Saphenous Vein or PTFE for Femoropopliteal Bypass

A Prospective Randomized Trial

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To evaluate the patency of PTFE (Gore-tex®) as a femoropopliteal bypass, a prospective randomized trial was performed between PTFE and saphenous vein. Forty-nine consecutive patients with intermittent claudication, rest pain, or tissue loss due to an occlusion of the superficial femoral artery entered the study. Randomization between PTFE and saphenous vein was performed at the time of operation after assessment of the quality of the latter. The two groups did not differ significantly regarding stage of peripheral ischemia, outflow tract, or localization of the distal anastomosis. The patency rate 6 weeks after operation was 92% for each group. After a mean follow-up of 54 months, the patency rate for the PTFE group was 37% and 70% for the saphenous vein group ($p < 0.001$). In the PTFE group, there were eight major amputations. No amputations were performed in the saphenous vein group. It is concluded from this study that the saphenous vein is by far superior to PTFE as a femoropopliteal bypass.

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SINCE ITS INTRODUCTION by Kunlin (1951), the autologous saphenous vein has been the material of choice for a femoropopliteal bypass.[1,2] However, in nearly one-third of the patients considered for operation, the saphenous vein is absent or of inferior quality.[3,4] Therefore, a prosthetic graft of quality equal to that of saphenous vein would be of great value. The results of femoropopliteal bypass surgery by means of various prosthetic materials are disappointing.[5,6] But since expanded polytetrafluorethylene (PTFE, Gore-tex®) was introduced as a vascular prosthesis in 1973, excellent experimental results were reported.[7,8] PTFE grafts with an internal diameter varying between 4 and 8 mm were successfully used as femoropopliteal bypass in patients with intermittent claudication, rest pain, or tissue loss, according to some studies with a short follow-up of up to 12 months.[9-12] In other retrospective studies, it was suggested that the patency of PTFE was equal to autologous saphenous vein as femoropopliteal bypass.[13,14]

However, no controlled prospective randomized study existed between PTFE and saphenous vein as femoropopliteal bypass. Such a study must be performed before we can abandon the use of the saphenous vein as the material of choice for femoropopliteal bypass and use prosthetic grafts instead, even when an adequate saphenous vein is available. This prospective randomized trial was performed to obtain an answer to the question whether PTFE can be applied as an equivalent to saphenous vein for a femoropopliteal bypass in patients with a symptomatic occlusion of the superficial femoral artery.

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Patients and Methods

Forty-nine consecutive patients, nine women and 40 men, with peripheral ischemia due to an occlusion of the superficial femoral artery were accepted for this study and operated on between April 1978 and August 1980. Before surgery, all patients had an angiography and the quality of the outflow tract was qualified according to Morton[15] as good, moderate, or bad in a progressive obstruction. All bypass operations were carried out by two surgeons using identical operative techniques. Patients were only admitted to the trial when, at operation, the ipsilateral saphenous vein had a diameter of 4 mm or more and the vein was thought to be usable as a femoropopliteal bypass. After this assessment, a card was drawn that randomized between PTFE and saphenous vein. If the vein was not usable, a bypass with PTFE was performed, but these patients (25) were excluded from this study. At the start of this trial, the optimal diameter of a PTFE bypass was not clearly defined in the literature. We chose an 8 mm graft because in our experiments in dogs we had seen a marked thickening of the inner lining of 4 mm PTFE grafts. In 24 patients PTFE was used, and in 25 patients the saphenous vein was used. All operations were carried out under cefamandole prophylaxis. Both groups, the PTFE group and the saphenous vein (SV) group, did not differ significantly with regard to distribution of sex, mean age, stage of peripheral ischemia, smoking habits, concomitant diseases, classification of the outflow tract, or localization

of the distal anastomosis (Table 1). All patients were kept on fenprocoumon or acenocoumarol after surgery. The operations were carried out only if before surgery the anticoagulation was in the therapeutic range of 10% (Thrombotest). After dismissal from the hospital, the control of the anticoagulation was handed over to the Netherlands Federation of Thrombosis Services responsible for the laboratory control of approximately 150,000 patients under oral anticoagulation. It is this existing outstanding network of laboratories in Holland that prompted us to keep our patients on oral anticoagulation. The follow-up period ranged from 3 to 5 years.

During the follow-up, the patients had Doppler treadmill tests every 3 months in the first year after operation and every 6 months after the first year. Statistical analysis was performed with the Fisher test and the Wilcoxon test. The patency rates were determined by the life table method.

TABLE 1. *Patient Characteristics*

	PTFE	Saphenous Vein
Total	24	25
Men	21	19
Women	3	6
Mean age (in yrs.)	61 (±9)	65 (±9)
Interm. claudication	11	9
Rest pain	7	7
Tissue loss	6	9
Smokers	21	21
Nonsmokers	3	4
Chronic pulmonary disease	5	4
A.S.H.D.	11	12
Diabetes mellitus	2	3
Outflow: good	9	11
moderate	9	9
bad	4	4
?	2	1
Above-knee anastomosis	8	7
Below-knee anastomosis	16	18

