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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

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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.