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PTA in treatment of long-segment (≥ 10 cm) femoropopliteal occluded artery – a success or a bust?

PTA w leczeniu długich niedrożności (≥ 10 cm) tętnic odcinka udowo-podkolanowego – sukces czy porażka?

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Summary

Background:

The purpose of the study was to evaluate percutaneous transluminal angioplasty (PTA) as a method of treatment for chronic long-segment (≤ 10 cm) occlusions of femoropopliteal artery.

Material/Methods:

45 patients underwent angioplasty. Angioplasty was performed on 52 totally occluded arteries. All the occlusions were chronic (> 30 days), they measured 10–35 cm (mean 18.9 cm). All the occlusions involved proximal and distal superficial femoral artery and only few extended to popliteal artery. The patency of an artery directly after PTA was controlled by angiography. Doppler ankle-brachial index (ABI) was used to evaluate the patient before PTA and at 24 hours, 1-month, 12-months and 24-months follow-up. The angiographic criteria for technical success was the restoration of the vessel lumen having no significant residual stenosis ($< 30\%$) and a rise in ABI of at least 0.15. Arterial patency ($> 50\%$ residual stenosis) was assessed also with color duplex sonography.

Results:

The technical success after PTA was achieved in 87% (45 PTAs) of patients. In this series, no complication related to the PTA necessitated emergency surgical intervention. The patency rate at the 1-month, 12-months and 24-months follow-up intervals was 82% (43 PTAs), 61% (31 PTAs) and 51% (30 PTAs) respectively. Finally after 24 months clinical symptoms have improved in 63% of patients.

Conclusion:

PTA has proven to be an effective and safe method of treatment for occluded long-segment (≤ 10 cm) femoropopliteal artery.

key words:

arteries • long-segment occlusion • percutaneous transluminal angioplasty

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Background

Transluminal angioplasty, a nonsurgical, x-ray controlled method for the treatment of arteriosclerotic disease, was first reported in 1964 by Dotter and Judkins [1]. These techniques have been gradually established as the treatment of choice for short-segment femoropopliteal occlusive disease [1–6]. The success of angioplasty in femoral stenoses and short occlusions is well established,

with good long-term patency rate, but most authors consider lesions that are 10 cm or longer unsuitable for PTA [2,6–9]. There is, however, little research that presents entirely promising results of PTA treatment of long-segment femoropopliteal occlusions [10,11]. The purpose of this study was to evaluate percutaneous transluminal angioplasty (PTA) as a method of treatment for occluded long-segment (≤ 10 cm) femoropopliteal artery.

Material and methods

Between 1996 and 1999 52 lesions (45 patients) underwent PTA for long-segment (≤ 10 cm) occluded femoropopliteal artery. All the patients had a long history of claudication; there were 37 cases in the 1st grade, 7 in the 2nd grade and 8 in the 3rd grade according to Rutherford's 3 grade scale [12,13] table 1. Among them, 37 (82.2%) were smokers, 21 (46.7%) had hyperlipidemia, 19 (42.2%) diabetes mellitus and 27 (60.0%) hypertension. There were 33 men (73.3%) and 12 women (26.6%), aged between 42–85 years (mean age 60.8 ± 10). Before all the procedures patient signed informed consent forms. Seven patients underwent bilateral PTA. All arteries were completely occluded at a distance of 10–35 cm (mean 18.9 ± 6.6 cm) these were only chronic occlusions (> 30 days). All the occlusions involved proximal and distal superficial femoral artery and only few extended to popliteal artery. The quality of the runoff vessels was also assessed according to the following scale: 2 points = patent, 1 point = diseased, 0 points = occluded [10]. The presence of superficial femoral artery patency of at least 1 centimeter of its most proximal part was necessary to qualify for the procedure. Patients' evaluation was based upon clinical examination and Doppler ankle-brachial index (ABI) performed before and after the treadmill test [12,13]. Disease severity was assessed before and after PTA according to categories proposed by ad hoc committees within the joint council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery [12,13].

