

OUTCOME OF POLYTETRAFLUOROETHYLENE VERSUS DACRON GRAFTS FOR SUPRAGENICULAR FEMOROPOPLITEAL ARTERIAL BYPASSES

By

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ABSTRACT

Background: Long saphenous vein (LSV) is used usually as the graft of the choice in the treatment of critical limb ischemia (CLI). LSV graft in femoropopliteal and femrodial bypasses is more durable and also associated with reduced surgical mortality ratios and good success rates in preserving the ischemic limb. Synthetic graft, i.e. Dacron /Polytetrafluoroethylene (PTFE) is a good alternative if the saphenous vein is not available. PTFE has been the most popular choice. However, the preference for PTFE over Dacron is not evidence-based. The optimum graft configuration for the above-knee femoropopliteal bypass, whether PTFE or Dacron, remains a subject of controversy.

Objective: To outcome whether Dacron versus PTFE Grafts as optimum in supragenicular femoropopliteal revascularization.

Patients and Methods: Fifty patients with critical limb ischemia referred to Vascular Surgery Department, Al-Azhar University, Sednawy and El-Araby Hospitals were included during the period from July 2018 to April 2020. They had foot lesions as ulcer, wound or tissue loss associated with non-palpable distal pulses, and long occlusion of superficial femoral artery (SFA) defined as TransAtlantic Inter-Society Consensus (TASC) II C or D lesions. End points were healed, healing, nonhealing wounds or amputation. Patients were divided into two groups: group A included 25 patients who underwent Dacron graft bypass "DB", and group B included 25 patients who underwent PTFE bypass "PB".

Results: Twenty- two patients (44%) reached the end point of complete healing (10 patients did "DB" and 12 did "PB"), whereas twenty-six patients (52%) had no or inadequate healing lesions. The limb salvage after one year was 40 patients (80%): 21 of them with 'DB' technique, and 19 with 'PB' technique. The remaining 8 patients (16%) underwent major amputation (5 with 'DB' technique and 3 with 'PB' technique) and two patients (4%) died. The early patency rate at 1 and 3 months was 92.43 % in the group with 'DB', and 94.39% in the group with 'PB'. The late patency rate at one year post-operatively was 63.63 % in the 'DB' group and 68.63 % in the 'PB' group.

Conclusion: Both Dacron and PTFE grafts were effective regarding wound healing and limb salvage as well as patency rate in supragenicular femoropopliteal revascularization.

Keywords: Diabetic foot, Dacron, Polytetrafluoroethylene, Supragenicular, femoropopliteal, Ankle Peak Systolic Velocity.

INTRODUCTION

Femoropopliteal graft bypass has been shown to be a durable and effective option for the treatment of femoropopliteal arterial diseases with superficial femoral artery (SFA) long occlusion, and has better long-term results than percutaneous transluminal angioplasty (PTA) (Veith *et al.*, 2018).

Autogenous venous conduits as LSV are associated with improved patency for both above- and below-knee femoropopliteal bypass (Cantelmo *et al.*, 2010).

Prosthetic graft material is still a frequently used alternative to venous conduits due to the absence of a good-quality long saphenous vein in many patients (Shandall *et al.*, 2019).

The choice of prosthetic graft material, such as PTFE or Dacron, for femoropopliteal bypass grafts has been controversial over the past decade (Rhodes *et al.*, 2016).

There is still debate which synthetic graft PTFE or Dacron is equivalent to vein as bypass graft material for the above-knee femoropopliteal bypass. No firm conclusions have been reached on whether ePTFE or Dacron is preferable (Stonebridge *et al.*, 2020).

The present study was to compare between PTFE and Dacron prosthesis for suprageniculate femoro-popliteal allograft bypass grafting.

PATIENTS AND METHODS

The study included 50 patients who presented to the Vascular Surgery Department, Al-Azhar University, Sednawy and Elaraby Hospitals during the period from July 2018 to April 2020. They

were randomly distributed into two equal groups: group A was treated with revascularization bypass surgery using PTFE graft, while group B treated with Dacron graft.

An approval of the study was obtained from Al-Azhar University academic and ethical committee. Every patient signed an informed written consent for acceptance to share in this research.

Inclusion criteria: Patients with CLI with long occlusion of SFA defined as TransAtlantic Inter-Society Consensus (TASC) II C or D lesions, and complaining of foot lesion (ulcer, wound or tissue loss), and reconstitution of the above-knee popliteal artery.

