Patency of Autologous Reverse Great Saphenous Vein Versus Polytetrafluroethylene in Below Knee Femoro popliteal Bypass Grafting

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ABSTRACT

Objective *To compare the patency rates of autologous saphenous vein and expanded polytetrafluroethylene graft in femoropopliteal below knee bypass grafting in patients with peripheral vascular disease.*

Study design *Comparative study.*

Place & Duration of study *Department of Vascular Surgery Combined Military Hospital Lahore, from January 2011 to January 2013.*

Methodology *Patients with disabling intermittent claudication, rest pain, impending gangrene were included. All patient had duplex scan of the affected limb to assess the velocity of the blood flow in infrainguinal vessels as well as. CTA from infra-renal aorta onwards distally. At operation popliteal artery was assessed for patency and runoff. Great saphenous vein was also assessed for diameter (at least 4mm was labeled as suitable). In non suitable cases PTFE was used.*

Results *A total of 200 bypasses were performed in 190 patients. Of these, 102 (51%) patients had reverse saphenous vein bypass (RSVB) graft and 98 (49%) received expanded polytetrafluroethylene (e-PTFE) graft. Common indications of operation were intermittent claudication in 101 (50.5%) and rest pain in 70 (35%) patients. At 3 year post surgery seven (3.7%) patients were lost to follow-up and 36 (19%) died. Primary patency rate for e-PTFE graft was 62.9% while it was 86.4% for RSVB graft (p =0.032). The secondary patency rate in e-PTFE graft was 64.1% and in RSVB graft 85.1% (P = 0.034).*

Conclusion *Saphenous vein graft had a superior patency rates at all intervals of time and it needed lesser redo operations when compared with e-PTFE graft.*

Key words *Femoro-popliteal bypass, Saphenous vein graft, Polytetrafluroethylene graft, Peripheral vascular.*

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INTRODUCTION:

First ever bypass grafting for peripheral vascular occlusive disease was performed by Kunlin in 1949 using an autologous saphenous vein as a conduit.[1] Since then many studies were performed to find out the best possible material for bypass grafting as venous conduit may not be always available. Most of the studies suggested saphenous vein as the best conduit for infragenicular bypasses.[2-6] Considering the refinement in the prosthetic material

these days, studies are still being performed whether prosthetic materials like Dacron or polytetrafluroethylene (PTFE) can be a useful equivalent to autologous vein.[7] In many cases suitable vein cannot be harvested hence synthetic materials become the only alternative available for bypass grafting.[8-10] Many authors have reported that PTFE has comparable patency rates to autologous veins and is considered as a good alternative in such cases.[11,12]

This study was conducted to find out if there is any difference in terms of primary and secondary patency rates between PTFE and autologous vein for infragenicular bypass, the probability of occlusion of these two conduits over the period of time and options in case of graft failure.

METHODOLOGY:

This was a comparative study performed on all the consecutive patients who were diagnosed with peripheral vessel disease and underwent bypass grafting between January 2011 and January 2013 at the Department of Vascular Surgery Combined Military Hospital Lahore. Patients with disabling intermittent claudication, rest pain, impending gangrene were included. Patients who had distal anastomosis done above the knee, previous bypass surgery in same limb, already removed great saphenous vein, where computerized tomographic angiogram (CTA) was not possible due to decompensated renal disease, those unwilling to undergo bypass grafting and unfit for anesthesia, were excluded from the study.

Clinical history was obtained from all the patients. All risk factors for atherosclerosis like diabetes mellitus, hypertension, smoking and hyperlipidemias were noted. Patients were also asked about other vascular events like ischemic heart disease and stroke. All patients had baseline investigations performed like complete blood count, renal, hepatic and coagulation profiles, hepatitis B and C status, electrocardiogram, echocardiogram. Every patient had duplex scan of the affected limb to assess the velocity of the blood flow in infrainguinal vessels. Furthermore, all patients underwent CTA from infra-renal aorta onwards distally including both lower limbs. The infragenicular arteries were scored from grade 1 to 3 in terms of their degree of occlusion to assess the distal runoff.[13]

