Bypass grafting for infrapopliteal occlusive disease with poor distal flow on angiography

Distal yatağı anjiyografik olarak kötü değerlendirilen infrapopliteal oklüzif hastalıklarda baypas cerrahisi ve sonuçları

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ABSTRACT

Objective: We aimed to investigate whether limb-salvage bypass operation improves outcomes in patients with critical infrapopliteal ischemia and poor or no distal arterial flow on angiography.

Methods: Forty-nine patients with severe tibial and peroneal occlusive disease and poor distal arterial flow on angiography were included in this prospective study. The age ranged from 57 to 82 years in the surgical group and 63 to 80 in the medical group. Patients had class III or IV disease according to Fontaine classification. Preoperative arterial Doppler ultrasonography and arteriography were performed in all patients. The ankle-brachial index (ABI) was calculated preoperatively and postoperatively in all of the cases. Twenty-three patients underwent distal bypass operation. Other 26 patients were followed with medical therapy. The outflow distal anastomoses were performed on posterior tibial, dorsal pedal, anterior tibial, peroneal, and lateral plantar arteries. All patients were followed-up for 3 years and clinical outcomes were recorded. The statistical analyses were performed using unpaired t, Mann Whitney and Wilcoxon tests.

Results: There were 3 early and 2 late graft failures. Limb salvage rates were 84.2%, 84.2%, 73.7% in the surgical group, and 82.8%, 69.9%, 64.3% in the medical group respectively in 6 months, 1 year, and 3 years. According to statistical analysis; the levels of the amputations tend to be lower in the surgical group than in the medical group but it was not significant statistically. Surgical treatment reduced the amputation ratio ($p<0.05$) but medical therapy did not ($p>0.05$). The difference between preoperative mean ABI [0.26±0.06] and postoperative mean ABI [0.80±0.24] was significant ($p<0.05$).

Conclusion: We think that limb-salvage bypass operation may be preferred for patients with critical limb ischemia and poor distal flow on angiography. Infrapopliteal bypass will provide limb salvage and a functional extremity. *(Anadolu Kardiyol Derg 2008; 8: 444-8)*

Key words: Distal, anastomosis, save, limb, graft, bypass

ÖZET

Amaç: Anjiyografik olarak distal arteryel akımı zayıf olan veya hiç olmayan kritik infrapopliteal iskemili hastalarda ekstremite kurtarıcı baypas operasyonlarının sonuçları araştırıldı.

Yöntemler: Ciddi peroneal ve tibiyal tıkayıcı arter hastalığı olup anjiyografik olarak distal arteryel akımı kötü veya zayıf olan 49 hasta bu ileriye dönük çalışmaya alındı. Yirmi üç hastaya distal baypas operasyonu uygulandı. Yirmi altı hasta ise medikal olarak takip edildi. Hastaların yaş aralığı cerrahi grupta 57-82, medikal grupta ise 63-80 yıl idi. Hastaların tümü Fontaine sınıflamasına göre klass III veya IV idi. Preoperatif ve postoperatif olarak kol-bacak indeksi bakıldı. Tüm hastalara preoperatif olarak arteryel Doppler ultrasonografisi ve arteriyografi uygulandı. Distal baypaslar arka tibiyal, dorsal pedal, ön tibiyal veya plantar lateral arterlere yapıldı. Tüm hastalar 3 yıl boyunca takip edildi ve klinik olaylar kaydedildi. İstatistiksel analiz eşleştirilmemiş t, Mann Whitney ve Wilcoxon testleri ile yapıldı.

Bulgular: Üç erken, 2 geç greft tıkanıklığı izlendi. Altı aylık, 1 ve 3 yıllık takiplerde ekstremite kurtarma oranları cerrahi ve medikal grupta sırası ile %84.8, %84.2, %73.7 ve %82.8, %69.9, %64.3 idi. Amputasyon düzeyleri açısından cerrahi grupta daha düşük olarak bulunmasına rağmen istatistiksel fark bulunamadı. Cerrahi grupta amputasyon oranı daha düşük bulundu ($p<0.05$). Preoperatif ve postoperatif kol-bacak indeksleri arasındaki fark istatistiksel olarak anlamlıydı ($p<0.05$).

