The Role of Transluminal Angioplasty in Limb Salvage and Claudication

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INTRODUCTION

With the introduction of the Grützig balloon catheter, percutaneous transluminal angioplasty has gained increased acceptance and has been used to dilate lesions in the coronary [7], renal [6, 9], mesenteric [4], aorta [5], iliac [11], femoral [3] and popliteal [3] arteries. In lower extremity ischemia it has been used primarily to treat patients with claudication and short segmental lesions [8] with relatively poor success in limb salvage situations with long segment obstruction and poor runoff [8, 12]. Because of a high initial success rate and low complication rate [8], the procedure has been used, at times, in patients with minimal symptoms who otherwise would not be considered for operation. However, objective documentation of the results of transluminal angioplasty and long-term follow-up have been lacking. In order to evaluate the procedure and help develop proper patient selection criteria, we recorded lower extremity systolic blood pressure indices before and after transluminal angioplasty in two groups of patients who were not candidates for operative revascularization. In one group were patients with claudication who had surgically correctable lesions, but did not undergo operation because they declined operation or were felt to have symptoms that were not severe enough to warrant operation. In the other group were patients with severe end-stage atherosclerosis and rest pain, ulceration, or gangrene who were not candidates for operative revascularization because of inadequate outflow vessels or medical contraindication to operation.

METHODS

Over a 14-month period, 42 patients underwent transluminal angioplasty. Nineteen patients had claudication and 23 had rest pain, ulceration, or gangrene (limb salvage group). All patients were evaluated with noninvasive vascular techniques and arteriography before and after transluminal angioplasty. Systolic blood pressures were measured using standard Doppler ultrasound techniques at four levels in the leg: upper thigh, above knee, below knee, and ankle. The pressure index for each level was calculated from the ratio of the segmental systolic pressure to the brachial systolic pressure. Ankle pressure indices were recorded on at least two occasions prior to transluminal angioplasty as well as after treadmill exercise or postocclusive reactive hyperemia. Repeat segmental pressure determinations were carried out at 1, 3, 5, and 7 days following transluminal angioplasty and at monthly intervals thereafter. Full arteriography of the aorta, iliac, femoral, popliteal, and tibial vessels was performed before transluminal angioplasty and limited angiography of the dilated segment and outflow vessels was performed following each procedure. Subsequent arteri-
TABLE 1
PATIENT POPULATION

<table>
<thead>
<tr>
<th></th>
<th>Claudication</th>
<th>Limb salvage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>19</td>
<td>23</td>
</tr>
<tr>
<td>Age (range)</td>
<td>64 (51–72)</td>
<td>74 (52–91)</td>
</tr>
<tr>
<td>Male:female</td>
<td>3:1</td>
<td>1:1.5</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>21</td>
<td>56</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>63</td>
<td>89</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>95</td>
<td>61</td>
</tr>
<tr>
<td>Coronary artery disease (%)</td>
<td>32</td>
<td>61</td>
</tr>
<tr>
<td>Resting ankle pressure index</td>
<td>0.58 ± 0.03</td>
<td>0.27 ± 0.04</td>
</tr>
<tr>
<td>Range of ankle pressure indices</td>
<td>0.41–0.89</td>
<td>0.00–0.68</td>
</tr>
</tbody>
</table>

An angiography was performed if indicated by the patient’s clinical condition.

Transluminal angioplasty was performed as previously described [8, 11]. An arterial puncture was performed in the contralateral or ipsilateral common femoral artery and a catheter was positioned just proximal to the obstructing lesion. In order to prevent spasm and thrombosis, aqueous heparin, lidocaine, and priscoline or papaverine were infused through the catheter. A Teflon-coated guide wire followed by the Gruntzig balloon catheter was advanced through the occluding lesion and additional heparin was infused into the distal arterial bed (total dose 5000 units). The balloon was inflated for a period of 30 sec, deflated, and retracted more proximally allowing a 1-cm overlap. Sequential 30-sec inflation and deflation of the balloon was carried out until the full extent of the lesion was dilated. A continuous infusion of dilute heparin solution was administered through the catheter during inflation of the balloon catheter. Following the dilatation procedure, the patient was maintained on intravenous heparin (1000 units/hr) for a period of 3 days and thereafter maintained on long-term Coumadin or aspirin therapy.

The results of transluminal angioplasty were determined by the angiographic appearance of the lesion before and after the procedure, the reported clinical symptoms, the healing of ischemic lesions, and the objective hemodynamic response. An ankle or segmental pressure index change of greater than 0.15 was considered to be a significant hemodynamic improvement. Statistical significance between the two groups was assessed using the nonpaired Student’s t test. Differences were considered to be significant if P < 0.05.