Angioplasty was accomplished through an antegrade puncture of the common femoral artery. A digital road map was used in all PTAs. The majority of lesions were crossed in tandem with a angled hydrophilic guide wire 0,035" (Glidewire; Terumo, Tokyo, Japan) and 5-F angled catheter (Glidecath; Terumo, Tokyo, Japan). In difficult cases, a hydrophilic stiff guide wire (Glidewire; Terumo, Tokyo, Japan) was used.

Heparin (100–150 mg/kg b.w.) was given intra-arterially to all patients once the lesion was crossed. Procedures were performed with 10 cm long and 5–6 mm width, 10-atm burst pressure balloons (Opta 5; Cordis EuropaNV, Roden, The Netherlands). The balloons diameters were equal to vessels diameters measured on the diagnostic arteriogram. The balloon was inflated three times for 3 minutes.

An overlap of 1 cm was maintained between adjacent inflations. In a case of popliteal, tibial or peroneal arteries constriction a medium dose of 200 μ g nitroglycerine was administered directly into a vessel. We have not used protamine to reverse the heparin effects. All patients were given ticlopidine three days before and 6 months after PTA.

After dilatation, technical success or failure was assessed according to angiographic appearance (measured by angiograph Siemens Multistar Top software) and by ABI. Technical success was defined as a restoration of vessel lumen with less than 30% residual stenosis and a rise in ABI values at least 0.15 at 24 hours. At 1 month, 12 months and 24 months intervals after PTA, the patients' clinical examinations and ABI were performed before and after the treadmill test. The site of PTA was deemed patent if recorded ABI values had not decreased by more than 0,15 from the maximal value recorded after procedure [12,13]. PTA was judged to have failed if ABI values decreased by more than 0.15 from the maximal value recorded after procedure. Arterial patency in the legs at the site of PTA were assessed with color duplex sonography with a 7-MHz probe. Examinations were read by radiologist who was unaware of the ABI findings. Vessel occlusion were diagnosed when there were complete absence of both color and Doppler signal. Arterial stenosis ($>50\%$) were diagnosed when there were a local doubling of the peak systolic velocity ratio. To differentiate restenosis at the site of PTA from disease progression in adjacent arterial segments, the color duplex sonographies were compared with the original diagnostic arteriograms.

Table 1. Categories of Chronic Limb Ischemia.

Tabela 1. Kategorie przewlekłego niedokrwienia kończyn.

Grade	Category	Clinical description	Objective criteria
0	0	Asymptomatic, no hemodynamically significant occlusive disease	Normal results of treadmill*/stress test
I	1	Mild claudication	Treadmill exercise completed, postexercise AP >50 mmHg, but >25 mmHg less than normal
	2	Moderate claudication	Symptoms between those of categories 1 and 3
	3	Severe claudication	Treadmill exercise cannot be completed, postexercise <50 mmHg
II	4	Ischemic rest pain	Resting AP of 40 mmHg or less flat or barely pulsatile ankle or metatarsal plethysmographic tracing, toe pressure <30 mmHg
III	5	Major tissue loss, nonhealing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP of 60 mmHg or less, ankle or metatarsal plethysmographic tracing flat or barely pulsatile, toe pressure <40 mmHg
	6	Major tissue loss, extending above transmetatarsal level, functional foot no longer salvageable	Same as for category 5

* Five minutes at 2mph on a 12° line;

AP – ankle pressure

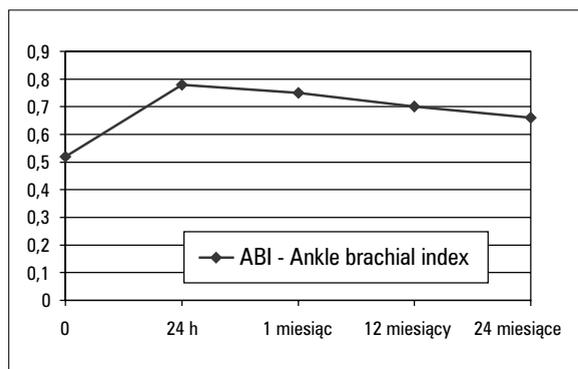


Figure 1. ABI values recorded before PTA and follow-up at 24h, 1 month and 12, 24 months after PTA.

