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Comparison of outcome after infrapopliteal angioplasty and pedal bypass surgery

Blauzdos arterijų endovaskulinių procedūrų ir šuntų į pėdos arteriją rezultatų analizė

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Objective

Percutaneous transluminal angioplasty (PTA) of crural arteries remains a valuable procedure for limb salvage in critical limb ischemia (CLI). Patients with anatomically unfavourable occlusive lesions of infrapopliteal arteries are usually offered a bypass surgery. The aims of this study were to report our experience, compare long-term results of surgical revascularization of pedal arteries and infrapopliteal PTA in patients with CLI, and assess the impact of diabetes mellitus and the type of treatment on limb salvage rates.

Methods

All tibial interventions to treat CLI, which were performed during the period of January 1999 to December 2013, were retrospectively analysed. The outcomes of tibial PTA procedures and open surgery – bypasses to dorsal pedal artery (DP) – were compared. The impact of diabetes mellitus control on the primary revascularization procedures' outcomes was analysed.

Results

Three patient groups were formed: the open repair group (treated by dorsal pedal artery bypass operation) – 193 patients, the endovascular repair group – 103 limbs in 98 patients, and the combined treatment group (endovascular repair and dorsal pedal artery bypass) – 84 patients. The cumulative patency rate in the open repair group at a 1-year period was 47.5%, in the endovascular repair group – 6.9% and in the combined treatment group – 79.6%. The best results of revascularization were achieved in the combined treatment group ($p < 0.007$). The limb salvage rate at the 1-year follow-up was 84.1% in the open repair group, 35.4% in the endovascular repair group, and 83.1% in the combined treatment group. In the combined treatment group, limbs were saved for a longer period ($p < 0.01$). The patency rates for DP artery bypasses at the 1-year follow-up in diabetic patients were 60.4%, in non-diabetic patients – 21.8% ($p = 0.013$), and for PTA procedures in diabetic patients – 3.6%, in non-diabetic – 10.1%. The patency rate in patients under tight plasma glucose control was 55.2%, in uncontrolled diabetes group – 43.6% after two years. The limb salvage rate in patients under a tight plasma glucose control was 79.31%, in uncontrolled diabetes group – 61.82% after two years. These findings had no significance ($p > 0.05$).

Conclusion

Both infrapopliteal angioplasty and bypass surgery provide an acceptable limb salvage rate, but the follow-up patency appears to be better after bypass surgery. The duration of revascularization in the open repair group was longer as compared to the endovascular repair group. The best revascularization results were in diabetic patients after open surgery combined with PTA (combined treatment group). DP artery bypass is a safe and durable procedure in patients with CLI and patients with diabetes mellitus. Tight plasma glucose levels control has no effect on primary revascularization outcomes.

Key words: percutaneous transluminal angioplasty (PTA), dorsalis pedis artery (DP) bypass, critical limb ischemia, diabetes mellitus

Įvadas/tikslas

Blauzdos arterijų angioplastika yra vertinga galūnės išsaugojimo procedūra ligoniams, sergantiems kritine kojų išemija. Esant blauzdos arterijų užakimui, dažniausiai atliekama arterijų šuntavimo operacija. Šio tyrimo tikslas buvo parodyti mūsų gydymo rezultatus bei palyginti arterijų šuntavimo operacijų į pėdos arteriją ir blauzdos arterijų perkutaninės transliuminalinės angioplastikos vėlyvuosius rezultatus esant kritinei kojos išemijai. Taip pat įvertinti cukrinio diabeto įtaką operacijų rezultatams.

Metodai

Retrospektyviuoju būdu išanalizuotos visos gydomosios blauzdos arterijų procedūros, atliktos nuo 1999 m. sausio iki 2013 m. gruodžio mėnesio. Buvo palyginti blauzdos arterijų perkutaninės transliuminalinės angioplastikos ir atviros chirurgijos – šuntų į pėdos arteriją gydymo rezultatai. Išanalizuota cukrinio diabeto įtaka gydymo rezultatams.

