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Permalink

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Journal

The American Journal of Surgery, 168(2)

ISSN

0002-9610

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Publication Date

1994-08-01

DOI

10.1016/s0002-9610(94)80048-0

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Peer reviewed

Determinants of Patency After Percutaneous Angioplasty and Atherectomy of Occluded Superficial Femoral Arteries

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BACKGROUND: Patients undergoing percutaneous recanalization of chronically occluded superficial femoral arteries were studied to determine which factors correlated with 1-year patency. Immediate change in ankle:brachial index (ABI), length of occlusion, tibial run-off, and the performance of supplemental catheter atherectomy were evaluated.

METHODS: Eligible patients had at least one patent tibial run-off vessel and the absence of limb-threatening ischemia. Recanalization was performed via passage of a guidewire followed by balloon angioplasty. Tibial run-off was scored based on a modification of the angiogram scoring system of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery. Supplemental transcatheter extraction catheter atherectomy was randomly assigned to a sub-group of patients after initial experience with the recanalization technique. Clinical follow-up was employed to determine patency.

RESULTS: Forty-two of 57 attempts (74%) at recanalization were immediately successful. Overall 1-year patency was 40% in 40 limbs that could be followed. In limbs with balloon angioplasty alone ($n = 23$), patency was 43% compared with 35% in those having supplemental atherectomy. Tibial run-off did not vary significantly between patent and occluded groups. When ABI increased by 0.3 or more, patency was 56% compared with 26% when the ABI increase was less than or equal to 0.1 ($P = 0.13$). Occlusion length averaged 18.1 ± 10.6 cm for all limbs and did not vary significantly between early successes and failures. Limbs with short occlusions (less than or equal to 5 cm, $n = 8$) had 63% patency compared with 38% patency for limbs with long occlusions (greater than 25 cm, $n = 16$), but the difference was not significant by analysis of variance.

CONCLUSIONS: An initial change in ABI was most predictive for patency, whereas no correlation with tibial run-off was demonstrated. Atherectomy did not increase patency. Short occlusions

were more likely to remain patent than long ones, but overall patency was lower than described in other series.

The patient with claudication because of chronic occlusion of the superficial femoral artery (SFA) is not generally considered a suitable candidate for bypass surgery unless the symptoms are incapacitating. The possibility that percutaneous recanalization of the occluded SFA with interventional radiology techniques can yield satisfactory clinical results has led us to study this approach. Our basic method entails penetrating the occlusion in the SFA with a guidewire and positioning the tip in the true lumen distally; this recanalization step is then followed by balloon catheter angioplasty. We report here the results of attempted mechanical SFA recanalization in 57 limbs with patency analyzed based on the length of the SFA occlusion, whether supplemental catheter atherectomy was performed, the immediate change in ankle:brachial index (ABI) pressures achieved by the procedure, and the quality of the tibial run-off vessels.

PATIENTS AND METHODS

Between June 1989 and October 1993, recanalization was attempted in 57 occluded SFAs (49 patients total) at the Veterans Administration Medical Center (Long Beach, California) according to one of two protocols approved by the institutional review board. In both protocols, only patients with angiographically demonstrated complete SFA occlusion and supragenicular popliteal reconstruction with one or more intact tibial run-off vessels were eligible. The length of occlusion and the presence of calcification were not criteria for inclusion or exclusion. Patients were excluded if ischemic rest pain, ulceration, or gangrene was present or if previous vascular reconstruction of the femoral or distal vessels had been performed. Until October 1991, patients underwent balloon angioplasty after recanalization only. After October 1991, catheter atherectomy was randomly assigned to two thirds of the patients, with one third undergoing balloon angioplasty alone.

