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Extra-anatomical bypass operation in patients with unilateral graft limb occlusion after endovascular aneurysm repair for abdominal aortic aneurysm

Short title: Extra-anatomical bypass in graft limb occlusion after EVAR

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INTRODUCTION

Femorofemoral crossover bypass is performed in high-risk patients who are not a candidate for invasive open surgery due to comorbid conditions that exclude them from the procedure and in patients with critical limb ischemia or intermittent claudication where anatomic constraints exclude them from endovascular procedures in re-establishing in-line flow [1].

Abdominal aortic aneurysm (AAA) is an abnormal dilatation of the abdominal aortic diameter by more than 50% which is irreversible and permanent [2, 3]. Following endovascular aneurysm repair (EVAR) for AAA, graft limb occlusion is a serious and severe complication [4].

The management options for symptomatic patients with graft limb occlusion are endovascular or surgical. The endovascular options include thrombolytic therapy, angioplasty with or without stenting, and rheolytic therapy. Whereas, surgical treatment includes thrombectomy or

extra-anatomical bypass in the form of femorofemoral crossover bypass. Each treatment option has its drawbacks and should be tailored to the individual patient.

Thrombolysis therapy can be complicated by hemorrhages, new endoleak due to thrombus lysis in the aneurysm sack, and leg embolism. It is also time-consuming. Whereas, surgical thrombectomy has disadvantages such as thrombus migration in the contralateral limb and hypogastric artery, component separation in modular devices, and stent-graft dislodgement [5].

The main objective of our study was to determine the durability of an extra-anatomical femorofemoral crossover bypass procedure in patients with unilateral graft limb occlusion after EVAR for AAA over a 20-year period.

METHODS

From January 2001 to March 2021, 1611 patients with AAA were treated with EVAR using a bifurcated stent-graft at the Department of General, Endocrine and Vascular Surgery at the Independent Public Central Clinical Hospital in Warsaw, Poland. A total of 33 high-risk patients (ASA class III & IV) required an extra-anatomical procedure in the form of femorofemoral crossover bypass due to occlusion of one of the limb branches of the bifurcated stent-graft. The patients were included in the study continuously and all primary procedures carried out were elective. Patients were re-examined at one month, six months, and one year and then every year after with a clinical examination and computed tomography scan. Four patients died during the follow-up period, all cardiac-related.

Devices commercially available that were used included: Zenith (Cook Medical, Bloomington, Ind), Endurant (Medtronic, Minneapolis, MN, US) and Excluder (W. L. Gore & Associates, Newark, DE, US). Of the 33 patients that had a graft limb occlusion; one patient had an Endurant stent-graft and the remaining patients had a Zenith stent-graft. The type of stent-graft used was based on institutional practice and vascular surgeon's preference depending on the technical aspects of the procedure.

The AAA diameter range was from 48mm – 75mm. The aortic bifurcation diameter range was from 21 mm to 40 mm. The right and left iliac diameter range was from 10 mm to 46 mm and from 10 mm to 87 mm, respectively. Six mm, 7 mm and 8 mm prostheses were used.

Computed tomography angiography was used to determine the occurrence of an occlusion. Patient operative details, immediate and long-term clinical outcomes, aneurysm characteristics, perioperative arteriograms, and computed tomography scans were stored prospectively in a specific database and analyzed retrospectively. An extra-anatomical procedure was performed

when the patient was symptomatic. Patients were found to have an occluded graft-limb when they presented with claudication or acute limb ischemia to the accident and emergency department or during their follow-up appointment.

Ethics

The study was conducted according to the guidelines of the Declaration of Helsinki, and was approved by the Bioethics Committee at the Medical University of Warsaw (AKBE/108/2022) in Warsaw, Poland. The need for informed consent was waived owing to the retrospective study design.

Statistical analysis

Statistical analysis was performed using STATISTICA for Windows (StatSoft, Inc.) program. Patients were considered as the unit of analysis for clinical data analysis. The Kaplan-Meier method was used to show percentage of patients free from secondary intervention and percentage
of patients with patent graft including secondary interventions.