Sonuç: Kritik bacak iskemili ve anjiyografik olarak zayıf distal akımı olan olgularda ekstremite kurtarıcı distal baypas cerrahisi uygulanabilir. Infrapopliteal arterlere uygulanan bu baypas cerrahisi ile fonksiyonel bir ekstremite elde edilebilir. *(Anadolu Kardiyol Derg 2008; 8: 444-8)*

Anahtar kelimeler: Distal, bacak kurtarılması, greft, anastomoz, iskemi, baypas

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Introduction

Peripheral vascular disease of the lower extremities comprises a clinical spectrum that includes asymptomatic patients and patients with chronic critical limb ischemia (CLI) that might result in amputation and limb loss. Critical limb ischemia is a persistent and relentless problem that severely impairs the patient functional status and quality of life, and is associated with an increased cardiovascular mortality and morbidity.

Lower extremity critical ischemia represents only 1-3% of those with peripheral occlusive disease (1). Modification of risk factors, drug therapy, and other nonpharmacological interventions such as exercise have, for the most part, brought only transient, modest improvement in the evolution of the disease and are essentially ineffective in treating severe disease (1, 2). Despite the advances that have been made in understanding and treating this disease, distal bypass surgery remains the gold-standard for treating threatened limbs.

Distal vein bypass to the dorsalis pedis artery and paramalleolar posterior tibial artery are now routine procedures for most vascular surgeons (3). Several reports have reported acceptable patency, limb salvage, and operative mortality with arterial bypasses to the ankle and foot (4, 5).

The results of bypass surgery for patients who have tibial or peroneal occlusive disease with poor distal flow on angiography are not well known. Benefit of medical therapy is limited for these patients. These patients usually undergo limb amputation surgery.

The aim of the study was to compare effects of surgical and medical treatments on the ankle-brachial index (ABI), claudication and walking distances, and early-midterm outcomes as limb salvage, graft patency and survival in patients CLI and poor distal flow on angiography.

Methods

Patients characteristics

Forty-eight patients admitted to our hospital because of critical leg ischemia between January 2000 and September 2008 were included in this prospective study. A written informed consent was obtained from all patients (who accepted surgical procedure). Patient characteristics and operation variables were retrieved from medical records and computer files of the Department of Cardiovascular Surgery, Atatürk Training and Research Hospital, Izmir. All patients were assigned to medical or surgical therapy and were followed-up prospectively. The collected information described age, sex, presence of major risk factors (diabetes mellitus, hypertension, smoking habits, and hyperlipidemia). All patients had class III or IV disease according to Fontaine classification. Exclusion criteria; patients who were admitted to the hospital in an emergent situation, including sudden occlusion of the lower extremity, sudden onset of high fever, distal embolization, external compression, redo cases, bilateral critical limp ischemia, bedridden patients, acute thrombosis were not included to the study.

Twenty-three patients, (17 males and 6 females) underwent distal bypass operation and 25 (19 males and 7 females) patients received medical therapy. The mean age was 59.0±8.7 in the surgical group and 63.0±6.4 in the medical group. Risk factors are summarized in Table 1.

Doppler ultrasonography

Preoperatively all patients underwent arterial Doppler ultrasonography and arteriography. The best quality vessel was determined by performing the angiography, Doppler ultrasonography and surgical exploration for the distal anastomosis procedure (Table 2). Doppler signals over major vessels in the foot were useful in determining a recipient site when arteriography was inadequate. We performed our surgical procedure with the aid of arterial Doppler ultrasonography. During the surgical procedure, the exploration and Doppler study showed the pulsation in monophasic and biphasic forms in the vessels, which were bad or invisible on angiographic evaluations. Arterial Doppler ultrasonography was used to more clearly define outflow vessels in the foot. We measured the lower and upper extremity arterial pressures and calculated the mean ankle-brachial index (ABI). We measured the claudication distance for each group preoperatively and postoperatively.

