

Midterm Outcomes of Fenestrated and Branched Stent Grafts After Failed Endovascular Infrarenal Aortic Aneurysm Repair Due to Type IA Endoleak: A Prospective Multicentre Study

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STUDY PROTOCOL

Between January 2010 and December 2019, all patients (n=85) who developed after EVAR, a secondary type IA endoleak, and received a F/BEVAR stent graft were entered in a prospective multicentre study bringing together 8 French university centres (Toulouse, Marseille, Amiens, Nancy, Nice, Lyon, Lille, and Rennes).

Type IA secondary endoleak was defined as an endoleak appearing during follow-up, but absent on computed tomography angiography (CTA) within 30 days of EVAR ⁱ.

We included all aetiologies leading to the development of this endoleak, any abnormality of the infrarenal stent graft, any aneurysmal evolution of the neck of the infra-renal aneurysm, and of the inter-renal or thoracoabdominal aorta.

The study protocol was approved by the institutional review board of the Toulouse University Hospital. All patients gave their informed consent for the operation. Following RGPD regulation, the database was anonymised, upon completion.

All patients had a preoperative assessment of cardiac, renal, respiratory function and underwent an ASA physical status classification. All preoperative imaging was performed on <1.5 mm slices CTA. Aneurysm proximal extension was classified according to Chaufour et al. ⁱⁱ.

All F/BEVAR were performed using a COOK Zenith stent graft (Cook Medical Inc. Bloomington, Ind). The number of fenestrations used was based on the preoperative sizing made from 3D-CTA reconstructions. We only used on-label F/BEVARs which were approved by the Zenith cook planning centre. A fenestrated cuff was implanted when there was no anomaly in the distal part of the previous stent graft and a sufficient length prior to its bifurcation. Alternatively, a bifurcated stent graft was added to the pre-existing EVARⁱⁱⁱ.

Procedures were performed under general, epidural or local anaesthesia, depending on the preference of the anesthesiologist, surgeon or patient. Procedures were performed in a conventional operating theatre or a hybrid room as described elsewhere ^{iv}. General postoperative complications included any cause mortality.

Acute kidney injury was defined following the KDIGO criteria^v, and myocardial infarction according to the generally accepted criteria ^{vi}. Postoperative respiratory complications were defined by the need for mechanical ventilation for more than 48 hours or re-intubation. SCI

was classified according to the severity of the American Spinal Injury Association score ^{vii} and stroke was classified according to National Institute of Health Stroke Scale (NIHSS)^{viii}.

Outcomes

The European Society for Vascular Surgery guidelines were used to define technical success, major adverse events, aneurysm sac changes, endoleak and device integrity ^{ix}. F/BEVAR procedures were analysed in an intention to treat. A procedure was considered successful if the stent graft was implanted without any Type IA or type III endoleak, and with patent target arteries on peroperative angiography and on CTA or contrast enhanced ultrasound performed within the first week following the procedure.

Target artery instability was defined as any branch-related death, rupture, occlusion or reintervention for stenosis, kink, endoleak, or disconnection. Monitoring during follow-up was carried out by CTA, at 3, 6 and 12 months and annually thereafter. Any endovascular or open revision related to the procedure was recorded during follow-up.

Statistical Analyses

Univariate analysis was performed using t-tests for normally distributed continuous variables, and Wilcoxon rank sum test for non-normally distributed continuous variables. Chi-square or Fisher tests was used when appropriate for categorical variables. Time-dependent outcomes including patient survival, freedom from reintervention, freedom from endoleak and target arteries patency were reported using Kaplan-Meier time-to-event method. A p-value < .05 was used to assess statistical significance. All analyses were performed with SPSS V26, (IBM Corp.) and MedCalc ®.

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