Limb salvage by percutaneous transluminal recanalization of the occluded superficial femoral artery


Six patients with rest pain and gangrene or ulceration were treated by percutaneous transluminal angioplasty using the Grünzig balloon catheter. All had superficial femoral artery occlusion with severe stenosis or occlusion of the popliteal and tibial arteries. Two patients had previous distal bypass procedures which had failed, and none was a candidate for arterial reconstruction. The superficial femoral artery was recanalized in five patients with an increase in the above-knee pressure index from 0.5 ± 0.1 to 1.0 ± 0.1 (P < 0.001) and ankle pressure index from 0.2 ± 0.1 to 0.5 ± 0.1 (P < 0.001). All five patients avoided early amputation and were able to ambulate when discharged. The sixth patient could not be recanalized and required above-knee amputation. Restenosis of the recanalized superficial femoral artery occurred in four patients 2 to 5 months later, and repeat transluminal angioplasty was successful in three patients. Two patients have required below-knee amputation 4 and 5 months after recanalization. Transluminal angioplasty can extend our capability of early limb salvage.

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Limb salvage in patients with severe arterial insufficiency is usually accomplished by direct arterial reconstruction. However, many patients have extensive distal occlusive disease with poor run-off, making revascularization procedures impossible and resulting in amputation. Percutaneous transluminal angioplasty using a coaxial catheter system was introduced by Dotter and Judkins in 1964. Grünzig improved the technique by introducing a catheter with an inflatable balloon near its tip, allowing high pressure transluminal compression of atherosclerotic plaques. Various forms of this catheter have been used to recanalize or to dilate femoral, iliac, coronary and renal arteries. As is true in femoropopliteal arterial reconstruction, the initial and long-term success rates of transluminal angioplasty are closely related to the severity of disease and the quality of outflow vessels, with poor results in long-segment occlusions and poor run-off situations. We have evaluated the effectiveness of transluminal balloon catheter recanalization in extending our capability of limb salvage in a group of elderly patients who were not candidates for arterial reconstruction.

METHOD

All patients threatened with limb loss due to ischemia were evaluated with full angiography of the aortoiliac, femoral, popliteal, and distal vessels, using standard transfemoral Seldinger catheter technique. Delayed filming technique and selective injection of the femoral artery was carried out in order to identify tibial and pedal vessels. Patients with superficial femoral artery occlusion who were not candidates for arterial reconstruction were considered for femoral recanalization using the balloon catheter developed by Grünzig. The catheter consists of an inner flexible polyethylene catheter coated with relatively inelastic polyvinyl chloride which forms an inflatable balloon near the tip. The balloon portion of the catheter can be inflated with considerable force without distending it beyond its preformed diameter, allowing relatively high pressure compression of the stenosis with little danger of overstressing or rupturing the artery.

The procedure was usually performed through an arterial puncture in the contralateral common femoral artery. A “pigtails” catheter was advanced to the
Table I. Systolic blood pressure index

<table>
<thead>
<tr>
<th>Level</th>
<th>Before recanalization</th>
<th>After recanalization</th>
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<tr>
<td>Upper thigh</td>
<td>0.9 ± 0.1</td>
<td>1.0 ± 0.1</td>
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<tr>
<td>Above knee</td>
<td>0.6 ± 0.1</td>
<td>1.0 ± 0.1†</td>
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<tr>
<td>Below knee</td>
<td>0.3 ± 0.1</td>
<td>0.6 ± 0.1†</td>
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<tr>
<td>Ankle</td>
<td>0.2 ± 0.1</td>
<td>0.5 ± 0.1†</td>
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*± SEM, n = 6
†P < 0.001 (Student’s paired t test)

mg) were administered through the catheter and followed with a continuous infusion of dilute heparin solution during the dilating procedure. The balloon was inflated to its maximum diameter for a period of 30 seconds. After balloon deflation the catheter was retracted into the more proximal lesion, allowing a 1 cm overlap. Sequential 30-second inflation and deflation of the balloon were carried out until the full extent of the lesion was dilated. The catheter then was withdrawn into the femoral artery 5 cm above the lesion, and repeat angiography was carried out. A total of 5,000 units of aqueous heparin was administered during the dilating procedure. Intravenous heparin (1,000 units/hr) was continued for a period of 3 days, after which the patients were maintained on Coumadin therapy.

Lower extremity perfusion was objectively assessed in all patients by recording Doppler ultrasound flow velocity and measuring systolic blood pressure at four levels in the leg: (1) upper thigh, (2) above knee, (3) below knee, (4) and ankle, as well as in both arms. Leg pressure was related to systemic pressure by calculating the ratio of leg to arm in each instance and expressed as the systolic pressure index (normal 1.1 ± 0.1). Lower extremity pressure indices were recorded at daily intervals after dilatation and at monthly intervals after discharge. Follow-up arteriograms were obtained 2 to 4 weeks after dilatation and subsequently as clinically indicated.