The technique employed for recanalization has been described in detail elsewhere.¹ In this series, only one radiologist (RMC) performed the recanalization. All patients underwent initial antegrade ipsilateral common femoral artery puncture and placement of a 7F or 8F introducer sheath with a hemostatic valve into the common femoral artery. Under fluoroscopic guidance, a stiff straight 0.038-inch guidewire was inserted through a 7F plastic Torcon 7 Fr catheter tapered to 5 Fr with a right angle tip (Cook Inc., Bloomington, Indiana) and passed to the point of obstruction. The area of obstruction was probed under fluoroscopy, and the catheter and guidewire were advanced

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Presented at the 22nd Annual Meeting of the Society for Clinical Vascular Surgery, Tucson, Arizona, March 2-6, 1994.

progressively through the arterial obstruction by the operator applying graded force. In cases in which the wire could not be passed completely through the occlusion, a preliminary 6-mm balloon angioplasty of the portion of the occlusion already penetrated by the wire was usually performed. This tends to create a dissection that assists in penetrating the atheroma and positioning the guidewire in the true lumen distally. In a few cases in which either long occlusions (greater than 15 cm) or occlusion of the SFA flush with its origin were present, the antegrade approach was supplemented by a popliteal puncture and retrograde passage of wires and catheters through the occlusion.

Once a guidewire had been passed through the occlusion into the true lumen proximally and distally, angioplasty was performed using 6- or 7-mm diameter balloon catheters. In patients undergoing supplemental catheter atherectomy, a 2.7-mm diameter (or larger) transcatheter extraction catheter (TEC)² was passed through the occlusion, and the cutting mechanism was engaged. During the atherectomy, a suction bottle was connected to the central lumen of the catheter to aspirate debris. Systemic anticoagulation with heparin (5,000 units intravenous bolus followed by 1,000 units per hour intravenously) was routinely instituted after the initial arterial puncture, but discontinued at the conclusion of the procedure. Completion angiograms were obtained in every case if fluoroscopy demonstrated blood flow connecting the distal and proximal SFA lumens. Patients were observed 48 hours in hospital after the procedure and discharged on aspirin without other anticoagulation therapy. ABI measurements made prior to hospital discharge were compared with pre-procedure ABIs to calculate the net change.

The length of the SFA occlusion was determined by direct measurement of the angiogram obtained immediately prior to recanalization. Completion angiograms were quantitated to assess the tibial run-off according to the scoring system proposed by the Ad Hoc Committee on Reporting Standards for the Society for Vascular Surgery and the International Society for Cardiovascular Surgery (SVS-ISCVS).³ With this system, each tibial vessel is scored from 0 to 3; 0 represents little or no disease, and 3 represents 50% or more occlusion of the entire vessel length. The overall score assigned was the sum of the values obtained for each tibial vessel (no scoring of the pedal arch was performed, since this was not uniformly evaluable on each angiogram).

Each patient was followed at 3, 6, and 12 months to assess patency. Only two patients have been excluded from the 1-year patency analysis due to inadequate follow-up; in the remaining patients, the determination of patency is based on physical examination of the popliteal and pedal pulses, ABI measurements, and detailed review with each patient of his or her claudication symptoms. Statistical analysis and analysis of variance were performed using a personal computer statistics program (GraphPAD Software, San Diego, California).

RESULTS

A total of 57 patients underwent attempted recanalization of an occluded SFA. Of these, 42 (74%) were immediately successful based on angiographic demonstra-

TABLE I
Patency Data for Different Subgroups

Subgroup	No.	Percent Patency*		
		3 Months	6 Months	12 Months
All†	40	82	50	40
Balloon‡	23	78	47	43
TEC§	17	88	52	35
Length ≤5 cm¶	8	87	62	62
Length ≤10 cm#	16	81	50	50
Length >25 cm**	16	87	43	37
ΔABI <0.1††	15	66	26	26
ΔABI ≥0.3‡‡	9	88	77	55

*Percentage of entire subgroup still patent at specified interval
 †Patients who underwent 6- or 7-mm balloon angioplasty alone.
 ‡Patients who had supplemental TEC catheter atherectomy.
 §Percentage of original group with continued SFA patency.
 ¶Patient subgroup with 5 cm or shorter occlusion.
 #Patient subgroup with 10 cm or shorter occlusion.
 **Patient subgroup with occlusions longer than 25 cm.
 ††Patient subgroup with initial change in ABI less than 0.1.
 ‡‡Patient subgroup with initial change in ABI of 0.3 or more.
 TEC = transcatheter extraction catheter; ABI = ankle-brachial index.

