possible, as described previously.[16]

The Charlson index[18] was chosen to compare patient comorbidities at baseline because it could be scored using hospital discharge data and has been validated for use with the claims database, including the French hospital discharge database.[19,20]

Data sources

For f/b EVAR patients, both case report forms (CRF) from the WINDOW registry and national discharge data were available. However, as only data from the national discharge database were available for the OSR patients and as the 30 day analysis found that the two databases were not fully concordant, only the results obtained from the national discharge database for both groups are presented in this article so as to be comparable. As such, comorbidities at baseline as well as complications and other outcomes were drawn from the discharge database for patients treated with f/b EVAR and OSR. Mortality data were extracted from the national discharge database and the primary diagnosis for the admission during which death occurred was recorded.

Readmissions to any hospital were identified in the national discharge database for both endovascular and OSR patients using record linkage. All readmissions were included in the analysis, after excluding patients who had died within the first 30 days of the study.

Economic evaluation

The economic evaluation was carried out at 2 years from the all-payers perspective (including statutory health insurance, complementary health insurances, and patients' out of pocket expenditures) and included all acute hospital admissions. A detailed method of the cost computation for the initial admission has been published previously.[16] Readmissions within 2 years of the initial intervention were included in cost computations using their diagnosis related group tariffs.

An incremental cost-effectiveness ratio was calculated at 2 years to assess the incremental cost per additional percentage of averted death with f/b EVAR versus OSR. Both costs and effectiveness occurring after the first year were discounted at a rate of 4% in accordance with French guidelines on health technology assessment.

Statistical analysis

Analyses were performed for the entire population and for the three prospectively defined subgroups. 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. Univariate and multivariate analyses were also performed on 2 year 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 .05 significance level but age, sex, group, and Charlson index were forced. Hazard ratios (HR) and their 95% confidence interval (95% CI) were calculated.

Sensitivity analyses were performed to test the robustness of the model, including propensity score matching between f/b EVAR and OSR patients (1 f/b EVAR patient for 2 OSR patients) based on age, sex, type of aneurysm, and Charlson index.

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