Rycina 1. Wartości ABI uzyskane przed PTA oraz po 24 godz., 1 miesiącu, 12 i 24 miesiącach po PTA.

The chi-squared test was used to compare the arterial patency in patients with poor runoff (0–2 points) with that in patients with good runoff (3–6 points). The influence of diabetes, hypertension, hyperlipidemia, tobacco use were assessed by using the chi-squared test. A probability value of less than 0.05 indicated a statistically significant difference.

Results

In our series occlusions were successfully crossed with a guide wire and subsequently dilated in 50 of all 52 cases; the technical success rate was 87% (45 PTAs). The average procedure time was 120 minutes. Our initial 1-month success rate was 82% (43 PTAs) and at the 12-months follow-up (31 patients) was 61% and finally at the 24-months follow-up (30 patients) 51% (Table 1, Figure 1). In patients who had the PTA done, the runoff vessels were qualified as 'good' in 25 cases (50%), 'diseased' in 24 (48%) and 'occluded' in one case (2%). There were 7 (13%) initial failures; in two cases the lesion could not be traversed by guide wire (cross-over techniques). Other technical failures involved an early reocclusion at the PTA site (after 24 hours) or absence of clinical and haemodynamical improvement after PTA. In one patient, embolectomy and regional infusion of urokinase was used for lysis of a thrombus at the angioplasty site and in posterior tibial artery. None others patients had distal embolisation. This may, however, result from PTA only chronic occlusions, gentle transversing the lesions by hydrophilic guidewire and starting PTA from distal part of the lesion. There were no perforations. There were 15 small dissections (no needs to stent placement) in this series, however no complication relating to PTA necessitated emergency surgical intervention. Two patients developed local groin hematomas that were managed conservatively and did not necessitate blood transfusion or surgical repair at the puncture site. Fourteen patients did not attend the follow up visits at 12 months and finally fifteen at 24 months not explaining the reasons.

ABI values before PTA, at 24 hours, 1 month, 12 month and 24 month follow-up intervals after PTA follow-up and numbers of patients that were followed-up are shown in

Table 2. Mean values of ABI in the followed group.

Tabela 2. Średnie wartości ABI w badanych grupach.

Ankle Brachial Index (ABI)	Mean ± SD*	Number of patients followed-up
ABI before PTA	0.52 ± 0.14	45
ABI 24 hours after PTA	0.78 ± 0.15	45
ABI 1 month after PTA	0.75 ± 0.15	43
ABI 12 months after PTA	0.70 ± 0.15	31
ABI 24 months after PTA	0.68 ± 0.14	30

SD – Standard deviation

figure 1 and table 2. Finally sixty-three percent of patients reported improvement in symptoms. Only one risk factor—poor arterial runoff of the risk factors on long-term patency at angioplasty site assessed had a statistically significant effect on arterial patency at 12 and 24 month follow-up. None others of the risk factors had. This may, however, represent a type II error (incorrect acceptance of the null hypothesis) due to small sample size. All factors affecting initial and 12–24 months patency rates after PTA and complete statistical analysis will be subject of the next publication.