tion of blood flow through the previous occlusion at the end of the procedure. **Table I** shows the patency data for the 40 patients with adequate 1-year follow-up. The patency at 1 year was 40% (16 of 40) for the entire group who had successful initial recanalization with adequate follow-up. This corresponds to an aggregate patency of 29% (16 of 55) in patients undergoing attempted recanalization. In the 23 patients undergoing balloon angioplasty after successful recanalization, 1-year patency was 43% (10 of 23) compared with 35% 1-year patency in the patients undergoing supplemental TEC atherectomy (6 of 17). This difference in patency was not significant by Mantel-Haenszel life-table analysis.

As shown in **Table I**, as the length of occlusion increased, patency decreased. For short occlusions of 5 cm or less, 1-year patency was 62%, compared with 50% 1-year patency for occlusions 10 cm or less, and 37% for long occlusions of 25 cm or more; these differences were not, however, statistically significant. When initial ΔABI was used to identify two groups, patients with an increase in ABI less than 0.1, and patients with a ΔABI of greater than or equal to 0.3, 1-year patencies were 26% and 55%, respectively. This latter difference approached marginal significance (Mantel-Haenszel *P* = 0.13).

Table II shows more information regarding the relation between the ΔABI and the various subgroups chosen for analysis. The mean ΔABI for all patients was 0.159 ± 0.211, with a median value of 0.165. When the balloon and TEC groups are compared, the mean ΔABI achieved was slightly smaller for the atherectomy group, but the difference was not significant. When the length of patency was used as a variable, patients with less than 3-month patency had a significantly lower ΔABI, -0.038 ± 0.255, compared with a ΔABI of 0.210 ± 0.175 for those with 3 or more months of patency (*P* = 0.0049). Similar relationships held for 6- and 12-month patency, with the ΔABI being significantly larger in the subgroup whose vessels remained patent compared with its opposite.

TABLE II

Correlation of Δ ABI With Treatment Group and Patency

Subgroup	No.	Post-Procedure Δ ABI				
		Mean	Standard Deviation	Median	Minimum	Maximum
All*	40	0.159	0.211	0.165	-0.380	0.650
Balloon†	23	0.166	0.205	0.170	-0.380	0.640
TEC‡	17	0.148	0.225	0.160	-0.310	0.650
<3 month‡	7	-0.038‡	0.255	-0.050	-0.380	0.340
≥3 month§	33	0.210‡	0.175	0.180	-0.060	0.650
<6 month¶	20	0.072§	0.200	0.065	-0.380	0.490
≥6 month#	20	0.245§	0.189	0.215	-0.060	0.650
<12 month**	24	0.102¶	0.197	0.105	-0.380	0.490
≥12 month††	16	0.246¶	0.207	0.200	-0.060	0.650

*Patients who underwent 6- or 7-mm balloon angioplasty alone.

†Patients who had TEC catheter atherectomy and angioplasty.

‡Subgroup with superficial femoral artery (SFA) patency <3 months.

§Subgroup with SFA patency ≥3 months.

¶Subgroup with SFA patency <6 months.

#Subgroup with SFA patency ≥6 months.

**Subgroup with SFA patency <12 months ABI <0.1.

††Subgroup with SFA patency ≥12 months.

‡‡When the Δ ABI distributions are compared by Student's t-test for the <3-month and ≥3-month subgroups, the two-tailed $P = 0.0049$.

§§When the Δ ABI distributions are compared by Student's t-test for the <6-month and ≥6-month subgroups, the two-tailed $P = 0.0077$.

¶¶When the Δ ABI distributions are compared by Student's t-test for the <12-month and ≥12-month subgroups, the two-tailed $P = 0.0308$.