Operation

Autogenous veins were used in all procedures. The vein was completely exposed and mobilized through a continuous incision. If necessary the prosthetic graft and the vein was sutured to perform a good flowing anastomosis with the aid of

Table 1. The patients' basal demographic and clinical features

Parameters	Surgical Group	Medical Group	p
Number of patients	23	25	
Age, years	58.3±12.7	65.5±20.5	0 .86*
Male gender, n	17	19	0 .78
Diabetes, n	13	14	0.87
Hypertension, n	7	8	0 .07
CAD, n	4	5	0 .62
Prior MI, n	2	3	0.87
CHF , n	3	4	0 .63
Prior CABG, n	3	6	0 .38
CR>2mg/dl	2	3	0 .68
Current smoker, n	3	7	0 .47
Hyperlipidemia, n	7	9	0 .67

*unpaired t test, all other p values generated with Chi-square test
CAD-coronary artery disease, CR - creatinine, CHF-congestive heart failure, MI-myocardial infarction, CABG-coronary artery bypass grafting

Table 2. Proximal and distal anastomoses in the surgical group

Proximal	n
Common femoral artery	3
Supragenual femoral artery	11
Infragenual popliteal artery	9
Distal	n
Anterior tibial	3
Peroneal	1
Plantar lateral	1
Dorsal pedal	6
Posterior tibial	12

end–to-side technique. Selection of the proximal anastomotic site was dependent on the distribution of atherosclerosis in the native vessels. Short bypasses originating from the popliteal artery were performed when angiographic and noninvasive studies excluded significant proximal occlusive disease. All distal anastomoses were performed with autogenous veins. Circumferential calcification of distal vessels was not a contraindication for establishment of an anastomotic site. Outflow anastomoses were performed with systemic heparinization, loop magnification, and continuous suture technique with 6-0 or 7-0 monofilament suture and inflow anastomoses were performed by 5-0 or 6-0 monofilament. The necessary dose of protamine was often used to reverse the heparin dose that was given at the start of the procedure.

Both groups were maintained on cilostazol (cilastazol is available within last 2 years in Turkey), acetylsalicylic acid and /or clopidogrel therapy after hospital discharge (Table 2).

Follow-up

Patients were followed up at regular intervals of every 3 months during the first year, every 6 months during second year, and annually thereafter. During follow up the ABI, distance of walking, claudication distance and patency of grafts were recorded for each patient. Patency of the grafts was determined by palpation of the pulses in the foot and along the graft in the subcutaneous tissue. Doppler ultrasonography was performed if the pulse was not palpable. Limb salvage is defined as any revascularization procedure, surgical or percutaneous aimed at improving the blood flow in the ischemic limb with the purpose of preventing limb loss, and ideally achieving wound healing and resolution of chronic ischemic pain or gangrene.

This included foot requiring toe, ray or transmetatarsal amputations, as well as partial or complete resection of the calcaneus.

Statistical analysis

Patients' demographic data, indications for surgery, details of the surgical procedure and follow-up data were analyzed with a commercially available statistics software program (Statview 5.0 software; SAS Institute). Results are presented as mean±standard deviation. All data are presented in accordance with the revised reporting standards of the council Society for Vascular Surgery (6). Graft patency, limb salvage, and patient survival were calculated with the Kaplan-Meier life table method. Normally distributed continuous variables were compared between the groups using the unpaired Student's t test, and abnormally distributed variables were compared using Mann-Whitney U test. Chi-square test and Fischer exact test were used for comparison of ordinal and nominal data. The intragroup changes before and after operation were compared using paired Student's t test or Wilcoxon test. P<0.05 was considered as statistically significant.

Results

Demographic features were not significantly different between surgical group and medical group (Table 1). Diabetes mellitus was found in 56.6% of patients in surgical group and 56% of patients in medical group.

Twenty-three patients underwent lower limb revascularization procedure (Table 2) . The graft material was only autogenous vena saphena magna in 20 patients. Prosthetic graft was used additionally in 3 patients. Median hospital stay was 11.5 days (range, 3- 37 days) and it was not different in two groups.

The difference between preoperative mean ABI [(0.26±0.06 (min 0.17, max 0.38)] and postoperative mean ABI [0.80±0. 24 (min 0.4, max 1)] was significant in the surgical group (p<0.05). In the medical group initial mean ABI was 0.30±0.08 (min 0.15, max 0.42). Mean ABI increased to 0.46±0.12 (min 0.15, max 0.8) after at least two weeks of medical therapy and this increase was statistically significant (p<0.05).

Perioperative complications are summarized in Table 3. In the surgical group, there was 1 (4.3%) death because of myocardial infarction within 30 days after operation. He had end-stage renal failure and was receiving hemodialysis. In the medical group one patient died because of cerebrovascular hemorrhage on the second month of the therapy. Midterm follow-up (36 months) revealed two more deaths in the surgical group and three more deaths in the medical group. Late deaths were related to primarily cardiovascular diseases.