Discussion

Lesion length has become one of the principal selection criteria in determining the suitability for angioplasty [2,6–9]. Several factors contributed to improving the rate of technical success and long-term patency of PTA in the treatment of long-segment atherosclerotic femoropopliteal disease. Recently both the equipment and the technical skills of angiographers have been considerably improved [10,11]. Balloons have a lower profile, and we now use hydrophilic catheters and 5-F balloons in the femoropopliteal system. Further progression is the introduction of hydrophilic guide wires [14,15] and the use of digital subtraction angiography as a road map. The administration of effective antispasmodic agents such as nifedipine and nitroglycerin is now a routine part of the PTA procedure, whereas in earlier experience vasodilators (e.g. talazoline and lidocaine) were either not employed or less effective [8]. All these advances contributed to the reduction of the frequency of thrombosis or reocclusion following an initially successful recanalization. Only one clinically significant distal embolisation was reported in our study, this decreased frequency of postangioplasty emboli is lower than those reported in other series (3–5%) [8,9,16–18]. Patient selection for PTA has also changed as experience with the procedure has developed.

Most authors consider lesions that are 10 cm or longer unsuitable for PTA [2,6–9]. Overall, technical success rate and long-term patency reported in our series was 87% at 24 hours, 82% at 1-month, 61% at 12-months and 51% at 24-months follow-up intervals. In the 1970s, Wierny and colleagues reported initial success in 76% and long-term success in 37–40% of their patients [19]. Zeitler [18] and Lu in the 1980s, recorded initial success rates of 48% and 76% but only of 43% at 12-month follow-up intervals [20]. Murray et al. in 1987 reported an initial success rate of 93% but after 6-month follow-up was poor at only 23% [9].

Jorgensen et al. noted 98% of initial technical success and only of 59% for early patency for occlusion [21]. Capek et al. in 1991 reported a 6-month patency of 22% and noted that the femoropopliteal lesion could not be crossed in 18% of occlusions [2]. Jeans et al. noted poorer results in femoropopliteal occlusions with meagre runoff (25% at 3 years) [22]. Our results are slightly worse than Murray's and al, who recorded 93% technical success and 69% after an 18-month follow-up period [10]. Their study, however, involved patients with long-segment stenosis and different types of occlusions whereas in ours, all occlusions were continuous.

Evaluation of many of the reported series of PTA is difficult because definitions for success or patency rate had not been clearly stated until Rutheford and Becker set commonly accepted standards for evaluating and reporting the results of PTA for peripheral arterial disease [12]. Also the patients in other series are followed-up at different intervals [2,5,9,18-21]. Many of the authors tend to present overall assessment of their results without separate estimation of the success rate in long-segment occlusions, probably because of the small number of such cases [5,8,18,19].

To determine patency rates we assessed vessels and flows by ABI and color duplex sonography. Most studies have relied on changes in only ABI values to detect late failure at PTA site. ABI values may also be elevated in diabetic patients with noncompressible vessels. They are inaccurate in distinguishing the recurrence of lesions at the PTA site from disease progression in the adjacent arteries [10,12,13,23]. It is therefore important to use an objective measure of patency and hemodynamic improvement when treatment modalities are assessed [12,13].

Surgical bypass grafting is the standard therapy for long-segment femoropopliteal arterial disease [6]. At 1 year, autologous vein grafts have a 79-88% patency rate and polytetrafluoroethylene grafts have 61-81% patency rate at 1-year [6,24-27]. Although both these procedures may have a higher 1-year patency than angioplasty in long segment femoropopliteal arterial, but they also have a higher associated morbidity and cost [6].

Repeat angioplasty, which is performed to correct a failed initial PTA, results in a good long-term prognosis in contrast to graft failure caused by thrombosis or initial hyperplasia [2,5,20,28,29]. Failed PTA rarely precludes subsequent surgical bypass grafting [8].

Conclusions

In summary, we report an overall high technical success rate for PTA and satisfactory success at 12-months and 24-months follow-up in total occlusion of the femoropopliteal vessels. In our material PTA has proven to be an effective and safe method of treatment for occluded long-segment (≤ 10 cm) femoropopliteal artery. We believe it could be considered as the primary treatment in patients with severe claudication especially with contraindications to surgery due to other comorbidities.

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