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Comparison of Renal Complications between Endografts with Suprarenal and Infrarenal Fixation☆

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WHAT THIS PAPER ADDS

This study adds to the understanding of differential outcomes in patients undergoing EVAR with suprarenal versus infrarenal fixation devices.

Objectives: Surgeons have multiple grafts options available for the endovascular treatment of abdominal aortic aneurysm (EVAR), and some hypothesize that suprarenal fixation endografts may result in higher rates of renal complications than infrarenal endografts. This study aimed to compare the outcomes of contemporary suprarenal and infrarenal endografts.

Methods: The Targeted Vascular Module of the National Surgical Quality Improvement Project was utilised to identify patients undergoing EVAR for infrarenal aneurysm from 2011 to 2013. Pre-operative and operative variables and 30 day outcomes were compared among suprarenal (Zenith and Endurant) and infrarenal fixation devices (Excluder). Renal complications included creatinine increase $>$ 2 mg/dL or new dialysis, as defined by NSQIP. Multivariate regression was completed to account for patient demographics, comorbidities, and operative characteristics.

Results: A total of 3587 patients were evaluated including 2273 (63%) with suprarenal grafts and 1314 (37%) with infrarenal grafts. Patients with suprarenal grafts were less commonly white (84% vs. 88%, $p < .01$) and more commonly male (83% vs. 80%, $p = .03$). There were no differences in age or comorbidities. Renal complications (1.1% vs. 0.1%, $p < .01$) and length of stay more than 2 days (34% vs. 25%, $p < .01$) occurred more commonly after suprarenal fixation. After adjustment, suprarenal grafts had significantly higher rates of renal complications (OR, 12.0; 95% CI, 1.6–91) and length of stay more than 2 days (OR, 1.4; 95% CI, 1.2–1.7).

Conclusion: Overall rates of renal complications following EVAR are low. Patients selected for suprarenal stent grafts are at increased risk of renal complications and prolonged length of stay, which may be due to selection bias, deployment techniques, or the presence of a bare stent overlying the renal arteries. Further studies are necessary to evaluate the mechanism and duration of renal dysfunction and important long-term outcomes of interest.

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INTRODUCTION

Since it was first described in 1991 by Juan Parodi, endovascular repair of abdominal aortic aneurysms (EVAR) has gained widespread prominence for the treatment of aortic aneurysmal disease.[1,2] As a result, a wide variety of endografts are available for surgeon selection. The safety and efficacy of such devices have been shown in clinical trials as well as Food and Drug Administration (FDA) post-market studies.[3–6]

Despite similar safety profiles, one major difference between endografts is their mechanism of fixation. Today, surgeons have the option of using endografts with suprarenal or infrarenal fixation. Several previous studies have found no differences in most outcomes between grafts with different fixation; however, such research has been limited to small single institution studies and sponsored trials from the early era of EVAR.[7–11] Other studies, bound by similar limitations, have identified increased renal complications among those grafts with suprarenal fixation.[12,13] To date, few studies have evaluated the effect of fixation among patients treated after 2010, and given the dramatic evolution in endovascular technology over the past decade, many

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of the grafts previously studied are no longer widely utilised, are currently unavailable, or have undergone significant changes in design. Moreover, many of the most commonly used grafts today were not available for inclusion in prior studies. Therefore, this study aims to describe outcomes following EVAR in patients chosen to have a suprarenal versus infrarenal fixation device in the current era.

METHODS

Population

The Targeted Vascular Module of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) was utilised to identify all patients undergoing elective endovascular repair of infrarenal abdominal aortic aneurysm (AAAs) from 2011 to 2013. Patients treated for a rupture ($n = 353$, 7%) and those treated with fenestrated grafts ($n = 112$, 2.2%) were excluded. As a national clinical registry, NSQIP aims to improve surgical care by providing risk adjusted clinical outcomes in the first 30 days following the operative procedure. The targeted module, developed in 2011, greatly expanded the variables collected and allowed for more tailored disease and procedure specific analyses with additional variables such as aortic diameter, operative time, and concomitant procedures, among other pertinent variables. As of the time of analysis, 83 centres contributed to the targeted data. Clinical reviewers prospectively collect demographics, intra-operative details, and 30 day surgical outcomes in a standardised fashion according to NSQIP protocol. NSQIP methodology has been validated for data input accuracy and regular quality assessments are performed through internal and external audits.[20–22] Further information is available at www.facs.org/quality-programs/acs-nsqip.