Rezultatai

Sudarytos trys pacientų grupės: I grupė – 193 ligoniai, kuriems atliktos šuntavimo į pėdos arteriją operacijos; II grupė – 103 atvejai 98 pacientams, kuriems atlikta blauzdos arterijų perkutaninė transliuminalinė angioplastika; III grupė – 84 pacientai, kuriems taikytas sudėtinis gydymas – perkutaninė transliuminalinė angioplastika ir šuntavimas į pėdos arteriją. Kumuliacinis kraujotakos atkūrimas po 1 metų atlikus atvirą operaciją – 47,5 %, atlikus blauzdos arterijų angioplastiką – 6,9 %, atlikus sudėtinį gydymą – 79,6 %. Geriausi rezultatai gauti sudėtinio gydymo grupėje ($p<0,007$). Galūnės išsaugojimas po vienų metų atlikus operaciją – 84,1 %, po endovaskulinės chirurgijos – 35,4 %, po sudėtinio gydymo – 83,1 %. Ilgesnį laikotarpį galūnės išsaugotos po sudėtinio chirurginio gydymo ($p<0,001$). Cukriniu diabetu segantiems ligoniams kumuliacinis kraujotakos atkūrimas praėjus vieniems metams po šuntavimo į pėdos arteriją operacijų – 60,4 %, nesergantiems cukriniu diabetu – 21,8 % ($p=0,013$), po atliktos blauzdos arterijų angioplastikos cukriniu diabetu sergantiems ligoniams – 3,6 %, nesergantiems – 10,1 %. Kumuliacinis kraujotakos atkūrimas, praėjus dvejiems metams po rekonstrukcinių procedūrų, jei cukrinis diabetas kompensuotas, sudarė 55,2 %, o jei nekompensuotas – 43,6 %. Galūnės išsaugojimas esant kompensuotam cukriniam diabetui sudarė 79,31 %, o nekompensuotam – 61,82 %. Rezultatas nėra statistiškai patikimas ($p>0,05$).

Išvados

Blauzdos arterijų angioplastika ir šuntavimo operacija yra tinkamos procedūros išsaugoti galūnę ligoniams, sergantiems kritine galūnės išemija. Vėlyvieji kraujotakos atkūrimo rezultatai buvo geresni po šuntavimo į pėdos arteriją atliktų operacijų. Geriausi kraujotakos atkūrimo rezultatai ligoniams, sergantiems cukriniu diabetu, pasiekti taikant sudėtinį gydymo metodą – angioplastiką ir atvirą operaciją. Šuntavimas į pėdos arteriją yra saugi ir efektyvi procedūra cukriniu diabetu sergantiems pacientams, turintiems kritinę kojos išemiją. Glikozilinto hemoglobino kiekis neturi įtakos kraujotakos atkūrimo rezultatams.

Reikšminiai žodžiai: perkutaninė transliuminalinė angioplastika (PTA), šuntas į nugarinę pėdos arteriją, kritinė kojos išemija, cukrinis diabetas

Introduction

Critical limb ischemia (CLI) describes a condition when the peripheral artery disease has progressed and results in resting leg pain or in a breakdown of the skin causing tissue loss. If not revascularized, CLI patients are at a risk for limb loss. The management of CLI requires a multidisciplinary team. Most patients with CLI have multisegmental lesions involving infrapopliteal arteries. PTA of crural arteries remains a valuable procedure for limb salvage in CLI. The limb salvage rate after PTA is higher than the angiographic patency rate. Patients with long lesions in infrapopliteal arteries are usually offered a bypass surgery [1]. Direct pedal bypass is performed most frequently. CLI treatment guidelines recommend the bypass surgery only and the use of saphenous vein graft only in case of long (>15 cm) lesions of the artery in younger and healthier patients with the life expectancy of more than two years [1].

An aggressive treatment approach towards threatened ischemic limbs is supported by numerous studies which

present high limb salvage rates after revascularization procedures of infrapopliteal arteries. Primary major amputation rates decreased from 41% to 5%, and the total amputation rates decreased from 49% to 14% in cases of CLI caused by femoral, popliteal and tibial arteries with the occlusive disease [2]. The treatment of diabetic patients with chronic arterial insufficiency has changed. The term "diabetic small vessel disease" removed such patients from the realm of the vascular surgeon, and the treatment generally involved major amputation [3, 4, 5, 20]. Multiple reports have demonstrated similar patency and limb salvage rates following infrapopliteal reconstruction in diabetics and non-diabetics. The aim of this study was to assess the impact of diabetes mellitus on limb salvage rates in patients with CLI, to compare the results of infrapopliteal PTA and surgical revascularization of pedal arteries, and also to report our long-term results and experience in these procedures.

Patients and methods

A retrospective review of patients who were treated surgically and / or endovascularly due to CLI with infrapopliteal atherosclerotic arterial lesions from January 1999 to December 2013 was performed. Patients with type 1 diabetes mellitus (due to the insufficient number of patients) or endarteritis were excluded from the study. A consented permission for this study was issued by the Vilnius Regional Biomedical Research Ethics Committee on January 11, 2013, permission number 158200-13-572-167.

