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Mid-term Outcomes of Renal Branches Versus Renal Fenestrations for Thoraco-abdominal Aneurysm Repair☆

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WHAT THIS PAPER ADDS

This is the first study to compare mid-term renal outcomes following endovascular repair of thoraco-abdominal aortic aneurysms using either a branched or fenestrated design. Within the limits of this study, endograft designs incorporating renal fenestrations seem to be associated with improved mid-term patency rates, but it is acknowledged that a future prospective trial is required to confirm these results.

Objective/Background: The objective was to investigate renal outcomes following endovascular repair of thoraco-abdominal aortic aneurysms (TAAA) comparing fenestrations with branches for the renal arteries.
Methods: Renal outcomes following TAAA endovascular repair performed with renal branches were collected from five high volume European centers and compared with renal outcomes following TAAA endovascular repair performed with renal fenestrations at one center. Renal re-intervention and occlusion rates, and freedom from any renal outcome and death were analyzed by patient and target vessel. Estimated glomerular filtration rate (eGFR) was calculated and collected pre-operatively and at the last available follow up.
Results: In total, 449 patients were included in this retrospective study (235 treated with branched devices [BEVAR] and 214 with fenestrated devices [FEVAR]). Altogether, 856 renal vessels were analyzed (445 perfused by branches and 411 by fenestrations). Both groups were comparable except for sex and smoking habits. Technical success rates were 95% and 99%, respectively. Mean ± SD follow up was 19 ± 18 months after BEVAR and 24 ± 20 months after FEVAR. During follow up, renal re-intervention rates were similar in both groups (4.7% vs. 5.2%). The renal occlusion rate was significantly higher following BEVAR (9.6% vs. 2.3%; $p < .01$), and the 2 year freedom for renal occlusion rate was 90.4% (SE 85.8—95.3%) following BEVAR and 97.1% (SE 94.6—99.7%) following FEVAR ($p < .01$). During follow up, a 12% median decrease in eGFR was observed following BEVAR versus 9% following FEVAR (non-significant). The 2 year survival rates were 73.4% (SE 66.6—80.9%) and 81.8% (SE 76.1—87.9%) following BEVAR and FEVAR, respectively.
Conclusion: Mid-term renal outcomes following endovascular repair of TAAA are satisfactory. Endograft designs incorporating renal fenestrations rather than renal branches are associated with significantly lower occlusion rates. A prospective trial is now required to confirm these results.

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INTRODUCTION

The treatment of thoraco-abdominal aortic aneurysms (TAAA) remains a major challenge for vascular surgeons. TAAA are relatively uncommon, with an estimated incidence of six per 100,000 person years.[1] The first endovascular treatment of a TAAA was reported by Chuter et al. in 2001.[2] Since then, the technology has improved and satisfactory mid-term durability has been reported. In the experience of Mastracci et al.,[3] the 5 year freedom from secondary interventions was 89% following TAAA endovascular repair with branched and fenestrated endografts, with fenestrations used for most of the renal arteries in that experience.

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The complexity of renal artery anatomy including variable branch origin angulations, depending on aneurysm morphology[4] and respiratory and circulatory movement,[5] are a challenge when designing endovascular devices. The purpose of this study was to investigate and compare renal outcomes following endovascular repair of TAAA with renal fenestrated and branched endografts.

MATERIALS AND METHODS

Study population

All TAAA endovascular repairs with renal branches (BEVAR) performed at five high volume centers to December 2014 were included and compared with all TAAA endovascular repairs with renal fenestrations (FEVAR) performed at one high volume center. Ruptured or symptomatic aneurysms and acute aortic dissections were excluded from the current study. The Crawford classification was used to categorize the extent of the aortic coverage by the endograft (type I—IV).[6]

All endovascular procedures were performed with fenestrated or branched endografts manufactured by Cook Medical (Bloomington, IN, USA). The design of those custom made devices was performed by the treating surgeon, which evolved over time, based on experience. The BEVAR group also included patients treated with the "off the shelf" t-branch endograft (Cook Medical).