Δ ABI = change in ankle:brachial index; TEC = transcatheter extraction catheter.

When the length of the initial occlusion was correlated with the patency subgroup, the results shown in Table III were obtained. The mean length of occlusion for all patients with SFA in whom recanalization was attempted was 18.1 ± 10.6 cm. The 15 patients who did not achieve a successful recanalization had a mean occlusion length of 17.4 cm compared with 18.4 cm for the 42 patients who had successful recanalization. Although analysis of variance showed no significant difference between mean or median occlusion lengths for any subgroups, it is noteworthy that, as patency increased, both the mean and median occlusion lengths tended to decrease.

When the quality of the tibial run-off was scored with the SVS-ISCVS scale and correlated with patency results, the data shown in Table IV were obtained. No significant differences were found between the mean or median scores for the patency subgroups using parametric or nonparametric analysis of variance (Kruskal-Wallis).

There were no deaths or amputations within 30 days for any of the treated patients. The overall number of patients experiencing significant immediate morbidity was 12% (7 of 57). Two patients required immediate surgery for worsened ischemia after failed attempts at recanalization; both had tibial emboli and were managed with femoropopliteal bypass and concomitant fluoroscopically guided tibial embolectomy. Four patients had bleeding requiring transfusion; two of these patients required groin exploration for surgical control of continued hemorrhage from the femoral artery puncture site. One patient had a myocardial infarction related to the bleeding episode. There was one permanent sciatic nerve injury secondary to a popliteal puncture. Although complete 1-year follow-up on all limbs is not available for all complications, there were 2 amputations and 4 bypass operations performed

by 1 year in the 34 patients for whom such information is available, including 3 limbs in which the recanalization was initially successful.

COMMENTS

Our series shows an overall patency rate of 29% for all limbs in which an attempted recanalization was performed and 40% when the recanalization was successful. Balloon angioplasty alone yielded equal patency to angioplasty supplemented by catheter atherectomy. The quality of the tibial run-off did not correlate with patency; length, however, did seem to exert some influence, although the differences between the shortest and longest subgroups did not reach statistical significance. The initial change in ABI did, however, correlate significantly with patency rates, with patients who had patent vessels at 1 year having initial Δ ABI more than twice that of patients who had a failure of the recanalization by 1 year.

Previous reports of the results of recanalization angioplasty of occluded SFAs have yielded results comparable to our own in several regards. Improvement in ABI has strongly correlated with patency in virtually all such studies. Tibial run-off, however, was found to correlate with patency in two other studies^{3,4} in which reduced run-off (less than two patent tibial arteries) resulted in significantly reduced patency, although not in another.⁵ Whether a patient had rest pain or tissue loss versus claudication, however, did correlate with patency in the latter study, with much worse 1-year patency (23%) found for patients with limb threat compared with those with claudication only (85%).⁵ It is possible that our exclusion of patients with severe symptoms and the requirement for one intact tibial vessel (as well as ignoring the patency of the pedal arches in scoring tibial outflow) made our treatment group

TABLE III

Correlation of Occlusion Length With Patency and Treatment Group

Subgroup	No.	Length of Occlusion (cm)				
		Mean	Standard Deviation	Median	Minimum	Maximum
All*	40	18.4	11.8	22	2	45
Never†	15	17.4	11.7	10	7	39.5
Balloon‡	23	15.9	12.2	10	3	45
TEC§	17	21.9	10.6	26	2	34
<3 month¶	7	17.0	11.3	16	2	32
≥3 month#	33	18.7	12.1	24	3	45
<6 month**	20	19.3	11.5	24.5	2	34
≥6 month††	20	17.6	12.3	16	3	45
<12 month‡‡	24	19.5	11.0	24	2	34
≥12 month§§	16	16.9	13.2	10	7	39.5

*All who had successful recanalization and adequate follow-up
 †Patients who had unsuccessful recanalization.
 ‡Patients who had balloon angioplasty alone.
 §Patients who had TEC catheter atherectomy and angioplasty.
 ¶Subgroup with SFA patency <3 months.
 #Subgroup with SFA patency ≥3 months
 **Subgroup with SFA patency <6 months.
 ††Subgroup with SFA patency ≥6 months.
 ‡‡Subgroup with SFA patency <12 months.
 §§Subgroup with SFA patency ≥12 months.
 TEC = transcatheter extraction catheter.

too homogeneous to allow a correlation between run-off and patency to be demonstrated.