This study involved 296 patients – 193 patients had dorsal pedal artery (DP) bypass operation (open repair group), 103 patients underwent infrapopliteal PTA procedures (endovascular repair group), and 84 patients experienced both DP bypass and PTA (combined treatment group). All patients were treated for resting pain and gangrene in the leg. Patients were either at risk of imminent limb loss or had a severe rest pain. Non-invasive treatment methods involved smoking cessation and an aggressive medical treatment to control the present risk factors such as hypertension and elevated serum glucose levels. All arterial lesions were confirmed by conventional angiography. The main indication for DP bypass was the insufficient run-off from tibial arteries to the foot, multisegmental stenosis of tibial arteries, stable general condition and the absence of wounds on the predicted area of incision. All bypasses to the dorsal pedal artery were performed with an autologous vein graft. The greater saphenous vein was used as a conduit in 96.7% of the cases. The choice of the conduit and the site of proximal anastomosis were based on the surgeon's preference. The anastomosed dorsal pedal artery had a direct inflow to the pedal arch in all cases. Immediate patency of the graft was confirmed with intraoperative duplex ultrasound or angiography. All interventions were performed by one team following the same method of reversed vein, anastomosing the DP artery and angioplasty. Initially, the choice for PTA as the therapeutic method was made for patients with TASC A and B lesions, technical limitations to open surgery (wounds near to surgical access sites and absence of proper vascular substitutes) or a high operative risk. All endovascular interventions were performed under local anesthesia with a 1% lidocaine solution. Lesions were passed with 0.018–0.035 inch guide wires. Long extension balloons were the treatment of choice for extensive lesions. When feasible, two or more infrapopliteal arteries were treated. Intraoperative success criteria were defined as residual stenotic lesions <20% of the adjacent normal arterial diameter with a regular surface and absence of any evidence of arterial dissection or distal embolization. All patients treated by PTA received anticoagulation therapy during the procedure and were prescribed aspirin and / or Clopidogrel once daily following their intervention. If proximal and distal stenosis were angiographically found (for example, stenosis in femoral and multiple stenosis in tibial arteries), the patient was assigned to combined treatment. First, proximal stenosis was dilated and the next day distal bypass surgery was performed. This way the inflow was improved and there was no need for a long vein graft. Short-term results were assessed 24 hours after the procedure and on the day of discharge from the hospital, and long-term results were assessed 6 months, 1 year and 2 years after the procedure. During these visits, blood circulation of the lower extremity was evaluated by the arterial-brachial index calculations and duplex ultrasound scanning. Angiography was performed only when non-invasive tests suggested a

significant restenosis or occlusion of the artery or the bypass. Success was accounted as the improved subjective condition of the patient (disappearance of rest pain, improved walking distance without pain, decreased need for pain killers), improved ankle-brachial index (>0.4) or successful wound healing. The amputation of the involved limb was performed when the revascularization was not possible. The coronary artery disease was identified if there was a history of *angina pectoris*, myocardial infarction or prior coronary artery revascularization. The cerebrovascular disease was determined if there was a history of stroke, transient ischemic attack, or carotid artery revascularization. Hypertension was defined as a systolic blood pressure greater than 140 mmHg or diastolic blood pressure greater than 90 mmHg over a period of time or the documented diagnosis by a cardiologist. Chronic renal insufficiency was defined if an impaired renal function was found for >3 moths based on an abnormal structure or function, or the GFR <60 mL/min/1.73 m^2 was found for >3 months with or without evidence of kidney damage, and the diagnosis was documented by a nephrologist. Diabetes was diagnosed if fasting plasma glucose level was >126 mg/dL, or a 2-hour plasma glucose level >200 mg/dL during a 75 g oral glucose tolerance test or accidental plasma glucose >200 mg/dL with classic symptoms of diabetes, and this diagnosis was approved by the consulting endocrinologist or patient history data. We considered a well controlled Type 2 diabetes when HbA1 was <7%, and the value of >7% was considered as uncontrolled diabetes. These distinctions were made in accordance with the patient history data and endocrinologal diagnosis. Limb ischemia was diagnosed if the brachial-ankle index was less than 0.5 and / or more than 60% stenosis was found in the affected artery by a duplex ultrasound investigation. Peri-interventional morbidity included all events that occurred during and up to 30 days following the initial intervention. Systemic antibiotics were prescribed each time a wound infection was reported.

Statistical analysis

Providing descriptive statistics, the mean values of various variables, their standard error, 95% CI were calculated. Based on these data, cumulative primary patency and limb salvage rates were calculated by Kaplan–Meier analysis for different patient and case groups. The results were presented in percent with the standard error and expressed by curves which were compared by the long rang test. Statistical significance was accepted at a level of $p < 0.05$. The statistical analysis of the results was performed using the program packages SPSS statistics 17 and Microsoft Office Excel 2007.

Results

Epidemiological and clinical data, as well as anatomical and morphological characteristics of both groups are summarized in Table 1. The angioplasty and anatomical arterial sites are described in Table 2.

