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Polytetrafluorethylene Prosthesis Interposition in Vascular Access

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Abstract: *The purpose of this study was to investigate how well a polytetrafluoroethylene graft interposition works in limited situations to avoid the use of prosthetic venous access grafts or installing a permanent dialysis catheter. A retrospective examination of clinical data from a single institution was undertaken on a case series from January 2018 to September 2019. We included in our study 28 polytetrafluoroethylene interpositions, done using a mean prosthetic length of 3.5 cm and diameters of 5 and 6 mm. The patency at 24 months was 71.43%, higher than the literature percentages. We found that these interventions were successful and long-lasting, and the technique we used has a minimal risk of thrombosis, infection, or bleeding.*

Keywords*: arteriovenous fistulas, polytetrafluoroethylene, prosthesis interposition, vascular access*

1. Introduction

One of the biggest complications of patients with end stage kidney disease (ESKD) on hemodialysis is the lack of vascular access. Recently, this subject has been intensively studied and attempts have been made to implement new techniques in terms of vascular access, such as prosthetic arteriovenous fistulas and permanent dialysis catheters [1]. In the short term, we had impressive results, but in the long run, the patency and the probability of complications that may occur were signaling better results for autologous arteriovenous fistulas. Currently, the main sites for vascular access are the radio-cephalic arteriovenous fistula, followed by the brachiocephalic fistula, with the exploitation of all the arterio-venous resources of the upper limb [2,3].

Among the most common complications of the arteriovenous fistulas, we list thrombosis, bleeding, aneurysmal dilation of the fistula with risk of rupture, and arterial theft syndrome producing upper limb ischemia [4 - 7]. Another major problem we face is the presence of thrombosis, partially recanalized, and fibrotic stenosis in the veins eligible for arteriovenous fistula, due to peripheral venous punctures and repeated superficial vein cannulations in these patients, whenever they are hospitalized for various pathologies. If this problem occurs in the cephalic vein in the forearm, the option of performing a brachiocephalic arteriovenous fistula (AVF) remains valid, but the presence of this situation in the cephalic vein at the brachial level may lead to the actual impossibility of establishing vascular access [8].

Polytetrafluoroethylene (PTFE) prostheses are biologically stable and have an electronegative surface, thus minimally interacting with the blood cells. These grafts are produced by elongating a polymeric tube, which, by melting, is transformed into a non-textile porous tube. This type of graft doesn't need pre -coagulation and has a far superior infection resistance when compared to other

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 # These authors share first authorship, their contribution on study design and manuscript preparation was equal.

materials. In the vascular access field, PTFE is the material of choice when there is the need to use a synthetic graft [9,10].

The advantages of a prosthetic AVF are rapid accessibility for dialysis, a somehow easier technique, and a wider surface that can be used for puncturing, during dialysis. Unfortunately, the prosthetic vascular access graft was shown to be more susceptible to infection, thrombosis, and bleeding in the long term [11,12]. In vascular surgery, grafts are used for both surgical revascularization and access vascular surgery [6, 13–19]. Numerous studies have been performed in recent years to monitor the biocompatibility of grafts and their resistance to infection [20-22].

This paper aims to analyze the patency and the complications of performing a brachiocephalic AVF with the interposition of a PTFE prosthesis of 5-6 mm diameter.

2. Materials and methods

For this paper, we performed a retrospective study in which we included 28 patients with chronic kidney disease stage 5 on hemodialysis, for whom we performed a brachiocephalic AVF with a PTFE prosthesis interposition. The patients were admitted to the Vascular Surgery Clinic of the Târgu-Mures County Emergency Clinical Hospital.

2.1. Selection of patients

As inclusion criteria in the study, we chose patients with ESKD pre-dialysis or on hemodialysis, with type II diabetes mellitus (T2D), with the impossibility of performing an AVF at the radio-cephalic level (cephalic vein thrombosis, absence of cephalic vein, significant hemodynamic stenosis of the radial artery) or previous non-functional radio-cephalic AVF with the presence of a cephalic vein at the brachial level, not patent for performing an AVF.