Exclusion criteria: Patients with poor tibial collateral circulation, no target runoff, a history of previous femoropopliteal bypass, less than 1 year of life expectancy, claudicants or asymptomatic lesions, unsalvageable limb, acute ischemia, known allergy to heparin, aspirin, or other antithrombotic agents and no valid informed consent documentation.

At the initial clinical presentation, full history was taken from every patient and prospectively. The clinical data were collected regarding gender, age, risk factors and comorbidities, ABI and duplex scanning, including APSV. Lesions were treated by daily dressings and followed up monthly 1, 3, 6 and 12 months. Post management, wound dressing protocol was standardized. Patients were followed up until they reached one of the end points of the study which were healed wound, healing wound, non-healing wound, and major amputation. A wound was considered completely healed if it was

fully covered with intact skin. It was considered adequately healing if it was completely covered with healthy granulation tissue, with absence of tissue necrosis or infection. It was considered nonhealed if it did not show signs of healthy granulation tissue during follow-up.

During follow-up, data were collected regarding wound status, the details of the management plan, details of duplex scanning including Arterial Peak Systolic Velocity and Ankle Brachial Index.

Revascularization bypasses surgery using PTFE/Dacron grafts: General or spinal anesthesia, a thigh incision to identify the target proximal arteries (CFA, SFA and profunda artery), then another above knee to expose the target distal artery (popliteal artery). The suitable PTFE/Dacron grafts were prepared. The distal anastomosis was performed. The

tunneling of the bypass graft was performed anatomically. After accomplishing the proximal anastomosis, distal pulsation and hemostasis were confirmed then wounds were closed in layers.

Statistical analysis:

Data were collected, revised, coded and analyzed using statistical package for social science (IBM SPSS) version 23. The quantitative data were presented as number (No.), percentage (%), mean (X), and standard deviation (SD) were determined. The comparison between two independent groups with quantitative data and parametric distribution was done by using One Way Analysis of Variance (ANOVA). Significance level (P) value: P value >0.05 was considered non-significant (NS) and P value <0.05 was considered significant (S).

RESULTS

The demography of the patients and the risk factors distribution are shown in the following Table.

50 limbs were included in this study of 50 patients; the patient population consists

of 24 males and 26 females with a mean age 68.6 years (± 4.8) in the following table.

Table: Baseline clinical characteristics of patients

Parameters	Patients		No.	Percent (%)
		Mean ± SD		
Age (year)			68.6 years ± 4.8	
Gender	Male		24	48
	Female		26	52
Diabetes	Positive		50	100
	Negative		0	0
Smoking	Negative		20	40
	Positive		30	60
Hypertension (HTN)	Negative		19	38
	Positive		31	62
History of previous Amputation	Negative		13	26
	Positive		37	74
Ischemic heart disease (IHD)	Negative		18	36
	Positive		32	64

In the present study, all 50 patients were diabetics, 31 patients (62%) were hypertensive, 30 patients were smokers (60%), 32 patients (64%) were suffering from ischemic heart disease(IHD)and 37

patients (74%) with history of previous Amputation.

The procedure time was estimated from the time of anaesthesia to the end of the procedure. It ranged from 90 min to 120 minutes, **Figure 1 and 2.**



Figure (1): A case of RT supragenicular femoropopliteal bypass using Dacron graft



Figure (2): A case of RT supragenicular femoropopliteal bypass using PTFE graft

Twenty-two limbs (44%) with diabetic foot lesions reached the end point of complete healing: (10 patients did Dacron graft bypass “DB” revascularization and 12 did PTFE bypass “PB”).

Twenty-six limbs (52%) had nonhealing or inadequate healing lesions: six limbs (12%) ended with nonhealing lesions, conservative therapy and dressing continued (4 with ‘DB’ technique and 2

with ‘PB’ technique), 12 limbs (24%) had success re-intervention by femoropopliteal infragenicular bypass following occluded graft with inadequate healing (7 with ‘DB’ technique and 5 with ‘PB’ technique), Eight limbs (16%) (5 with ‘DB’ technique and 3 with ‘PB’ technique) had below knee amputations following failed revascularization. Two patients (4%) died, shown in **Figure (3)**.