Table 1. Patients characteristics and stage of the disease

Demographics	Open repair group	Endovascular repair group	Combined treatment group
Age	63 (41–85)	70 (48–91)	68 (41–86)
Male gender	84 (43.5%)	67 (65%)	23(25%)
Diabetes mellitus	131 (68%)	49 (48%)	27 (27.4%)
Hypertension	92 (47,6%)	98 (95%)	47 (56%)
Heart disease	89 (46.1%)	91 (89%)	51 (62%)
Renal insufficiency Dialysis	3 (1%) 3 (1.5%)	9 (8.7%) 7 (6.8%)	2 (2.4%) 1 (1.2%)
Current smoker	46 (23.8%)	83 (80.6%)	58 (69%)
Indications: Rest pain	59 (30.6%)	22 (21.4%)	36 (42.9%)
Gangrene	57 (29.5%)	88 (85.4%)	34 (40.5%)
Infection	10 (5.1%)	16 (15.5%)	7 (8.3%)

Table 2. Arteries treated by angioplasty and bypass graft surgery

Proximal anastomosis: Poplitea artery	 38 (19.7%)
Superficial femoral artery	138 (71.5%)
Ex autovena bypass	12 (6.2%)
Tibial arteries	5 (2.6%)
Distal anastomosis: Dorsal pedis artery	 193 (100%)
PTA anterior tibial artery	62 (60.2%)
PTA posterior tibial artery	7 (6. 8%)
PTA fibular artery PTA iliac artery	34 (33.0%) 23 (27.4%)
PTA superficial femoral artery	54 (64.3%)
PTA popliteal artery above knee	5 (5.9%)
PTA popliteal artery below knee	2 (2.4%)

103 endovascular procedures infrapopliteal arteries were performed. In 84 cases treatment of iliac, femoral, popliteal and tibial arteries was combined – endovascular procedures in suprapopliteal arteries and open repair in tibial arteries (combined treatment group).

Intraoperative technical success was achieved in 100 out of 103 cases in endovascular treatment group (95.8%). Two patients had plaque dissection followed by immediate thrombosis and required immediate surgical intervention. One patient had distal embolization and thrombosis. He was treated with heparin.

All 193 DP artery bypasses presented with 100% intraoperative success. Five (2.6%) bypasses stopped functioning in early postoperative period. They were not included in statistical analysis. One patient presented with pneumonia and six patients presented with skin dehiscence at the incision site. There was one perioperative death related to cardiovascular event.

The mean period of the follow-up was 17 months. There were some patients lost during the follow-up period. The primary patency rate in the open repair group was 67.3 ± 5.4% after 6 months, 47.5 ± 8.3% after 1 year, 27.5 ± 9% after 2 years. The primary patency rate in endovascular repair group was 65.5 ± 5.2% after 6 months and 6.9 ± 4.6% after 1 year. The primary patency rate for the combined treatment group was 91.5 ± 3.6% after 6 months, 79.6 ± 7.2% after 1 year and 73.5 ± 8.8% after 2 years ($p < 0.05$)

The limb salvage rate for the open surgery group in the 24-month follow-up period was 81.4 ± 4.3% after 6 months, 68.2 ± 6.5% after 1 year, 57.5 ± 7.9%

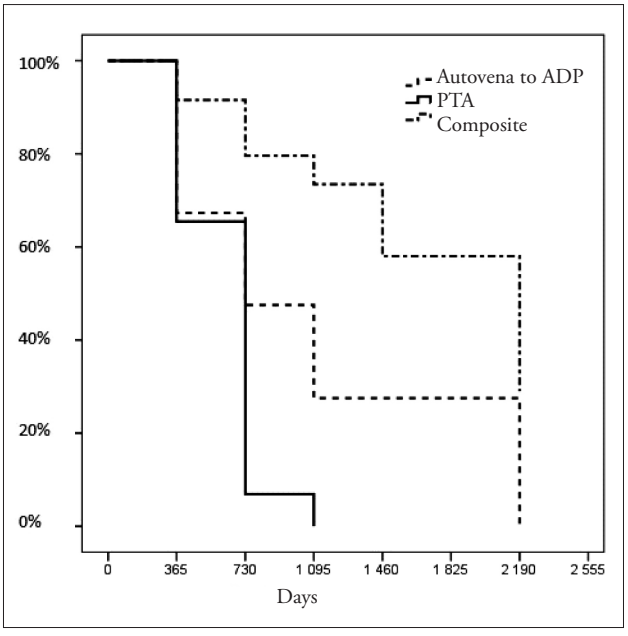

Fig. 1. Kaplan–Meier life-table analysis (long-rank test) of function rates in open surgery and percutaneous transluminal angioplasty in infrapopliteal arteries. Primary patency