Results

In the PTFE group, two reoperations were necessary: one for control of bleeding on the distal anastomosis and one for thrombectomy of an early occlusion of the PTFE bypass. Wound infections grades 1 and 2, according to Szilagyi,[16] were seen in nine patients, four in the PTFE group and five in the SV group, and were of no clinical consequence. Eighteen patients in the PTFE group and 20 patients in the SV group were free of symptoms after operation ($p > 0.10$). The Doppler ankle-brachial ratios after operation were compared with the preoperative values. The mean ankle-brachial index before surgery for the PTFE group was 0.49 (S.D.: 0.20) and also 0.49 (S.D.: 0.17) for the saphenous vein group. After operation, the mean index for the PTFE group was 0.95 (S.D.: 0.13) and 0.88 (S.D.: 0.20) for the SV group. In the PTFE group, the index after operation was 0.95 or more in 15 patients. In nine patients, the index was less than 0.95. In the SV group, the index after operation was 0.95 or more in 16 patients. In nine patients, the index was less than 0.95. The difference between the two groups regarding the improvement of the ankle-brachial index is not significant ($p > 0.10$). Within 6 weeks after operation, four bypasses occluded, two in each group. Thus the early patency rate, 6 weeks after operation, is 92% for each group. During a late follow-up period from 3 to 5 years, another 13 of the 24 PTFE grafts occluded, a patency rate for the PTFE group of 37%. Of these 15 patients, five patients were primarily operated on for disabling intermittent claudication, and 10 patients were operated for rest pain or tissue loss. Two patients had the distal anastomosis above the knee; 13 patients had the distal anastomosis below the knee. Despite various kinds of reoperations, eight major amputations had to be carried out, two of them in patients primarily operated on for intermittent claudication. In both cases, the distal anastomosis was below the knee.

Six saphenous vein grafts occluded during the follow-up, a patency rate after 5 years of 70%. Of these six patients, three patients were operated on for intermittent claudication, and three were operated on for rest pain or tissue loss. One patient had the distal anastomosis above the knee; the other five patients all had the distal anastomosis below the knee. One patient was reoperated. No amputations were necessary in the saphenous vein group.

There were no operative or postoperative deaths in either group. The difference in patency rates between the two groups is statistically significant ($p < 0.001$) (Fig. 1).

Discussion

The indication for surgery of atherosclerotic occlusive disease of the superficial femoral artery is a matter of con-

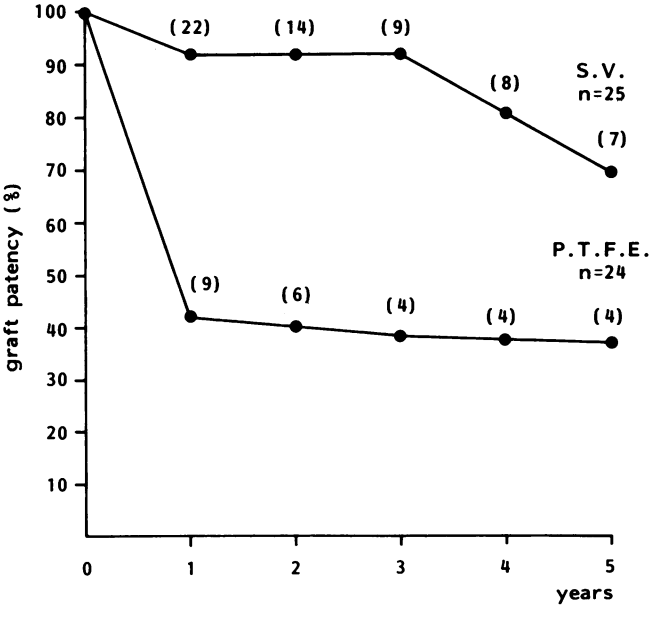

FIG. 1. Cumulative patency rates of vein and PTFE grafts.

troversy. In patients with intermittent claudication, the results of the operation, *e.g.*, a femoropopliteal bypass, must be excellent, while the natural history of intermittent claudication is favorable, especially when patients stop smoking completely,[17,18] In patients with rest pain or tissue loss, the need for revascularization is apparent. The results of femoropopliteal bypass operation with saphenous vein for limb salvage as well as for intermittent claudication have been reported as good to excellent.[2,3] Results with prosthetic materials must be compared to results with saphenous vein femoropopliteal bypass.

If in a prospective randomized trial, the quality of venous and prosthetic femoropopliteal bypasses are proved to be equal, then and only then are we allowed to use prosthetic material for femoropopliteal bypass in patients with a good saphenous vein.

The two groups in this trial did not differ significantly with regard to stage of peripheral ischemia, quality of the outflow tract, and localization of the distal anastomosis. The short-term patency was 92% in both groups. Therefore, it is unlikely that the difference in the late patency rate in favor of the saphenous vein group could be attributed to an insufficient surgical technique or any other cause other than the difference in bypass material.

One advantage of the use of prosthetic material in femoropopliteal bypass would be a reduced operating time.[9,13,14] This could be confirmed in our study without a difference in operative or postoperative complications. Thus, a reduced operating time cannot be a real argument for the use of prosthetic material.

The patency rate of 37% for the PTFE group is very disappointing but is compatible with the results in various other studies,[19,20] although it is in contrast with the results of Bergan et al.[21] However, in this last study, there may be some flaw in the randomization procedure because three different methods of randomization were carried out *before* assessment of the quality of the vein. Thus, after randomization of 388 patients, 161 patients had to be withdrawn from the study because they had an absent or inadequate vein. After thrombosis of a PTFE bypass, a reoperation could never restore the long-term patency. Eight out of 14 patients with a thrombosed bypass had to have a major amputation. Two of these eight amputated patients were primarily operated on for intermittent claudication.

In sharp contrast with these figures are the six thrombosed vein bypasses. One venous bypass thrombosed after the development of an aneurysm of the vein graft. This was the only patient in the SV group who was reoperated. The other five were all treated conservatively. Three of them, operated on for rest pain or tissue loss, had only intermittent claudication after occlusion of the bypass. No amputations had to be performed in the saphenous vein group.

From this prospective randomized trial, it is evident that the material used for a femoropopliteal bypass is the most important factor for long-term patency. The saphenous vein is by far superior to PTFE. The latter should be reserved only for patients with rest pain or tissue loss when no autologous saphenous vein can be used.

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