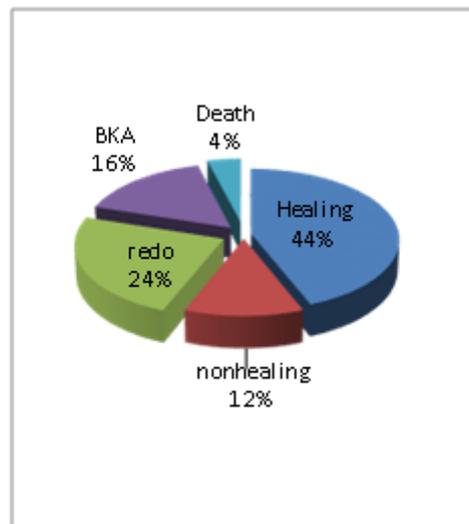


Figure (3): Results of studied patients (Supragenicular femoropopliteal arterial Bypass Using Dacron versus PTFE Grafts)

The Ankle Peak Systolic Velocity (APSV) was significantly higher in patients with Dacron Grafts compared with patients with PTFE Grafts: 57.8cm/s (± 12.72) versus 24.9 cm/s (± 9.55), $p < 0.001$. At a cutoff point of 40 cm/s, the APSV showed sensitivity of 90.91%, specificity of 100%, positive predictive value of 100%, negative predictive value of 92.3%, with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions. There was a significant difference between the APSV before and after revascularization: 23.4 cm/s (± 6.5) versus 58.8 cm/s (± 12.3), $p < 0.001$.

The limb salvage after one year was 80% (40 patients) 21 of them with ‘DB’ technique and 19 with ‘PB’ technique. While the remaining 8 patients (16%) underwent major amputation (5 with ‘DB’ technique and 3 with ‘PB’ technique). Two patients (4%) died.

The early patency rate at 1 and 3 months was 92.43 % in the group with ‘DB’, and 94.39% in the group with ‘PB’. While the late patency rate at one year post-operatively was 63.63 % in the ‘DB’ group and 68.63 % in the ‘PB’ group.

DISCUSSION

To predict wound healing of foot lesions in patients with critical limb ischemia; many noninvasive methods have been described. These include ankle-brachial pressure, transcutaneous oxygen, toe-brachial pressure, skin perfusion pressure, photoplethysmography, radioisotope clearance, and laser Doppler ultrasonography (*Marks et al., 2016, Wengertter et al., 2019 and Mills et al., 2020*).

The utility of toe pressure measurement is limited by the fact that a significant proportion of diabetic patients suffer some degree of the digital arteries calcification (*Brown et al., 2020*).

The utility of the ankle-brachial pressure measurement is also limited by the possibility of arterial wall calcification, while APSV is not affected by such limitations (*Ballard et al., 2015 and Biancari et al., 2020*).

Skin perfusion pressure at a cutoff value of 41 mm Hg has a sensitivity of 70% and a specificity of 87% in predicting wound healing (*Moñux et al., 2011 and Grego et al., 2014*).

Transcutaneous oxygen measurements at a cutoff value of 33 mm Hg have a sensitivity of 77.5% and a specificity of 82% in predicting wound healing (*Galaria et al., 2015 and Albers et al., 2016*).

The sensitivity and specificity of APSV in our study compared favorably with previously reported results of ankle peak systolic velocity (APSV), skin perfusion pressure and transcutaneous oxygen.

In our study, 50 patients with critical limb ischemia having infra-inguinal arterial lesions, randomly distributed into two equal groups; 24 males and 26 females with a mean age 68.6 years (± 4.8). All patients were diabetics, 62% were hypertensive, 60% were smokers, 64% were suffering from ischemic heart disease (IHD), and 74% were with history of previous Amputation.

The present study agrees with the results reported by *Grus et al. (2017)*, that diabetes mellitus was predictive of restenosis and limb loss.

In this study 40 diabetic patients showed clinical success, while 16% underwent major amputation and 4% died.

These results nearly similar to the results of the study of *Goss et al. (2014)*.

In this study 44% reached the end point of complete healing (10 patients did Dacron graft bypass "DB" and 12 did PTFE bypass "PB"), 52% had no or inadequate healing lesions. The limb salvage after one year was 80%, while the remaining 16% underwent major amputation, and 4% died.

In the study by *Goss et al. (2014)*, the limb salvage was achieved in 90%.

The early patency rate at 1 and 3 months was 92.43 % in the group with 'DB', and 94.39% in the group with 'PB'. The late patency rate at one year post-operatively was 63.63 % in the 'DB' group and 68.63 % in the group with 'PTFE' bypass. Another previous study by *Kabra et al. (2018)*, showed a higher primary and secondary patency (94%) and (50%) respectively compared with our study.