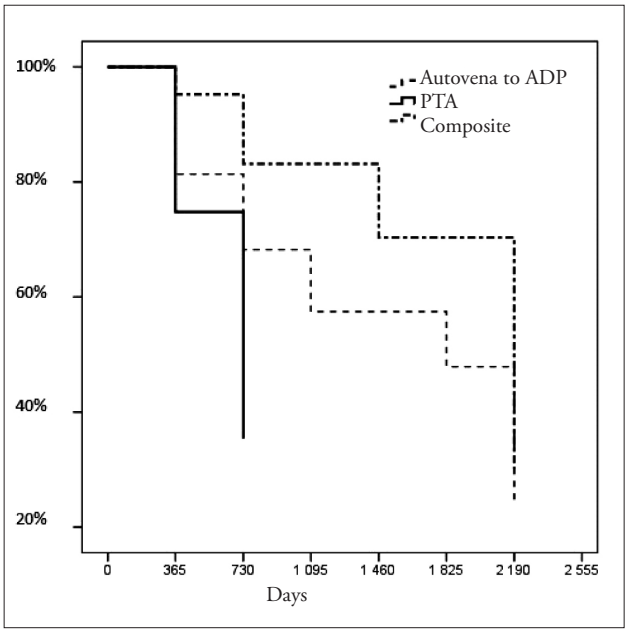

Fig. 2. Kaplan–Meier life-table analysis (long-rank test) of function rates in open surgery and percutaneous transluminal angioplasty in infrapopliteal arteries. Limb salvage

after 2 years, for the PTA group – 74.8 ± 5.4% after 6 months, 35.4 ± 1.2% after 1 year, in combined treatment group – 95.2 ± 2.7% after 6 months, 83.1 ± 6.1% after 1 year, 83.1 ± 6.1% after 2 years. The difference between the limb salvage rate of combined treatment and only open surgery or only PTA was statistically significant (p = 0.03).

In the diabetic patients group, the primary patency rate in the open repair group was 72.5 ± 6.0% after 6 months, 60.4 ± 9.3% after 1 year, 36.2 ± 1.2% after 2 years, in the endovascular repair group 60.5 ± 7.5% after 6 months, 3.6 ± 4.9% after 1 year, in the combined treatment group 91.1 ± 4.2% after 6 months, 81.0 ± 0.7% after 1 year, 72.9 ± 1.0% after 2 years.