**PATIENT SUMMARY**

Six female patients, 70 to 79 years of age, form the basis of this report. All had end-stage peripheral occlusive disease with rest pain and gangrene or ulceration. All patients were hypertensive and three had diabetes. Five were nonsmokers and the sixth had stopped smoking 2 years earlier. Extensive femoropopliteal occlusive disease was demonstrated arteriographically in all patients, whereas minimal disease was present in the aortoiliac system. Two
patients had failed vascular reconstructions and faced immediate amputation. Four were not candidates for operative revascularization.

Transluminal angioplasty using the Grünzig balloon catheter resulted in recanalization of the superficial femoral artery in five of the six patients, with an increase in systolic pressure indices in each (Table I). Early amputation was avoided, and these five patients were able to ambulate when discharged from the hospital. The superficial femoral artery could not be recanalized in one patient, and this patient had no change in systolic pressure indices and required early above-knee amputation.

Restenosis occurred in four patients 1 to 4 months after recanalization, and repeat transluminal angioplasty was successful in three. Two recanalized patients have required below-knee amputation: one after 4 months when repeat dilatation was unsuccessful, and the other after 5 months due to progression of infrapopliteal occlusion. This patient had avoided urgent above-knee amputation and had a patent superficial femoral artery at the time of below-knee amputation.

CASE REPORTS

Case 1. M.K., a 79-year-old woman, admitted with rest pain and cellulitis of the foot. Five months earlier she had rest pain and gangrene at the base of the fifth toe with no recordable ankle blood pressure. Angiography at the time revealed occlusion of the superficial femoral artery, severe popliteal stenosis and occlusion of the anterior tibial, posterior tibial, and peroneal arteries. A poor quality peroneal artery reconstituted 11 cm below the popliteal trifurcation. The dorsalis pedis artery was patent, but the posterior tibial artery in the foot was occluded. A Gore-Tex femoral to dorsalis pedis bypass graft was performed with complete relief of rest pain and prompt healing of the gangrenous area, allowing the patient to be fully ambulatory. The graft remained functional for 5 months, but required thrombectomy on three occasions. The patient was admitted with a fourth graft thrombosis, rest pain, and cellulitis about the exposed graft on the dorsum of the foot. Blood pressure below the knee and at the ankle was not recordable. The infected Gore-Tex bypass graft was removed and the patient faced the need for an immediate above-knee amputation. A 10 cm segment of superficial femoral and popliteal artery was recanalized using the Grünzig balloon catheter (Fig. 1). The patient had immediate relief of rest pain and had a warm, hyperemic foot. The ankle pressure index was 0.7 and the above-knee pressure index increased from 0.6 to 1.0. Five months following dilatation the patient returned with symptoms of rest pain and a decrease in the above-knee pressure index to 0.4. Angiography revealed a 6 cm stenosis at the adductor hiatus (Fig. 2). This lesion was redilated using the Grünzig balloon catheter with relief of the patient’s symptoms. The above-knee pressure index increased to 1.1. Six months since her initial dilatation she is ambulatory and asymptomatic.
Fig. 3. Case 2: A, Superficial femoral artery occlusion at adductor hiatus. B, Recanalized superficial femoral artery with residual stenosis proximal to recanalized segment (arrow). C, Area of proximal stenosis has been dilated but residual stenosis is present in popliteal artery (arrow). D, The popliteal stenosis has been dilated 4½ months after the original dilatation.

Fig. 4. Case 3: A, Occluded superficial femoral artery after failure of thrombectomy. Severe stenosis of popliteal artery in two places (arrows). B, Patent superficial femoral and popliteal artery after recanalization and dilatation.

Case 2. L.D., a 74-year-old woman, was admitted with severe rest pain and ischemic ulceration of the left great toe. Arteriography revealed occlusion of the superficial femoral artery at the adductor hiatus (Fig. 3, A). The popliteal artery was patent with poor run-off through a diseased peroneal artery which was occluded 5 cm above the ankle. The anterior and posterior tibial arteries were occluded with no distal reconstitution or visualization of the plantar arch, though collateral channels were present in the foot. A 7 cm segment of superficial femoral artery was recanalized with an increase in the above-knee pressure index from 0.7 to 1.1 and an increase in the ankle pressure index from 0.3 to 0.5. The patient's symptoms were relieved and the ulceration healed with a skin graft. Postdilatation angiography revealed residual stenosis in the superficial femoral artery proximal to the recanalized area (Fig. 3, B). The superficial femoral artery reclosed after 1 month, and dilatation of the proximal lesion was carried out successfully. Residual stenosis in the popliteal artery was seen at that time (Fig. 3, C). The patient again developed rest pain and great toe ulceration 4½ months after dilatation. Repeat Grünzig catheter dilatation of the popliteal and superficial femoral arteries was carried out with a good response and an increase in the ankle pressure index from 0.2 to 0.8 (Fig. 3, D). The above-knee pressure index increased from 0.6 to 1.1. Six months after the original dilatation, the patient is now ambulatory with a healed great toe amputation.