Grafts were selected for comparison in this study if they had been used more than 100 times (Zenith, Powerlink, Excluder, Endurant). Those grafts not evaluated included AneuRx ($n = 10$, 0.2%), Talent ($n = 19$, 0.4%), Aorfix ($n = 2$, 0%), Ovation ($n = 39$, 0.9%), and other/homemade grafts ($n = 185$, 4.3%). Grafts with suprarenal fixation included Zenith and Endurant. The only infrarenal graft used more than 100 times was Excluder. Because Powerlink can be used in both an infrarenal and suprarenal configuration, it was not included in the comparison between infrarenal and suprarenal endografts, but was assessed in a separate analysis comparing individual grafts.

Variables

Variable definitions for baseline characteristics and outcomes were chosen and clearly delineated by NSQIP and thus not modifiable.[14] Patient demographics, age, and comorbid conditions were compared. Smoking was defined as current tobacco use. Glomerular filtration rate was calculated in accordance with the Modification of Diet in Renal Disease (MDRD) equation, and chronic kidney disease was identified according to the Kidney Disease Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guidelines.[15–17] Among operative variables, distal aneurysm extent was defined as aortic or iliac. Percutaneous access was defined as a bilateral percutaneous approach. Renal revascularisation was defined by the NSQIP as any renal stent, although further granularity, including whether or not angioplasty was performed, was unknown.

All outcomes measured occurred within 30 days of operation. A renal complication was defined by the NSQIP as a post-operative creatinine increase >2 mg/dL from baseline at any point in the first 30 days post-operatively, or new dialysis. This was a binary variable, and there are no data regarding post-operative creatinine. Patients on dialysis pre-operatively were excluded from analysis of renal complications. A pulmonary complication was defined as pneumonia, failure to wean from mechanical ventilation within 48 h, re-intubation, or pulmonary embolism. Prolonged length of stay was defined as greater than 2 days after intervention.

Statistical analysis

Univariate analysis was performed to compare outcomes between infrarenal and suprarenal grafts, as well as individual graft types. The chi-square and the Fisher exact tests were utilised to compare categorical variables, and the Student *t* test, ANOVA, and Mann–Whitney were utilised to assess continuous variables, as appropriate. When all variables were evaluated, only distal extent exceeded 3% missing data, with 13% missing for both. Stepwise multivariate analysis was completed to account for demographics, comorbidities, and operative characteristics. For comparison of individual graft types, the Excluder was chosen as the reference group because it was the only infrarenal graft. Purposeful selection was utilised to select variables for inclusion into each model.[18] This included all variables with $p < .1$ on univariate screen as well as those variables shown to be predictive of each evaluated endpoint in previous studies. The Hosmer–Lemeshow goodness of fit test was used to evaluate the stability of each model. A p value $< .05$ was considered significant. Statistical analysis was performed using the SPSS statistical package (version 21.0). The institutional review board of Beth Israel Deaconess Medical Centre approved this study and waived consent due to the de-identified nature of the NSQIP database.

RESULTS

A total of 3587 EVARs were evaluated including 1977 (55%) with suprarenal fixation, 1314 (37%) with infrarenal fixation, and 296 (8%) with a Powerlink endograft placed, for which suprarenal or infrarenal fixation could not be identified. When individual grafts were compared, 1314 (37%) Excluder, 1166 (33%) Endurant, 811 (23%) Zenith, and 296 (8%) Powerlink grafts were evaluated.

Demographics and comorbidities

When baseline characteristics were compared, there were no differences in any comorbid conditions, including diabetes,

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