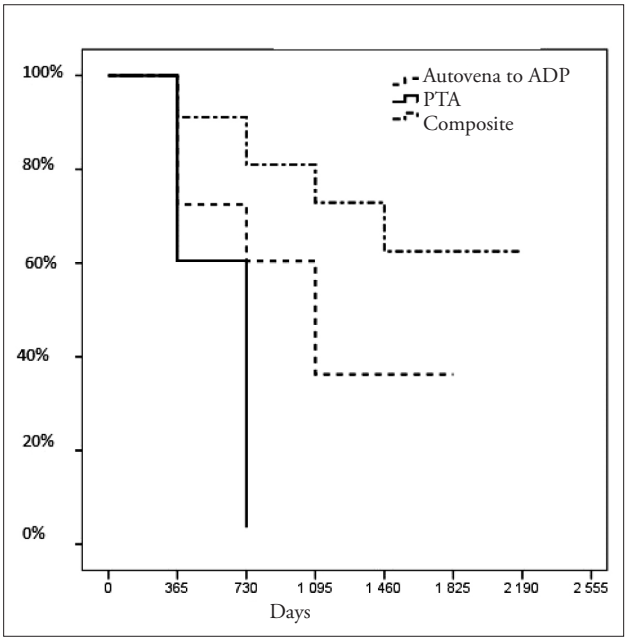

Fig. 3. Diabetic patients: primary patency

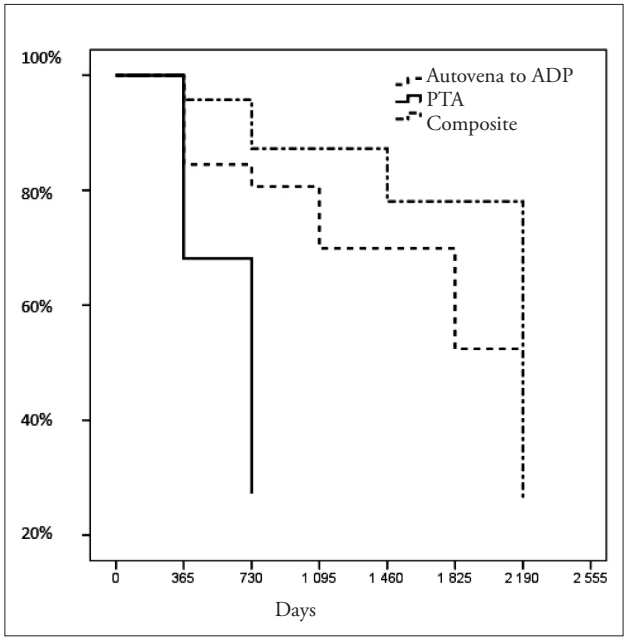

Fig. 4. Diabetic patients: limb salvage

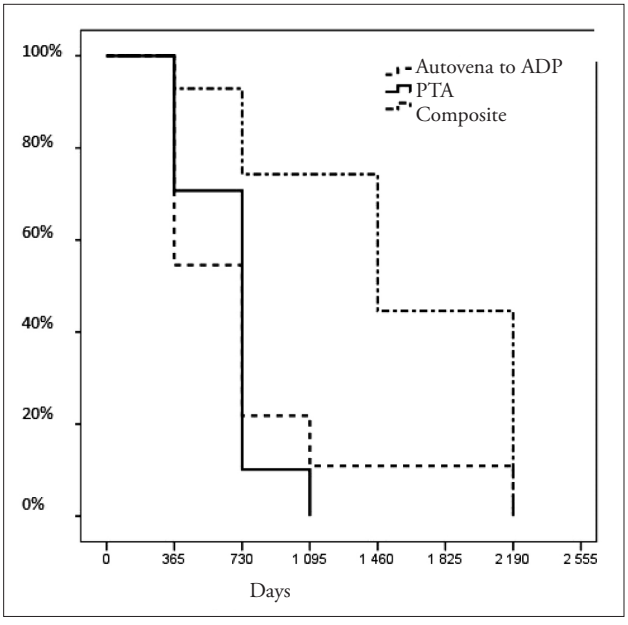

Fig. 5. Non-diabetic patients: primary patency

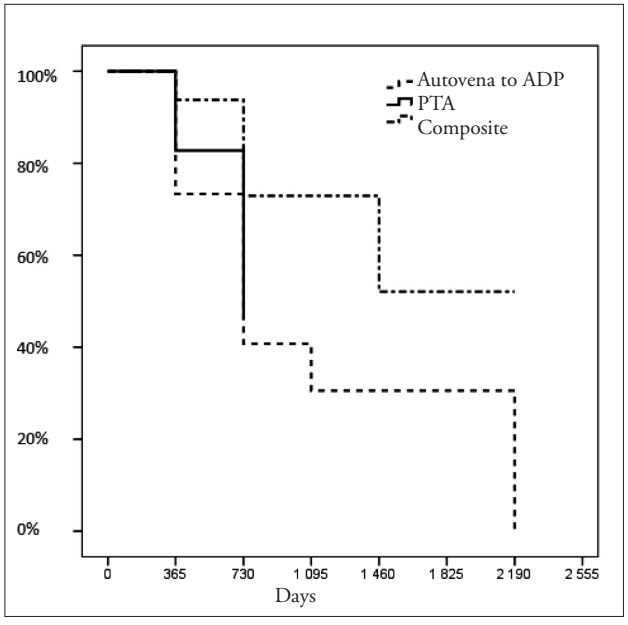

Fig. 6. Non-diabetic patients: limb salvage

In the non-diabetic patients group, the primary patency rate in open repair group was 54.5 ± 10.6% after 6 months, 21.8 ± 12.7% after 1 year, 10.9 ± 10.0% after 2 years, in the endovascular repair group 70.7 ± 7.1% after 6 months, 10.1 ± 7.7% after 1 year; in the combined treatment group 92.9 ± 6.9% after 6 months, 74.3 ± 1.7% after 1 year, 46.6 ± 1.7% after 2 years.

Statistically, primary patency was better in open surgery or combined treatment in diabetic patients ($p < 0.05$), but in non-diabetic patients the results were better in the PTA group ($p < 0.05$).

The limb salvage rate for diabetic patients: in the open surgery group 84.5 ± 4.8% after 6 months, 80.6 ± 5.9% after 1 year, 69.9 ± 8.7% after 2 years, in the PTA group 68.1 ± 7.9% after 6 months, 27.2 ± 1.5% after 1 year in the combined treatment group 95.7 ± 2.9% after, 6 months, 87.2 ± 6.3% after 1 year, 87.2 ± 6.3% after 2 years.

The limb salvage rate in non-diabetic patients: treated by open repair – 73.3 ± 9.3% after 6 months, 40.7 ± 13.2% after 1 year, 30.6 ± 13.3% after 2 years, treated endovascularly – 82.8 ± 7.0% after 6 months, 46.0 ± 1.9% after 1 year, in the combined treatment group – 93.8 ± 6.1% after 6 months, 72.9 ± 13.8% after 1 year, 72.9 ± 13.8% after 2 years.

Statistically, the limb salvage rate in diabetic patients was better in the open surgery and in the combined treatment groups ($p < 0.05$).

In the PTA group, the result was better for non-diabetic patients ($p < 0.05$).

Primary patency rates and limb salvage rates were compared among patients whose plasma glucose levels were well controlled and uncontrolled according to HbA1 levels. 84 patients were included in this comparison. 29 had well-controlled diabetes and 55 had unctontrolled diabetes.