The Ankle Peak Systolic Velocity (APSV) was significantly higher in patients with Dacron Grafts compared with patients with PTFE Grafts. At a cutoff point of 40 cm/s, the APSV showed sensitivity of 90.91%, specificity of 100%, positive predictive value of 100%, negative predictive value of 92.3%, with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions. There was a significant difference between the APSV before and after revascularization. These results nearly similar to the results of the study of *Bishara et al. (2017)*.

CONCLUSION

Both Dacron and PTFE grafts were effective regarding wound healing and limb salvage as well as patency rate in supragenicular femoropopliteal revascularization.

The limitations of this study were the relatively small number of limbs studied.

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نتائج الوصلات البولية تترافلورو إيثيلين مقابل الداكرون في المجازاة الشريانية الفخذية المأبضية فوق الركبة

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خلفية البحث: يستخدم الوريد الصافن الطويل عادة كأفضل وصلة في علاج نقص تروية الأطراف الحرجة؛ يعتبر طعم الوريد الصافن الطويل في المجازة الفخذية المأبضية الأكثر دواما ويرتبط أيضاً بنسب الوفيات الجراحية المنخفضة ومعدلات النجاح الجيدة في الحفاظ على وانقاذ الطرف السفلى. يعتبر الداكرون/بولي تترافلورو إيثيلين كوصلات اصطناعية بديلاً جيداً في حالة عدم توفر الوريد الصافن؛ كان البوليفلورا تترافلورو إيثيلين هو الخيار الأكثر شيوعاً. ومع ذلك، فإن تفضيل البوليفلورا تترافلورو إيثيلين على الداكرون لا يعتمد على الأدلة. لا يزال نوع الوصلة أو الطعم الأمثل للمجازة الفخذية المأبضية فوق الركبة، سواء أكان البوليفلورا تترافلورو إيثيلين أو الداكرون، موضع جدل.

الهدف من البحث: مقارنة الداكرون و البوليفلورا تترافلورو إيثيلين كوصلات اصطناعية في إعادة التروية الدموية فوق المفصالية.

المرضى وطرق البحث: تم إدراج خمسين مريضاً يعانون من نقص تروية الأطراف الحرجة لقسم جراحة الأوعية الدموية في مستشفيات جامعة الأزهر و صيدناوي والعربي خلال الفترة من يوليو 2018 إلى أبريل 2020. كان لديهم آفات في القدم مثل القرحة أو الجرح أو فقدان الأنسجة ويرتبط بنبضات طرفية غير محسوسة وانسداد طويل للشريان الفخذي السطحي المعرف على أنه آفات عبر الأطلسي المشتركة بين المجتمع وبحث فى نقاط نهاية البحث عن التئام الجروح أو البتر.

نتائج البحث: وصل اثنان وعشرون مريضاً (44%) إلى نقطة نهاية الشفاء التام (10) مرضى قاموا بتجاوز بوصلة الداكرون، 12 مريضاً تجاوزوا بوصلة البوليفلورا تترافلورو إيثيلين) في حين أن 26 مريضاً (52%) لم يكن لديهم ما يكفي التئام

الجروح. تم إنقاذ الأطراف بعد عام واحد من 40 مريضاً (80%) 21 منهم بتقنية الداكرون و 19 مريضاً بتقنية البولي تترافلورو إيثيلين. بينما خضع 8 مرضى الباقين (16%) لبتير كبير (5 بتقنية الداكرون و 3 بتقنية البولي تترافلورو إيثيلين. وتوفي مريضان (4%). وكان معدل السدد المبكر عند 1 و 3 أشهر 92.43% في المجموعة مع الداكرون و 94.39% في المجموعة مع البولي تترافلورو إيثيلين. في حين أن معدل السداد المتأخر بعد عام واحد بعد الجراحة كان 63.63% في مجموعة الداكرون و 68.63% في مجموعة البولي تترافلورو إيثيلين.

الاستنتاج: كل من وصلات الداكرون و البولي تترافلورو إيثيلين فعالة فيما يتعلق بالتئام الجروح وإنقاذ الأطراف وكذلك معدل الانفتاح في إعادة تكوين الأوعية فوق المفصالية الفخذية.

الكلمات الدالة: القدم السكرية، الداكرون، بولي تترافلورو إيثيلين، فوق المفصل، عظم الفخذ، سرعة الانقباض عند الذروة في الكاحل.