Data for all patients were prospectively collected in an electronic database in four of the five centers; at the other center, data were extracted from a surgeon's personal log and then retrospectively supplemented by a review of the medical records. All data were then retrospectively reviewed for the purpose of this study. The BEVAR group data were de-identified and combined in a spreadsheet (Excel; Microsoft, Redmond, WA, USA) for analysis, which was performed at the Royal Free London and University College London.

This study was approved by the institutional review board and passed the local ethics approval process at each institution.

Renal outcomes

Technical success was defined according to the Society for Vascular Surgery guidelines, using an intention to treat protocol that begins with the implantation procedure and requires the successful introduction and deployment of the device, in the absence of surgical conversion to open repair, death $\leq$24 h, type I or III endoleak, or graft obstruction.[7]

Incidences of renal occlusion were noted, as were all renal secondary interventions related to a fracture, stenosis, kinking, endoleak, or occlusion. Imaging renal outcome events was assessed using multiple detector computed tomography (MDCT scan) and complemented with duplex ultrasound. All imaging was reviewed at each participating center using center specific protocols. Duplex ultrasound criteria applied were defined by Mohabbat et al.,[8] and MDCT scan interpretation was based on the methods described by Dowdall et al.[9] Imaging outcomes were defined according to reporting standards and their modifications proposed by Mastracci et al.[3,7]

Early ($\leq$30 days) and late (>30 days) renal occlusions and deaths (procedure related and any kind of death), and early (re-interventions, <30 days) and late renal secondary interventions (>30 days) were analyzed. Renal occlusion during follow up was diagnosed, excluding failed renal vessel catheterization during the initial procedure. Branch instability was defined as the composite outcome of renal occlusion and/or renal related secondary intervention. "Total" event rates included early and late events.

Renal function

Estimated glomerular filtration rate (eGFR) was determined using the abbreviated modification of diet in renal disease (MDRD) study equation (eGFR [mL $\times$ min^{-1} $\times$ 1.73 m^{-2}] = 186 $\times$ [serum creatinine]$^{-1.154}$ $\times$ [age]$^{-0.203}$ $\times$ [0.704 if female] $\times$ [1.210 if African American]). The eGFR was calculated and collected pre-operatively and at the last available follow up.

Statistical analysis

Analyses were conducted using SAS software (SAS version 9.4; SAS Institute Inc., Cary, NC, USA) and R software (R version 3.1.2; R Foundation, Vienna, Austria)

Continuous variables are expressed as mean $\pm$ SD or median [25th—75th percentile], as appropriate. Categorical variables are presented as absolute numbers and percentages. The comparison of patients with fenestrated devices with those with multi-branched devices was performed using Student *t* tests or Mann—Whitney *U* tests according to normality assessed by the Shapiro—Wilk test and using the chi-square test or Fisher's exact test, as appropriate, for proportions of categorical variables. Event free survival curves were estimated using the Kaplan—Meier method and compared using the log-rank test. Median follow up time was estimated with the reverse Kaplan—Meier method. Cox proportional hazards models were used to test each outcome of interest. For specific covariate combinations, because of missing data, it was decided to run a multiple imputation analysis with 30 imputations using the multiple imputation by chained equations (MICE) algorithm and the predictive mean matching (PMM) method. The possibility of using a propensity score to correct for unbalanced data was investigated, but a reliable model to predict the probability of having one or the other treatment was not found. A two tailed type I error rate $<$ .05 was considered statistically significant.

RESULTS

This retrospective study included 449 patients: 235 (52%) patients were treated with renal and visceral branches (BEVAR) for a type II or III TAAA, and 214 (48%) patients were treated with renal fenestrations (FEVAR) for a type I, II, III (53%) or IV (47%) TAAA; the visceral vessels (celiac trunk and superior mesenteric artery [SMA]) in the FEVAR group