The primary patency rate after two years in the well-controlled diabetes group was 55.2% (16 grafts with primary patency vs. 13 trombosed grafts), in the uncontrolled diabetes group – 43.6% (24 grafts with primary patency vs. 31 trombosed grafts). Statistically, primary patency rates between these two groups are insignificant ($p > 0.05$).

The limb salvage rate after two years in the well-controlled diabetes group was 79.31% (6 amputated limbs), in uncontrolled diabetes group – 61.82% (21 limb lost).

Statistically, limb salvage rates between these two groups are insignificant ($p > 0.05$).

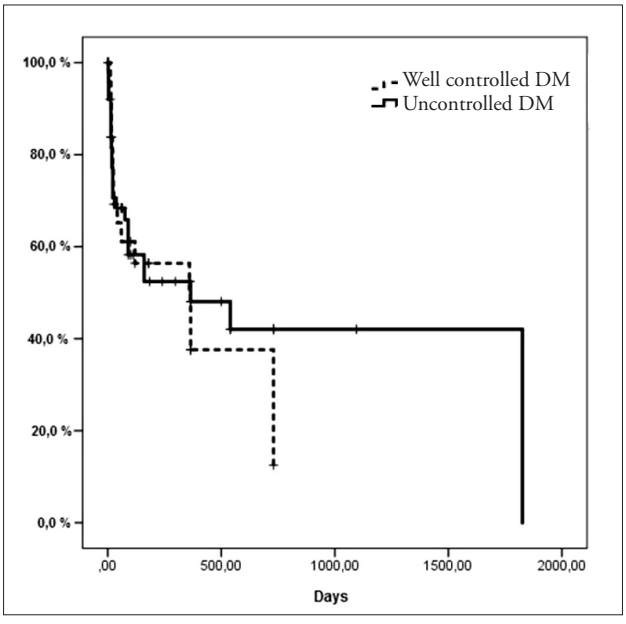

Fig. 7. Well controlled diabetes vs. uncontrolled diabetes primary patency

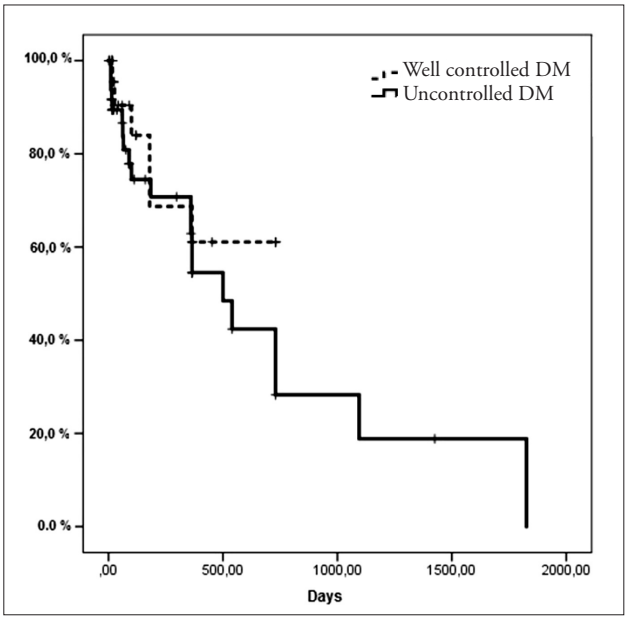

Fig. 8. Well controlled diabetes vs. uncontrolled diabetes limb salvage

Discussion

During the last decade, the frequency of endovascular treatment for the arterial occlusive disease has increased, even in the infrapopliteal segment. Low rates of early morbidity have been considered as an advantage of PTA compared to bypass surgery in the management of limb ischemia. The comparison of surgical and endovascular techniques in randomized controlled trials is almost impossible due to difficulties in forming comparable groups. Moreover, in retrospective studies, the patient characteristics for surgical and endovascular groups may differ significantly. In order to avoid the difficulties of comparing, the propensity score analysis may be used to adjust for such important differences. Our propensity score analysis included preoperative risk factors, indications for the procedure as well as leg status, target segment, previous revascularization procedure on the same segment, and patent target vessel down to the pedal artery. In the overall series and in the propensity score, matched pairs PTA and bypass surgery achieved similar 6 months leg salvage, survival and amputation-free survival rates. Both provide an acceptable limb salvage rate, but patency appears to be better after bypass surgery [1, 9, 15]. The greatest problem in treating lower limb ischaemia and trying to compare different methods of treatment is that it is very difficult to standardize the disease itself. Even when the propensity score analysis is applied, the comparison of bypass and PTA still faces a problem – the type of the treated lesion and the extent of arterial disease were not taken into account due to the lack of a proper classification of infrapopliteal lesions. There is a number of infrainguinal arterial lesions that cannot be easily classified, and the current classification systems are reported to have a poor reproducibility. Moreover, endovascular interventions are much more likely to be performed for stenotic segments than occlusions. As bypass surgery is particularly suitable for longer lesions, the incomparability of the treated segments may have influenced the present results. As previous randomized trials have demonstrated, only 4–29% of the lesions have been treated by either method which worsens the generalizability of the findings of randomized controlled trials [31].