Case 3. G.C., a 73-year-old woman with diabetes and severe coronary artery disease and previous myocardial infarction, was admitted with an acutely ischemic right leg with loss of motion and sensation in the foot. Below-knee and ankle blood pressures were unrecordable, and the above-knee pressure index was 0.5. Arteriography revealed acute occlusion of the superficial femoral artery. Following catheter thrombectomy, operative arteriography revealed stenosis of the superficial femoral artery at the adductor
Fig. 5. Case 3: A, Restenosis of the superficial femoral artery 3 months after recanalization. B, Redilatation of the superficial femoral artery lesion.

Fig. 6. Case 4: A, Occlusion of the superficial femoral artery at the adductor hiatus. B, Patency of the superficial femoral artery after recanalization (dilatation). C, Restenosis of the superficial femoral artery 4 months after dilatation.

The femoral artery rethrombosed 24 hours later and arteriography revealed a 10 cm occlusion of the superficial femoral artery with severe stenosis of the midpopliteal artery and popliteal trifurcation (Fig. 4, A). The anterior tibial artery was occluded, but the posterior tibial artery was patent to the distal calf. A femoral to posterior tibial Gore-Tex bypass graft was performed. Operative arteriography revealed poor outflow from the graft due to posterior tibial artery occlusion at the level of the ankle with no visualization of a plantar arch. The
bypass graft thrombosed 12 hours later, and the patient had a cold, numb leg to the level of the knee and would have required an immediate above-knee amputation. Transluminal recanalization of the superficial femoral artery and dilatation of the popliteal artery and popliteal trifurcation was carried out. Ankle pressure index increased to 0.4 and the above-knee pressure index increased to 1.0. Follow-up arteriography 2 weeks later revealed a patent superficial femoral and popliteal artery (Fig. 4, B). The anterior and posterior tibial arteries were occluded and the peroneal artery had severe stenosis. The patient had a warm foot with normal sensation and motion, but was left with a small area of dry gangrene on the tip of her great toe. She was able to ambulate with the aid of a walker and was discharged from the hospital. Three months later the patient developed increasing pain the gangrenous area of her toe, and follow-up arteriography revealed stenosis of the popliteal and peroneal arteries and restenosis of the superficial femoral artery. This was redilated with an increase in above-knee pressure index from 0.6 to 1.1 (Fig. 5). After 5 months the peroneal artery lesion had progressed to complete occlusion and the gangrenous toe became infected, but the superficial femoral artery remained patent. The ankle pressure index remained at 0.4 and the above-knee pressure index remained at 1.1. A below-knee amputation was performed 5 months after the initial dilatation and healed without difficulty.

**Case 4.** S.H., a 74-year old woman, was admitted with cellulitis and gangrene of the right second and third toe. Ankle pressure index was 0.1 and above-knee pressure index was 0.5. Seven years earlier the patient had gangrene of the left great toe, and angiography revealed the superficial femoral artery to be patent in both legs with infrapopliteal occlusive disease. A left lumbar sympathectomy was unsuccessful and the patient underwent below-knee amputation. Arteriography during the present admission revealed occlusion of the right superficial femoral artery at the adductor hiatus with severe stenosis of the popliteal artery and complete obstruction of the anterior and posterior tibial and peroneal arteries (Fig. 6, A). Blood flow to the foot was by small collateral channels. The patient was not a candidate for vascular reconstruction and underwent transluminal dilatation of a 10 cm segment of superficial femoral artery (Fig. 6, B). Ankle pressure index increased to 0.5, and the above-knee pressure index increased to 1.0. The patient's gangrenous areas healed, and she was discharged from the hospital ambulating with a walker. Four months later she was readmitted with wet gangrene of the foot. The ankle pressure index had decreased to 0.1, and repeat arteriography revealed restenosis of the superficial femoral artery (Fig. 6, C). An attempt to redilate the artery was unsuccessful due to spasm, and below-knee amputation was performed 4 months after initial dilatation.