All patients were assessed by anesthetist one week before surgery. Patients who were on oral antiplatelets had their medications stopped five days before surgery and started on 40mg enoxaparin subcutaneously till the day of operation. Written consent was obtained for the operation. Patients received 1.5gm cefuroxime at the time of induction of anesthesia. During operation, assessment of popliteal artery and its bifurcation into anterior and posterior tibial arteries through standard below knee medial approach was done. Fogarty Fr 4 catheter was used to assess patency and distal runoff. Bypass grafting was abandoned and patient was excluded from the study if distal runoff was felt inadequate at this stage. Next the great saphenous vein (GSV) was assessed. It was considered suitable if the diameter was 4mm or more proximally and distally. Patients with inadequate GSV underwent bypass grafting using expanded polytetrafluoroethylene graft of 6mm diameter. In those with suitable GSV, the vein was harvested and kept in the heparinized saline for grafting. The graft was tunneled sub-sartorially between the infrapopliteal and groin wounds using 1.2cm diameter tunneler. Before clamping the arteries, 5000 units of unfractioned heparin was given intravenously to the patient. Anastomosis was done in end to side manner using 6/0 polypropylene suture. The proximal anastomosis was with common femoral artery and distal was with popliteal artery (proximal to its bifurcation).

Postoperatively warfarin 5mg daily was started on the day of operation along with enoxaparin 1mg/kg body weight twice daily subcutaneously. Patient's International Normalized Ratio (INR) was checked on 4th postoperative day. Enoxaparin was stopped once the target INR between 2.0 to 3.0 was achieved. Oral warfarin was continued for six months post operatively. After six months, patients were continued on lifelong asprin 75mg and clopidogril 75mg daily.

Patients were discharged once they were independently mobile. Regular followup visits were carried out at 6 weeks, 12 weeks, 6 months and 1 year and then continued yearly for a minimum of 3 years. Patients underwent a Duplex scan on every followup visit. Graft was considered occluded if there was a drop in distal pressure of more than 20% when compared with previous visit and a velocity profile which was consistent with collateral flow in the tibial and popliteal arteries. Patients were clinically assessed for ischemia. Those with symptoms of intermittent claudication were put on 'wait and see' policy and in those with rest pain or impending gangrene, a redo bypass surgery was performed.

Primary patency was defined as uninterrupted patency with no further procedure performed on the bypass or the nearby native vessel. Secondary

patency was defined as patency after restoration ofan occlusion with most of the bypass or at least one anastomosis retained in continuity.[13]

The cumulative patency rates (CR) for both primary and secondary patency were calculated using the life-table analysis. Also calculated was the probability of occlusion (Qt) and probability of patency (Pt) in a given time interval. Patient's baseline characteristics were assessed using statistical package for social sciences (SPSS) version 20. The numerical outcome like age was calculated as mean and standard deviation. Gender was recorded as frequency and percentage. Student t-test was used to compare the baseline characteristics. The p-value was calculated and considered statistically significant if less than or equal to 0.05.

RESULTS:

A total of 216 cases with peripheral vascular disease needing bypass surgery fulfilling the pre-operative inclusion criteria were included in this study. Of these, 26 patients who had poor distal run off on initial exploration of the popliteal artery were excluded. Of the remaining 190 cases, bilateral reconstruction was done in 10 patients. In this group, seven patients had e-PTFE graft bilaterally and three had RSVBG bilaterally. Out of 200 bypass grafts, 102 (51%) underwent reverse saphenous vein bypass grafting and 98(49%) e-PTFE grafting.

The median age of patients was 58+12 year with a range from 42 year to 78 year. In RSVB group median age was 57+11 year as compared to e-PTFE group where it was 59+12 year. Patients' risk factors for atherosclerotic disease are enlisted in table I. The indications for operation included intermittent claudication in 101 (50.5%) patients. Details are given in table II.

The mean operation time from skin incision to skin closure was significantly longer in the RSVB (240 minutes) when compared to e-PTFE group (98 minutes) with p-value of 0.002. Superficial wound infection was noted in 16 (8%) patients which responded to oral antibiotics. Hematoma formation in the popliteal wound was observed in 8 (4%) patients. It needed evacuation under local anesthesia. None of such cases resulted in re-operation or graft loss. There was no reported

Table I: Baseline Characteristics of the Patients

	Total	Vein Graft	e-PTFE graft	p - value
Reconstructions	200	102	98	
Median Age(year)	58	57	59	0.12
Gender (Male)	121	70	51	0.24
Gender (Female)	79	32	47	0.21
Risk factors				
Diabetes Mellitus	170	76	94	0.04
Hypertension	74	41	33	0.03
Smoking	96	42	54	0.06
Cerebrovascular accidents	21	9	12	0.31
Cardiac history	65	39	26	0.16
Indications				
Claudication	101	51	50	
Rest Pain	70	37	33	
Impending Gangrene	29	14	15	
Tibial Runoff (Grade)				
3	120	64	56	
2	56	25	31	
1	24	10	14	

mortality during their hospital stay or for 4 weeks after operation.