RESULTS AND DISCUSSION

A total of 1611 patients with AAA were treated with EVAR using a bifurcated stent-graft. The current study included 33 high-risk patients (2.05%), ASA class III & IV (30 men; mean (SD) age 70 (7.7) years, range 48–90) who required an extra-anatomical procedure in the form of a femorofemoral crossover bypass due to unilateral graft limb occlusion of the bifurcated stent-graft.

Seven patients had a failed femorofemoral crossover bypass which occluded during the follow-up period. Five patients had a thrombectomy, one patient required an above-the-knee amputation of the right leg due to critical limb ischemia after a failed femorofemoral crossover bypass with unsuccessful attempts at restoring patency, and one patient was treated conservatively. However, four patients experienced femorofemoral crossover bypass re-occlusion. Two patients required another re-intervention and the remaining two patients were treated conservatively. One patient had re-intervention which consisted of an axillobifemoral bypass and the other patient had a successful thrombectomy. In total, three patients were asymptomatic after the occluded femorofemoral crossover bypass was incidentally found on follow-up computed tomography angiography and were treated conservatively.

Four patients died during the follow-up period, all cardiac-related. There were no infections reported during the follow-up period.

Late occlusion (>1 month) occurred in seven patients, whereas early occlusion (<1 month) did not occur in any patient. Primary patency was 78.8% while secondary patency was 90.9%. Kaplan-Meier curves were used to show percentage of patients free from secondary intervention (Figure 1A) and percentage of patients with patent graft including secondary interventions (Figure 1B).

Although EVAR is becoming the preferred treatment for AAA due to its clinical benefits and minimally invasive nature, there is an increase in the number of re-interventions and graft-related complications. Graft limb occlusion presents with severe acute rest pain in the lower extremity which is a severe complication following EVAR [6]. It is one of the top three reasons for readmission to the hospital [7, 8].

Our study shows good primary and seconday patency rates which goes along with other femorofemoral crossover bypass studies [9, 10]. Our primary and secondary patency rates were 78.8% and 90.9%, respectively. Park et al. [9] showed similar primary and secondary patency rates at 5 years at 70% and 85%, respectively. In the study by Park et al., 32 patients (24%) showed graft occlusion due to thrombosis compared to our study which only had 7 patients (21%). However, our study only had 33 patients where as, Park et al. had a total of 133 patients, which could make up for the difference.

In the study by Ricco et al. [10], primary and secondary patency rates were 71.8% and 89.8%, respectively. 30 patients (40%) had crossover bypass graft failure; 14 had graft occlusion, 12 had stenosis donor iliac artery and 4 had femoral anastomotic stenosis. However, if we are comparing graft occlusion, Ricco et al. had 14 graft occlusions (18.9%) which is similar with our study of 21%.

In our study, all 33 patients were high-risk patients (ASA class III & IV) with unilateral graft limb occlusion who presented with either leg claudication or acute limb ischemia. It is our experience, similar to Parent et al. [11], that femorofemoral bypass grafting is frequently required when there is endograft limb occlusion. The femorofemoral crossover bypass is a small procedure that can be performed under local anesthesia, making it particularly beneficial for patients who are high-risk and not suitable or have contraindications for major surgery. In addition, little or no preoperative preparation is required for this procedure to be carried out. All our patients were treated urgently from the time of unilateral graft limb occlusion resulting in continued patency of the limb. However, larger prospective studies are required to validate this hypothesis.

Limitations

This study had several limitations. First, this is a retrospective study which is limited by factors inherent in retrospective data analysis and interpretation. Second, the study was based on the experience of one institution with a moderate number of patients.

CONCLUSION

The femorofemoral crossover bypass as an extra-anatomical procedure following unilateral graft limb occlusion should be considered for high-risk patients who are not a candidate for major surgery. It is a small procedure, performed under local anesthesia with good patency in the long-term and low operative mortality and morbidity.