RESULTS

Claudication patients ranged in age from 51 to 72 years with a median age of 64 years: fourteen were male and five were female. Twenty-one percent had diabetes mellitus, 63% had hypertension, 32% had coronary artery disease, and 95% smoked cigarettes (Table 1). The resting ankle pressure index was greater than 0.4 (range 0.4 to 0.9) in all claudication patients with a mean resting ankle pressure index of 0.58 ± 0.03. None of the claudication patients had ischemic ulcerations, rest pain, or gangrene and all patients had lesions amenable to operative revascularization.

Limb salvage patients had severe distal ischemia and were threatened with amputation. Twenty-two of twenty-three patients (96%) had gangrene, 19 patients (82%) had rest pain, and 5 patients (22%) had prior major amputation of the opposite extremity. Four patients (17%) had previously undergone unsuccessful operative revascularization attempts.

Among limb salvage patients, operative revascularization was not technically feasible in 15 (65%) because of inadequate distal vessel reconstitution. In 8 patients (35%), operation was not possible because of severe medical contraindications including recent myocardial infarction, life threatening arrhythmias, and angina at rest. Limb salvage patients were, in general, older and with more medical problems than claudication patients (Table 1). The patients ranged in age from 52 to 91 years with a median age of 74 years. There were 9 males and 14 females. Diabetes mellitus was present in 56%, hypertension in 89%, coronary artery disease in 61%, and smoking in 61% of patients. The resting ankle pressure index was 0.4 or less in 21 of the 23 patients (91%). The mean resting ankle pressure
Claudication Patients

Transluminal angioplasty resulted in angiographic improvement of the arterial lesion in all 19 patients. Stenotic lesions were increase in luminal diameter or occluded segments were recanalized in each instance (Fig. 1). Along with the improved angiographic appearance, all patients had an initial improvement in their clinical symptoms with relief of their symptoms of claudication while in the hospital. However, 1 week after transluminal angioplasty, the ankle pressure index had increased by 0.1 or more in only 8 of 19 patients (44%). Only 7 patients (37%) had an increase in ankle pressure index of at least 0.15 (Fig. 2). In the claudication groups as a whole, ankle pressure index increased from 0.58 ± 0.03 before dilatation to 0.67 ± 0.04 (P < 0.05) after dilatation. Changes in segmental pressure indices paralleled the changes noted in the ankle pressure index.

One month after transluminal angioplasty, only 11 of the 19 patients (58%) continued to have subjective clinical improvement in their symptoms of claudication. One patient with an initial good angiographic, clinical, and hemodynamic improvement had hemodynamic evidence of reocclusion of her superficial femoral artery 6 months.
after the procedure with return of her ankle pressure index to her predilatation level. She continued to be symptomatically improved. Objective evaluation of the results of transluminal angioplasty for claudication after 5 to 15 months revealed that 8 of the 19 patients (42%) continued to be clinically improved but only 6 (32%) continued to have an improved ankle pressure index of at least 0.15. Eleven patients (58%) were unchanged, both in their clinical symptoms and in their ankle pressure index. No patient was worse and there were no complications.

Limb Salvage Patients

Angiographic improvement with recanalization of occluded segments 2 to 29 cm in length was achieved in 18 of the 23 patients (78%) (Fig. 3). Fifteen of these patients (65%) had an increase in ankle pressure index of at least 0.15 and each of these patients had clinical improvement with improved warmth and color in the foot, healing of ischemic lesions, or healing of toe amputations. Three patients had an improved angiographic appearance but did not have an increase in ankle pressure index of at least 0.15. These patients had no clinical improvement. Two avoided amputation by undergoing subsequent operation: one underwent successful femoral–femoral bypass after improvement in his medical condition and the other underwent successful femoral–peroneal bypass. One patient was unchanged by the procedure and con-
Fig. 3. Transluminal angioplasty of the right popliteal artery in a 69-year-old female with rest pain and an ischemic ulceration of the great toe. Ankle pressure index before dilatation (A) was 0.29 and increased to 0.49 after dilatation (B). Rest pain was relieved and the ulceration was successfully skin grafted.

continued to be ischemic following transluminal angioplasty. Five patients with unsuccessful dilatations underwent amputation. In the limb salvage group as a whole, ankle pressure index increased from $0.27 \pm 0.04$ before dilatation to $0.52 \pm 0.04$ after dilatation ($P < 0.001$).