After 3 years, 36 (19%) patients died and 7(3.7%) were lost to follow-up. At 3 years, primary patency rates for e-PTFE grafts were 62.9%; which was significantly lower than the RSVB where it was 86.4% (p = 0.032). Furthermore, the secondary patency rate in e-PTFE group after 3 years was 64.1% while it was 85.1% in RSVB (p=0.034). The probability of occlusion is given in table II and III. The probability of occlusion when assessed for secondary patency is give in table IV and V.

In RSVB, 14 (14.2%) bypasses failed. Out of these, in 11 cases no further intervention was done as the patients only had minimal symptoms of intermittent claudication. Two patients underwent redo bypass. One had autologous saphenous vein from opposite side and other had e-PTFE graft. One patient refused

Table II: Clinical Life-Table Analysis of the Primary Patency Rate of e-PTFE graft

Duration	Patients at risk (Pr)	Occluded (Oc)	Died (D)	Lost to Follow up	Pr' [=Pr-D/2]	Qt (=Oc/Pr')	Pt (=1-Qt)	Cp (=Cp*Pt)	CR (=Cp*100)
0-6 weeks	102	5	0	0	102	0.049	0.951	0.951	95.1%
6-12 weeks	97	6	0	0	97	0.061	0.939	0.892	89.2%
12-24 weeks	91	8	5	1	88.5	0.090	0.910	0.811	81.1%
24-52 weeks	77	6	5	1	74.5	0.080	0.920	0.746	74.6%
1-2 years	65	4	6	2	62	0.064	0.936	0.698	69.8%
2-3 years	53	5	4	0	51	0.098	0.902	0.629	62.9%

Table III: Clinical Life-Table Analysis of the Primary Patency Rate of Autologous Reverse Saphenous Vein Graft

Duration	Patients at risk (Pr)	Occluded (Oc)	Died (D)	Lost to Follow up	Pr' [=Pr-D/2]	Qt (=Oc/Pr')	Pt (=1-Qt)	Cp (=Cp*Pt)	CR (=Cp*100)
0-6 weeks	98	0	0	0	98	0	1	1	100%
6-12 weeks	98	2	2	1	97	0.020	0.980	0.980	98%
12-24 weeks	93	4	5	2	90.5	0.044	0.956	0.936	93.6%
24-52 weeks	82	5	5	0	79.5	0.062	0.938	0.877	87.7%
1-2 years	72	1	3	0	70.5	0.014	0.986	0.864	86.4%
2-3 years	68	0	1	0	67.5	0	1	0.864	86.4%

Table IV: Clinical Life-Table Analysis of the Secondary Patency Rate of e-PTFE Graft

Duration	Patients at risk (Pr)	Occluded (Oc)	Died (D)	Lost to Follow up	Pr' [=Pr-D/2]	Qt (=Oc/Pr')	Pt (=1-Qt)	Cp (=Cp*Pt)	CR (=Cp*100)
0-6 weeks	102	3	0	0	102	0.029	0.971	0.971	97.1%
6-12 weeks	99	6	0	0	99	0.060	0.940	0.912	91.2%
12-24 weeks	93	4	5	1	90.5	0.044	0.956	0.871	87.1%
24-52 weeks	83	5	5	1	80.5	0.062	0.938	0.816	81.6%
1-2 years	72	8	6	2	69	0.115	0.885	0.722	72.2%
2-3 years	56	6	4	0	54	0.111	0.889	0.641	64.1%

Table V: Clinical Life-table Analysis of the Secondary Patency Rate of Autologous Reverse Saphenous Vein Graft