The recent development of specific devices and techniques designed for the management of long extension lesions in infrapopliteal vessels has provided the opportunity to manage long stenosis or occlusions in tibial vessels by endovascular methods. PTA is a good treatment option for older patients who have higher operative risks and a shorter life expectancy [10, 17, 20, 21]. There is an increasing number of patients undergoing PTA instead of surgery with long tibial artery lesions and the multisegmental disease. A lot of research into arterial stenosis or occlusion treatment have been focused on the outcomes of endoluminal interventions. But the majority of them have relayed on short-term results only. Our study suggests that angioplasty provides an acceptable short-term limb salvage rate. Nevertheless, the goals for CLI treatment include the inline flow to the foot arteries to assist wound healing, rest pain relief, short-term morbidity, major amputation prevention, as well as patient function and life quality improvement.

Patients with diabetic foot ulcers and concomitant PAD are at a higher risk for limb loss and premature death. In our study, better results following PTA were shown in non-diabetic patients, possibly due to diabetic patients' arterial calcinosis and the lack of the pedal arch. However, when the patient clinical status is complicated by the presence of wound infection and diabetes, endovascular reconstruction is preferred [8, 18].

This study shows that the DP artery bypass for foot ischemia in diabetic patients is a safe, effective and durable procedure. Graft patency and limb salvage rates are comparable with more proximal infrainguinal arterial reconstructions and when performed with the autologous saphenous vein have an excellent durability with patency for 2 years or longer [24, 25, 26]. Pedal bypass is well suited to the anatomic pattern of atherosclerosis most commonly seen in patients with diabetes mellitus [10, 14, 28]. For many patients, dorsal pedal artery may be the only outflow target artery available for the bypass and should always be included in the preoperative arteriogram. Angiography and duplex scanning play an important role in assessing these patients. Foot angiographies are a useful adjunct in demonstrating the patency of such vessels and in planning surgery [16].

The use of DP bypass revascularization has reduced the primary amputation rate, especially in diabetic patients [11, 12, 13 16, 22, 23, 29, 30]. This study confirms that DP artery bypasses can be durable not only in diabetic but also in non-diabetic population.

The long-term patency appears to be better after open surgery. The duration of the revascularization effect after open surgery was longer as compared with PTA. Normal rates of limb salvage can be achieved in patients with critical limb ischemia undergoing multilevel interventions [7]. In our study, the best results of revascularization, especially in diabetic patients, were achieved in the combined treatment group (open repair + endovascular treatment). Dorsal pedal artery bypass results, especially combined with PTA (in order to shorten the bypass) and with good inflow, are rather promising despite the limited distal vascular bed. This kind of revascularization procedure has advantages over the more proximal infrapopliteal bypass, especially for diabetic patients whose estimated life expectancy is over two years [27].

One of our research questions was to assess the impact of diabetes mellitus on limb salvage rates in patients with CLI. Patients with well-controlled diabetes and uncontrolled diabetes were compared in terms of primary patency and limb salvage rates after two years. Our study suggests that diabetes control does not significantly affect primary revascularization outcomes in patients with CLI. This conclusion is supported by other studies where a strict glucose control was found to have effect only on patients with coronary artery disease [32, 33, 34]. Nevertheless, as routine HbA1 level monitoring was introduced to our hospital only in 2005, patient numbers are low and strict conclusions should not be drawn.

Our study has few drawbacks. Firstly, patients with Type 1 diabetes mellitus were not included in this study as very few of them were treated in our hospital (according to patient history data). Secondly, comparison between patients with well controlled diabetes and uncontrolled diabetes was made in a modest group of diabetics.

Conclusions

Both infrapopliteal angioplasty and bypass surgery provide an acceptable limb salvage rate, but the follow up patency appears to be better after bypass surgery. DP bypass is a safe and durable procedure in patients with CLI and diabetes mellitus. The duration of revascularization effect was longer in the open repair group as compared to the endovascular repair group. The best revascularization results were achieved in diabetic patients after combined treatment. Endovascular therapy may be preferred in patients with a reduced life expectancy, also for those who lack a suitable vein for bypass or who are at a higher risk for operation. No significant differences in primary revascularization outcomes were found between patients with well controlled and uncontrolled diabetes mellitus.

Requesting Competing Interests: the authors declare that they have no competing interests.

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