Early graft failure occurred in 3 patients within 7 days. We did not attempt any graft revision, but major amputation was not necessary for the patients with early graft failure within 7 days. One of the early graft failures was in a patient in whom we used polytetrafluoroethylene conduit additional to autogenous vein. No attempt for graft revision was done in this patient, and below-knee amputation was performed 1 month after bypass. Late graft failure occurred in 3 patients which required major amputation. Initial attempt to revise the graft was unsuccessful and amputation was performed on 6^{th}, 13^{th} and 27^{th} months of the initial bypass procedure. The levels of the amputations tend to be lower in the surgical group than in the medical group but it was not significant statistically (p<0.07) (Table 4).

During follow-up, which ranged from 1 to 36 months (median 9 months), limb salvage rates were 84.2%, 84.2%, 73.7% respectively at 6 months, 1 year, and 3 years in the study group, and 82.8%, 69.9%, 64.3% in the medical group. The limb salvage rates between two groups were different significantly at the end of 3 years (p<.05).

Table 3. Postoperative complications in the surgical group

Number of patients	
Wound infections/necrosis	3
Myocardial infarction	1
Graft infection with post-op bleeding	1
Congestive heart failure	none
Heel necrosis	1
Septicemia-urinary tract infection.	none
Mortality	1
Occlusion	5
Early	3
Aneurysm	none
Bleeding	1
Minor	1
Major	none
Graft infection	3
Amputation	1

Patency of the grafts, limb salvage and increased claudication distance are summarized in the Table 5. Claudication distance increased in both groups and the increments tend to be more in surgical group than medical group. Distance of walking increased in both groups ($p<0.05$).

Discussion

In this study there has been a statistically different reduction in the percentage of patients that required amputation in the surgical group as compared to the medical group both in the three months follow-up and also in the late follow up. Surgical treatment reduced the amputation ratio ($p<0.05$) but medical therapy did not ($p>0.05$). Limb loss occurred in 21.5% of patients in the surgical group, and 34.2% of patients in the medical group ($p<0.05$) at the end of the three years. The levels of the amputations tend to be lower in the surgical group than in the medical group but it was not significant statistically ($p<0.07$). Claudication distance increased in both groups and the increments tend to be more in surgical group than in medical group. Distance of walking increased in both groups ($p<0.05$).

Technical improvements in lower extremity arterial reconstructive surgery over the last 3 decades have greatly improved the immediate results after lower extremity greater saphenous vein bypass grafting, even to very distal target vessels (7-9). Ascer et al. (10) first demonstrated the technical feasibility of plantar and tarsal bypass in 1988.

The benefits of popliteal-to-distal (posterior tibial, dorsal pedal, anterior tibial, peroneal, and lateral plantar arteries) bypass procedure are limb salvage and improved quality of life (11).

Many recent studies on treating of infrapopliteal arterial stenosis or occlusion have focused on the effects of endoluminal interventions. Some studies have reported the results of the different invasive radiological studies as viable treatment options including; angioplasty, angioplasty with stent placement, subintimal angioplasty, cutting balloon angioplasty, and even vibrational angioplasty as viable treatment options. However, the majority of them have reported only short-term results and even these outcomes have been poor by traditional standards (12- 15). These treatment methods are not applicable for occlusions where distal arterial bed is poorly discernable or invisible on angiography.

Limb salvage in patients with extensive tibial and peroneal occlusive disease is feasible with aggressive revascularization of vessels of the ankle and foot (16, 17). Patient selection may be problematic in this population. Advanced age coupled with multiple medical problems place patients at increased risk. According to some surgeons, primary amputation may often seem a better mode of therapy (18). We believe that revascularization for limb salvage is possible in the majority of such patients. Primary amputation should be reserved for patients with extensive foot infection, gangrene extending above the transmetatarsal level, or bedridden patients with organic brain disease. Candidates for operation should have significant ischemic rest pain, non-healing ulceration, or gangrene limited to the forefoot or heel.