Among the patients with initial clinical improvement, two patients died of unrelated causes; one at 2 months and one at 4 months. Both had been relieved of ischemia, were ambulatory, and had been discharged from the hospital at the time of death. Seven of the thirteen patients (54%) followed 5 to 19 months developed restenosis at 1 to 5 months (Fig. 4): three were successfully redilated, two were salvaged by operation (profundaplasty and femoral-peroneal bypass) and two underwent below-knee amputation 3 and 5 months after transluminal angioplasty. Both amputation patients were felt, on clinical grounds, to be candidates for above-knee amputation prior to transluminal angioplasty. One patient had undergone two dilatation procedures of her superficial femoral artery during the preceding 6 months. She had not been an operative candidate because of occlusion of the popliteal, anterior tibial, posterior tibial, and peroneal arteries. On her initial arteriogram, a short segment of peroneal artery had reconstituted but was again occluded at the level of the ankle. Over the ensuing 6 months, the distal peroneal artery had recanalized and was now capable of accepting a femoral–peroneal bypass graft which has remained patent for 13 months.

The results in limb salvage patients 5 to 19 months following transluminal angioplasty revealed that 12 patients (52%) continued to be improved. Five were continuing to do well from their initial transluminal angioplasty procedure. Three patients were improved after repeat trans-
Fig. 4. Restenosis of the popliteal artery in patient three (see Fig. 3). (A) Immediately after dilatation—ankle index, 0.49; (B) 3 months later, ulceration is healed but rest pain recurred—ankle index, 0.24. Note restenosis (arrow). (C) Successful redilatation with increase in ankle index to 0.59 with relief of symptoms.

Transluminal angioplasty and three had undergone bypass grafting following transluminal angioplasty. Two patients had developed restenosis; one asymptomatic and one symptomatic. Seven had undergone amputation: five in the immediate transluminal angioplasty period and two at 3 and 5 months. Two patients had died; one at 2 months and one at 4 months with patent arteries at the time of their death. The overall amputation rate was 30% in this group of patients with severe end-stage atherosclerosis.

A total of 56 transluminal angioplasty procedures have been carried out in these 42 patients. There have been five complications. One groin hematoma required operative evacuation. Distal embolization was seen in one follow-up arteriogram in a patient with clinical improvement. Contrast extravasation occurred in two instances without hematoma formation or clinical sequela. There has been no mortality attributable to transluminal angioplasty.

DISCUSSION

Transluminal angioplasty has been an attractive procedure because of the low risk and complication rate and the high initial success rate [10] as determined by clinical and angiographic criteria. Gruntzig has reported an initial success rate of 92% for iliac lesions and 84% for femoropopliteal lesions with a 2-year iliac patency of 87% and a 2-year femoropopliteal patency of 72% [8]. However, objective documentation of vessel patency with hemodynamic measurements or follow-up angiography has been lacking. When objective measurements were applied, we found evidence of an increase in the ankle systolic pressure index in only 37% of claudication patients despite a favorable angiographic result and initial subjective clinical improvement in all patients. This demonstrates the difficulty in using subjective symptoms to evaluate the results of transluminal angioplasty and emphasizes the need for more rigorous and
standardized means of objectively evaluating the results. This is particularly true since most patients selected for transluminal angioplasty have claudication and short segment obstructions with absence of extensive distal disease [8, 10]. Such claudication patients would be expected to have good long-term clinical results without any intervention [2]. Our own experience has demonstrated that reocclusion of the previously dilated artery can occur with no change in clinical symptoms. Thus, clinical assessment is not sufficient to evaluate the results of transluminal angioplasty.

Our initial objective results in patients with claudication have not supported the use of transluminal angioplasty in patients with mild or nonlimiting claudication who otherwise would not be candidates for operation. It may be useful in relieving symptoms in patients with severe or limiting claudication but the long-term effectiveness in this group of patients is not yet known. Transluminal angioplasty does appear to have an important role in patients with severe or limiting claudication who are elderly or poor operative risks.

In patients with severe end-stage atherosclerosis who are faced with amputation, transluminal angioplasty is a significant addition to our armamentarium. It can safely be used in high-risk, elderly patients and is effective in short-term circulatory improvement in 65% of patients who otherwise would not be candidates for revascularization. Although restenosis develops in at least 50% of cases in a relatively short period of time, patients may be treated with repeat transluminal angioplasty. The procedure may buy time in the severely diseased group to allow healing of ischemic lesions and may permit the development of collateral vessels and outflow channels [10]. This may allow improvement in the overall medical condition of the patient or permit subsequent bypass grafting for limb salvage. Our overall amputatian rate over 5 to 19 months in this poor-risk patient population was only 30%. In some instances transluminal angioplasty may permit amputation at a level below the knee rather than above the knee. Thus, transluminal angioplasty is a useful procedure in this group of patients and can extend our capability of limb salvage in severe end-stage atherosclerosis in patients who are not candidates for operative reconstruction.

REFERENCES