From the hospital's electronic database, the patients' demographic data were extracted. The following comorbidities were extracted from the medical history: arterial hypertension (AH), atrial fibrillation (AF), chronic heart failure (CHF), ischemic heart disease (IHD), myocardial infarction (MI), chronic obstructive pulmonary disease (COPD), cerebrovascular accident (CVA), peripheral artery disease (PAD), dyslipidemia, tobacco usage, and obesity.

2.2. Medical procedure

Under local anesthesia, we performed all 28 brachio-cephalic AVFs with the interposition of a PTFE graft of 5 or 6 mm caliber, respectively. The average length of the prosthesis used was 3.5 cm.

Preoperatively upper limb Doppler ultrasound was performed, and the diameter and flow velocity of the cephalic vein was measured, highlighting the presence of thrombosis or fibrotic stenosis, and diagnosing the veins with a diameter of less than 2 mm or post-puncture lesions.

In this group of patients, we decided to exploit all the technical possibilities of performing an AVF, thus we interposed a PTFE type prosthesis of 5-6 mm diameter between the brachial artery and the portion of the patent cephalic vein. We performed two anastomoses: one being latero-terminal (L-T), between the brachial artery and the PTFE prosthesis, and the other termino-terminal (T-T), between the prosthesis and the cephalic vein with 5-0 double-reinforced polypropylene wire [23] (Figure 1).

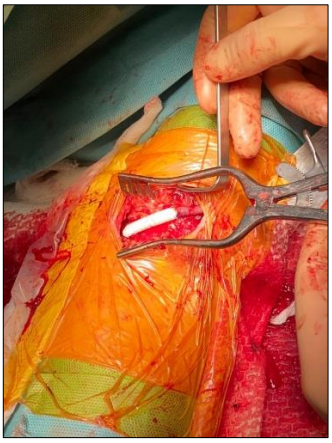

Figure 1. Intraoperative photo of a brachio-cephalic AVF with polytetrafluoroethylene graft interposition

2.3. Investigation of the results

We followed the primary patency and the occurrence of complications at 4 weeks, 6 months, 12 months, and 24 months after the surgery. This has been done with clinical examination, objectified palpable thrill, audible murmur, and ultrasound examination.

2.4. Statistical analysis

Data are presented as the mean±SD if normally distributed and median (Interquartile range) if non-parametrically distributed. Statistical analysis was performed using SPSS for Windows version 28.0 (SPSS, Inc., Chicago, IL).

3. Results and discussions

28 patients with ESKD who met all the criteria were included in the study. For the whole group, there was an average age of 62.35 ± 11.9, with ages between 36 and 84 years, and a predominance of males (71.42%). The comorbidities with the highest incidence were AH in 25 patients (89.29%), followed by IHD in 19 patients (67.86%), CHF in 11 patients (39.28%) and COPD in 10 patients (35.71%). As risk factors, dyslipidemia was encountered in 13 patients (46.43%), tobacco usage in 12 patients (42.86%), and obesity in 9 patients (32.14%). At 24 months postoperatively, in 71.43% of cases, the permeability of AVF was maintained, and 10.71% died (Table 1).

Table 1. Demographic, comorbidities, risk factors, and outcome of all patients included in the analysis

Variables	**All patients** n=28
Age mean ± SD (min-max)	62.35±11.9 (36-84)
Male sex no. (%)	20 (71.42%)
Comorbidities and risk factors	
AH, no. (%)	25 (89.29%)
AF, no. (%)	4 (14.29%)
CHF, no. (%)	11 (39.29%)
IHD, no. (%)	19 (67.86%)
MI, no. (%)	5 (17.86%)
COPD, no. (%)	10 (35.71%)
CVA, no. (%)	8 (28.57%)
PAD, no. (%)	6 (21.43%)
Tobacco, no. (%)	12 (42.86%)
Obesity, no. (%)	9 (32.14%)
Dyslipidemia, no. (%)	13 (46.43%)
Outcomes	
Primary patency 24 months, no. (%)	20 (71.43%)
Death, no. (%)	3 (10.71%)

Regarding the results, we noticed that at one month 92.86% of the fistulas included in the study were permeable and, at six months, only 82.14% (23 patients) of the patients have been starting dialysis, using the fistula. Furthermore, at 12 months, the AVF permeability was 78.57% and, at 24 months, it was 71.43% (Figure 2).