Duration	Patients at risk (Pr)	Occluded (Oc)	Died (D)	Lost to Follow up	Pr' [=Pr-D/2]	Qt (=Oc/Pr')	Pt (=1-Qt)	Cp (=Cp*Pt)	CR (=Cp*100)
0-6 weeks	98	4	0	0	98	0.040	0.960	0.960	96%
6-12 weeks	94	4	2	1	94	0.042	0.958	0.919	91.9%
12-24 weeks	87	4	5	2	84.5	0.047	0.953	0.875	87.5%
24-52 weeks	76	2	5	0	73.5	0.027	0.973	0.851	85.1%
1-2 years	69	0	3	0	67.5	0	1	0.851	85.1%
2-3 years	66	0	1	0	65.5	0	1	0.851	85.1%

redo bypass surgery and ended up with below knee amputation. In e-PTFE group, 32 (31.3%) bypasses failed. In 14 cases no further intervention was done as there was only mild intermittent claudication in such patients. Remaining 18 cases were offered redo surgery. In 14 such patients a redo surgery with e-PTFE graft was performed. Of these, 9 patients showed a graft failure again and ended up with amputations. One patient was lost to follow up and three patients refused further bypass surgery and ended up with below knee amputation.

DISCUSSION:

The question whether saphenous vein stands superior to e-PTFE as a conduit for below-knee bypass graft surgery is not addressed in studies from Pakistan. In this study majority of the patients were followed up in outpatient department. After 3 years of follow-up, a significant difference in primary patency rates of 86.4% for vein and 62.9% for e-PTFE (p=0.032) was found. The secondary patency rates were 85.1% and 64.1% respectively. Veith et al demonstrated a primary patency rate of 70% in vein versus 56% in e-PTFE at 3 years.[14] This differs from our series because he had more patients with gangrene and it can be expected that the outflow in patients with gangrene is poor compared with those with claudication. This might explain the less favorable long-term patency rates described by Veith et al. Michaels had estimated that 160 grafts are required in the each group to have a 95% chance of showing significance, assuming that there is a 20% difference in 5-year patency rates.[15] Despite the fact that we did not include that many patients, a statistical difference in favor of venous graft was noted. When the patency rates for vein and e-PTFE were compared it was found that at all intervals a better primary patency rate for vein graft was apparent. Many studies showed that the autologous vein was a superior conduit than artificial graft.[3-6,15]

The results of present study are comparable to international literature in terms of patency rates of vein when compared with artificial graft.

The statistically significant risk factor differences between the two groups were the presence of diabetes mellitus and hypertension. Diabetes mellitus was significantly more in patients with e-PTFE. Evans et al and Prendiville et al found that diabetes has a negative influence on the patency of the bypass, whereas others did not find that effect.[16,17,13] Index study showed similar effect of diabetes mellitus. However due to smaller number of patients a type II statistical error can exist.[18]

Quinones-Baldrich et al and Veith et al suggested that the e-PTFE graft promotes progression of distal atherosclerosis hence may be responsible for more failures.[12,14] In our study there were 14 failing venous bypasses. Of these only three patients had critical ischemia and needed a reoperation. In the e-PTFE group, 14 reoperations were performed for 32 failing bypasses. Clearly, less reoperations were performed in the venous group. Keeping in view the statistically significant difference in two groups in terms of re-operations, our study supports this theory.

An advantage of e-PTFE is the significantly shorter operation time. In our study the e-PTFE operation was time was 98 minutes as compared to 240 minutes for venous bypass and the difference was statistically significant thus one can prefer e-PTFE as bypass graft of choice in patients with short life expectancy and high operative risk.[2,11]

The use of e-PTFE did result in a significant increase in major limb amputation rates when compared with vein conduits. The patency rates for e-PTFE were distinctly inferior to those of vein hence significantly more re-interventions were necessary to maintain equivalent limb salvages rates. Thirteen below knee

amputations were performed in this series giving a limb salvage rate of 93.5% at the end of 3 years. In all of these cases, the indication for the femoropopliteal bypass was gangrene. Veith et al described limb salvage rates of 77% but when compared to our study they had a higher number of patients with gangrene and furthermore the salvage rate was reported at the end of 4 years period.[14]

CONCLUSIONS:

Saphenous vein was superior for bypass grafting when compared with e-PTFE in terms of higher patency rates and limb salvage. However when the vein is unsuitable or not available for bypass, e-PTFE was a good alternative.

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