**Case 5.** M.R., a 77-year-old woman with diabetes, was admitted with a 3 by 5 cm painful ischemic ulcer on the lateral aspect of her right ankle. The above-knee pressure index was 0.5 and the ankle pressure index was 0.3. Arteriography revealed five segmental occlusions in the superficial femoral artery, totaling 29 cm in length (Fig. 7 J). The popliteal artery had multiple stenoses, and the anterior tibial and posterior tibial arteries were occluded with no distal reconstitution. The peroneal artery was occluded at its origin and was reconstituted for a short segment in the midcalf. Pedal vessels were not visualized. Balloon catheter recanalization of the superficial femoral
artery was carried out, and postdilatation angiography revealed patency of the entire superficial femoral artery (Fig. 7, B). The above-knee pressure index increased to 0.9, and the ankle pressure index increased to 0.6. The patient had a warm, hyperemic foot, was able to ambulate with assistance, and left the hospital with a clean, granulating wound. Two months later she was readmitted with an acute abdominal catastrophe and died the same day of an acute small bowel infarction. Postmortem examination revealed superior mesenteric artery occlusion and revealed continued patency of the superficial femoral artery.

Case 6. C.H., a 70-year-old woman with diabetes, was admitted with severe rest pain and gangrene of the left fifth toe. Two years earlier she had undergone right above-knee amputation for gangrene. The ankle blood pressure index was 0.3, and the above-knee pressure index was 0.8. Angiography revealed profunda stenosis and a 19 cm segment stenosis and a 24 cm segment occlusion of the superficial femoral artery (Fig. 8, A). The anterior tibial, posterior tibial, and peroneal vessels were totally occluded, with no distal reconstitution. The origin of the profunda femoris artery was dilated, and the superficial femoral artery was recanalized for a distance of 17 cm. The guide wire would not pass through the plaque at the adductor hiatus and patency of the superficial femoral artery could not be attained (Fig. 8, B). The patient had mild symptomatic improvement with some relief of rest pain, but no change in the ankle or above-knee pressure indices. The gangrenous changes progressed and the patient required above-knee amputation 6 weeks following dilatation.

DISCUSSION

Transluminal angioplasty was introduced by Dotter and Judkins in 1964, but has received little support in the United States. Interest in this procedure has been more widespread in Europe. A total experience of 1,184 cases of femoropopliteal occlusion and stenosis treated by transluminal angioplasty was reported from 12 groups at an international conference in 1977. A primary success rate of 74% was reported, with an 11% early reocclusion rate. Introduction of the balloon catheter by Grünzig has resulted in a renewal of interest in transluminal angioplasty in the United States.

Success rates for transluminal angioplasty are best in patients with short-segment stenosis or occlusion of the superficial femoral artery with absence of extensive distal disease. Grünzig recommends that only occlusions less than 10 cm be treated because of low patency rates for longer recanalization. Such patients would be expected to have the most favorable results by any treatment program, and proper evaluation of the Grünzig technique would require prospective randomization against operative and nonoperative approaches. This has not yet been carried out. We have evaluated the technique in the least favorable group of patients with no therapeutic option other than amputation. In this population the Grünzig balloon catheter has been effective in short-term limb salvage. Even very long segment occlusion of the superficial femoral artery with very poor runoff vessels can be successfully treated. The limitation of applications of this technique appears to be the ability to introduce the guide wire through the obstruction plaque and inability to do so accounts for our only failure.

Technical considerations are very important in achieving a successful outcome. Spasm may be
induced by the guide wire and prevent introduction of the Grünzig catheter. This occurred during repeat angiography in case 4 after stenosis recurred at 4 months. The guide wire should not be interchanged or manipulated unnecessarily, and intraarterial vasodilators and heparin should be used. Long-term anticoagulation with Coumadin has been shown to improve the patency rate, whereas others have used antiplatelet therapy (aspirin).

Restenosis of the superficial femoral artery occurred within 2 to 5 months in all four patients who were followed at least 3 months. Ankle and thigh blood pressure measurements reliably reflected the status of vessel patency, and careful and repeated noninvasive follow-up was necessary so that restenosis could be detected. An above-knee systolic pressure index of 1.0 was seen in every patient after recanalization and was found to be decreased with restenosis. It is unclear whether refinement of the technique or drug therapy will be effective in reducing this rapid recurrence of obstructing lesions.

Despite an uncertain long-term success, short-term recanalization may be critical to allow ulcerations or gangrene to heal and to avoid amputation. In those patients where amputation is unavoidable, recanalization may permit amputation at a level below the knee rather than above the knee. The procedure may be performed safety in elderly, high-risk patients and may be repeated when restenosis occurs. We have had no evidence of distal embolization or worsening of ischemia and have had one groin hematoma in 30 angioplasty procedures. Transluminal angioplasty can extend our capability of limb salvage to patients with severe end-stage obliterative vascular disease.

REFERENCES