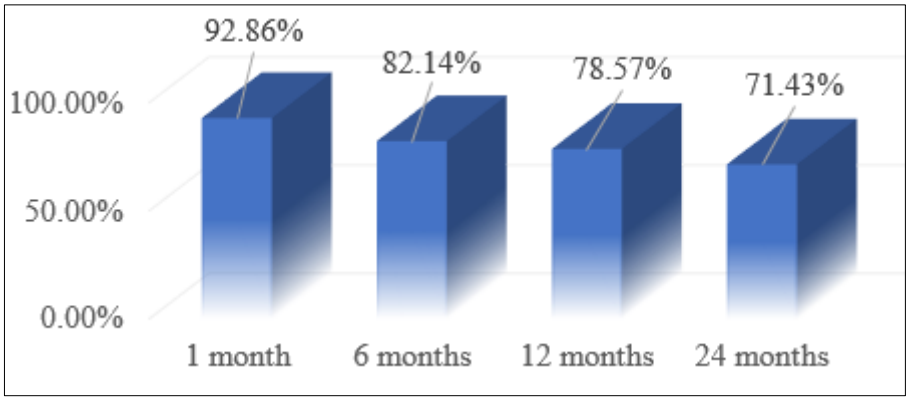

Figure 2. Arteriovenous fistula patency chart

28.57% of the patients had complications, including vascular steal syndrome in two of the cases, for which we had to close the AVF, aneurysmal dilatation in two cases, and AVF thrombosis in four patients, two of which benefitting from a balloon thromboembolectomy. None of the AVFs showed signs of infection or bleeding (Table 2).

Table 2. Postoperatively complications of all patients included in the analysis

Variables	**All patients** n=28
Steal syndrome, no. (%)	2 (7.14%)
Aneurysmal dilatation, no. (%)	2 (7.14%)
Thrombosis, no. (%)	4 (14.28%)
Graft infection, no. (%)	-
Bleeding, no. (%)	-

The Kaplan-Meier chart for 24 months patency for PTFE interposition AVF is shown in Figure 3. This graphical illustration displays the survival probability for the treated PTFE interposition AVFs, throughout the selected 24 months.

We consider this hybrid technique to be an innovation suitable in certain cases, having a low incidence of complications and excellent long-term patency, as well as a low risk of infection. The punctures of the matured AVF are performed exclusively at the level of the dilated cephalic vein, thus avoiding any hemorrhagic complications regarding the graft or the distal anastomosis between the graft and the vein.

If neither a radio-cephalic fistula nor a brachiocephalic fistula is eligible for vascular access, an interposition with a synthetic graft is the next best option [24]. Elevated postoperative blood flow through the AVF increases shear tension on the vascular wall and starts the process of vessel dilatation. The incapacity of veins to adjust is generally caused by the existence of severe stenoses or tiny arterial inflow vessels. If maturation fails, medical angiography examination is needed. Such individuals typically have heavy calcified and poor wall quality arteries and present proximal and/or distal artery blockage. Additionally, there is a considerable risk of ischemia. Diabetic individuals have a considerably greater risk of graft thrombosis, which leads to reduced graft survival [25]. But it has been shown that there are no correlations between patency and gender or age [24].