Article information

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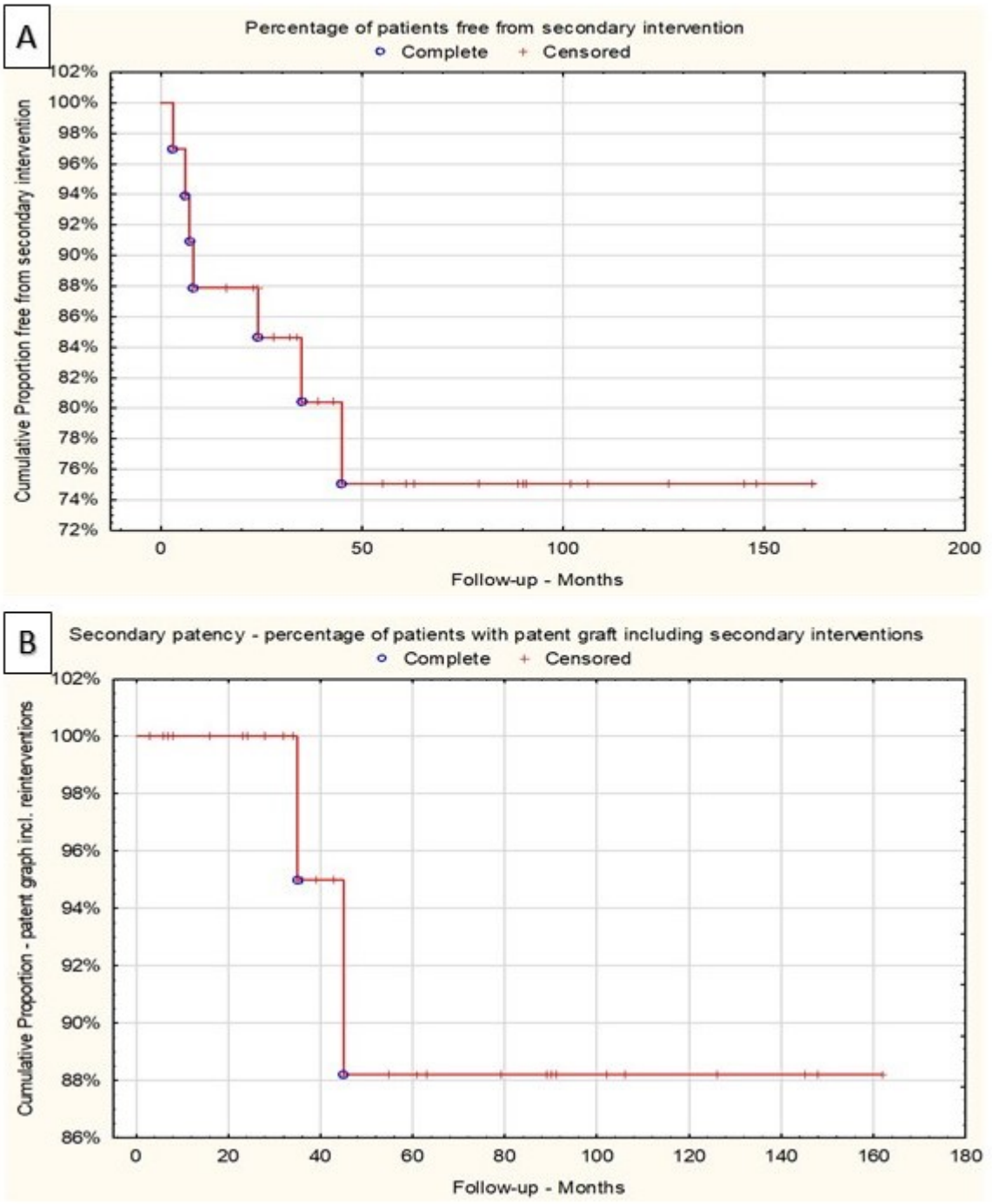

Figure 1. A. Percentage of patients free from secondary intervention. **B.** Percentage of patients with patent graft including secondary interventions