Quality preoperative angiography is essential for patient's candidate for operation. Digital substraction studies, delayed films, and lateral foot and ankle views delineate reconstructible vessels. With these techniques, suitable vessels for bypass can be outlined in most patients thus obviating the need for operative angiograms or exploration of non-visualized, but audible vessels. We performed our surgical procedure with arterial Doppler ultrasonography. We found pulses monophasic or biphasic on the foot or ankle which were with poor or invisible distal flow on angiography. The majority of our patients selected for arterial bypasses to the ankle and foot were diabetic. Tibial and peroneal occlusive disease is prevalent in this population, often with sparing of proximal vessels (19, 20). Pedal vessels are often less affected by atherosclerosis (21). The concept of the diabetic foot being overwhelmed with microvascular disease, and thus unsalvageable, should be discarded (22). Our results indicate that graft patency and limb salvage rate is 73.5% at 36 months in diabetic patients (there was no difference between diabetic and nondiabetic group, $p<0.073$).

A final issue pertinent to selection of patients for operative intervention is the quality of the vessels in the foot including patency of the dorsal or plantar arch should not exclude patients from revascularization. We have found that, as other authors did, successful results occur in the face of limited run off (23-26). Also circumferential calcification in recipient vessels should not prevent grafting (27). This factor does not influence patency. Davidson et al. (18) reported that they have poor correlation between angiographic appearances of foot vessels with preoperative angiography, delineation of dorsal or plantar arch

Table 4. Levels of the amputation in surgical and medical groups during follow-up

Levels of the Amputation	Surgical group	Medical group	p*
Toe amputation	1	2	
Metatarsophalangeal amputation	no	1	
Ray amputation	no	1	
Transmetatarsal amputation	1	1	
Syme amputation	1	no	
Transtibial amputation	1	2	
Transfemoral amputation	1	2	
Total	5	9	<0.07
*Fischer exact test			

Table 5. Three-year patency, increased claudication distance and limb loss in the surgical group

	N	3-Year Patency	Limb loss	Increased CD
Femoroposterior tibial	3	1	2	1
Supragenual femoroposterior tibial	8	7	1	5
Supragenual femoroanterior tibial	2	-	1	1
Supragenual femorodorsalis pedis	1	1		1
Infragenual popliteal tibialis posterior	5	5		5
Infragenual popliteal tibialis anterior	1	1		
Infragenual popliteal arteria lateralis tarsalis	1	1		1
Infragenual popliteal dorsalis pedis	1	1		1
Infragenual popliteal peroneal	1	1		1
CD-claudication distance				

was not always successful. They have thus abandoned attempts to correlate midterm patency with runoff in the distal foot, as it has limited practical application (18).

Basic vascular principles are key to the success of these procedures, but several operative decisions must be individualized for each patient. The origin of the proximal anastomosis of the graft is an important consideration. In the past, the common femoral artery was thought to the best site for inflow due to concern that progressive atherosclerosis in the superficial femoral or popliteal artery would lead to graft failure. Veith, who demonstrated no adverse effects on long-term patency when grafts originated from the superficial or popliteal artery (10), has refuted this concept. Short vein bypass has also been shown to be superior in patency to long vein bypass when outflow tracts are compromised (28). The advantages of short bypass from distal inflow sites include lower incidence of wound complications, increased vein utilization rates, and shorter duration of operation.

Autogenous greater saphenous vein is clearly the graft material choice. There are cases of synthetic grafts to the ankle and foot with limb salvage, but the long-term patency is marginal (29). For this reason, we have used vein exclusively used for all procedures. When vein was not enough we added synthetic graft but we used autogenous vein for outflow anastomosis.

The ABI is routinely used to assess the lower extremity arterial pressure. The ABI is aimed to be ≥1.0 with treatment in patients with ischemic leg. In our study mean ABI increased in both groups during short-term and midterm follow-up ($p<0.05$).

Study limitations

There were no differences in patency or limb salvage rates between posterior tibial, dorsal pedal, anterior tibial, peroneal, and lateral plantar arteries. We think that our patient's number was not enough to discriminate a difference among these arteries. There was an inverse correlation between graft patency and the length of the graft. Although patient number did not allow us to perform statistics short grafts tend to have longer patency duration than long grafts.

Conclusion

We think that limb-salvage bypass operation is effective for patients with critical limb ischemia and poor distal flow on angiography. At least surgery may decrease the level of amputation. Further studies are needed to confirm our results.

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