Previous reports on the efficacy of catheter atherectomy have shown mixed results. In general, it is believed that when atherectomy significantly decreases residual stenosis remaining after balloon angioplasty, patency is improved,³ although a previous trial comparing balloon angioplasty alone to atherectomy with the Simpson atherectomy catheter showed significantly better results for angioplasty.⁶ Our measurements of the amount of atheroma removed by the TEC using intravascular ultrasound imaging indicate that only about 10% of the material impinging on the lumen after recanalization is in fact removed by atherectomy (ILG et al, unpublished data). As a consequence, the failure in this study for TEC atherectomy to improve patency is not surprising.

The most striking difference between this and earlier reports is the low overall patency we found compared with the 1-year patency rates of 55% to 80% described by other researchers for patients undergoing successful recanalization.⁴⁻¹¹ This discrepancy is partly attributable to the different distribution of occlusion lengths in our patients compared with the lengths present in these other studies. Most investigators have excluded patients with occlusions greater than 10 cm and concentrated on occlusions 5 cm or shorter, although two investigations^{9,11} reporting on occlusions averaging greater than 10 cm did find better patency than we have experienced for reasons that are not clear. When long (greater than 10 cm) and short occlusions have been included, increasing length is generally found to result in decreased patency.^{4,9,10} Given the long lengths of occlusion we have treated, we believe our results are consistent with the patencies found after recanalization of short occlusions. Further refinement of the technique allowing its application to long occlusions seems warranted. We are currently studying placing intraluminal

TABLE IV

Correlation of Tibial Run-Off With Patency

Subgroup	No.	SVS-ISCVS Score		
		Mean	Standard Deviation	Median
All*	40	3.16	2.56	3.0
<3 month†	7	4.00	2.65	6.0
≥3 month‡	33	2.98	2.55	3.0
<6 month§	20	3.30	2.64	3.0
≥6 month¶	20	3.02	2.54	3.0
<12 month#	24	3.15	2.58	3.0
≥12 month**	16	3.19	2.60	3.0

*All who had successful recanalization and adequate follow-up.
 †Subgroup with SFA patency <3 months.
 ‡Subgroup with SFA patency ≥3 months
 §Subgroup with SFA patency <6 months.
 ¶Subgroup with SFA patency ≥6 months.
 #Subgroup with SFA patency <12 months.
 **Subgroup with SFA patency ≥12 months

stents after recanalization in the hopes that this modification will improve patency.

Given the results in this series of patients with claudication, we do not recommend percutaneous recanalization and angioplasty as primary therapy in patients with limb-threatening ischemia in whom femoropopliteal bypass is feasible. Short SFA occlusions in less symptomatic patients can perhaps be appropriately managed percutaneously, but further development of this technique is required before it can be considered equal to bypass with either prosthetic or autologous conduits.

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DISCUSSION

Dr. Baker: Do you have any follow-up angiography or ultrasound data?

Dr. Gordon: In the last two years we have been routinely using intravascular ultrasound to assess the lumen we create. It does not look good by intravascular ultrasound; there is a lot of irregularity. The atherectomy is only removing 10% of the plaque that was present. We compare the lumen by intravascular ultrasound before and after the atherectomy, so the atherectomy does not seem to be achieving much.

Dr. Rutherford: Seventy percent of the patients were not benefited at 1 year. Could you tell us what happened to the patients after treatment failure?

Dr. Gordon: We had no immediate deaths, no immediate amputations, emergency bypass in two patients who embolized to their tibial vessels, and several patients required bypass within one year. Two patients required amputation within the first year.