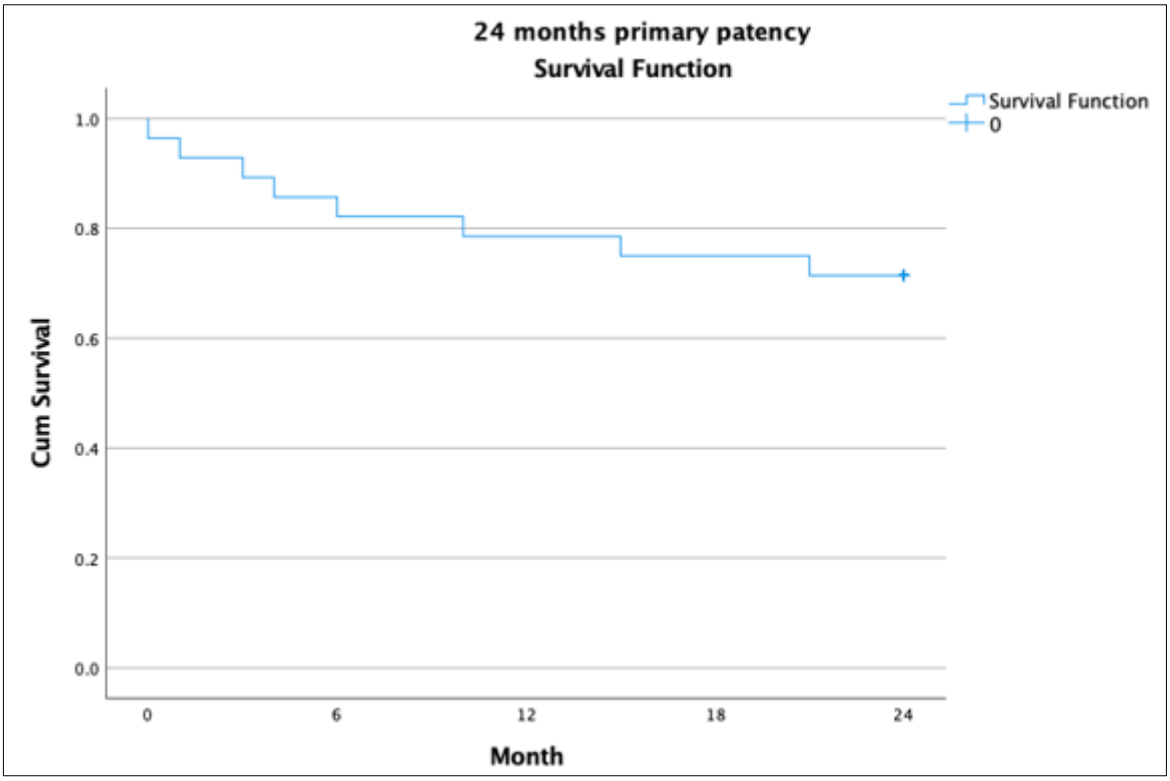

Figure 3. Kaplan-Meier 24 months primary patency for PTFE interposition AVF (Cum survival = Cumulative overall survival rate)

In complicated hemodynamic conditions that involve high flow and venous stenosis, flow rate restriction with no intervention on revascularization may lead to an access failure. Therefore, graft interposition may be an option for distal inflow correction in patients with symptoms from high-flow AVF who do not have confirmed distal artery illness [26].

One research compared short (less than 6 cm) PTFE components with autologous material in stenotic or thrombotic fistulas. The study revealed that these types of PTFE outperform native restoration while preserving original access. Poor blood circulation and insufficient hemodialysis are caused even by minor stenotic venous lesions. Yet, if caught early enough, they may be surgically repaired, and access could be preserved with no drastic reduction to the length of the cannulable vessel [27]. For its extended lifespan, an autogenous arteriovenous approach for severe hemodialysis is preferred over prosthesis access. Regarding patient outcome, a meta-analysis based on comparing the two access methods showed that the use of autogenous access was linked to a significantly lower incidence of mortality and infections [28].

A meta-analysis conducted by Thomas Huber et al., emphasizes the superior 6 months and 18 months patency of the AVF using autologous material over the PTFE fistula, showing an 86% patency at 6 months and a 77% patency at 18 months, which are similar to the patencies in our study, highlighting the utility of our method [29]. The average lifespan of an AVF found in the literature is between 3-5 years, respectively 1-2 years for PTFE fistula. The AVF patent with graft interposition at two years is 71.43%, thus, exceeding the worldwide patent at AVG level, an aspect that demonstrates the hypothesis of this study and the quality of this innovative technique [30-32].

The strong point of this paper is long term primary patency follow. The study's limitations are the relatively small number of patients from a single-center, mainly men, making extrapolation difficult. In the future we recommend multicentric, prospective studies, for better accuracy of the results.

4. Conclusions

PTFE interposition AVF is a good alternative in all the cases where the autologous vein cannot be used. This technique renders new possibilities in vascular access surgery and is suitable, we believe, for being studied on a larger number of cases and for a longer period.

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