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Original Scientific Paper

PREDICTIVE FACTORS FOR SUCCESSFUL PROSTHETIC REHABILITATION AFTER VASCULAR TRANSTIBIAL AMPUTATION

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SUMMARY – Lower extremity amputation is a very common amputation and successful prosthetic rehabilitation is a desirable outcome. The aim of this study was to determine which factors affect the success of prosthetic rehabilitation after transtibial vascular amputation. The study included 61 patients who had undergone transtibial amputation (mean age, 64.2±10.4 years; 50 (82%) males). Patients who were able to walk at least 45 meters without aids or with only one walking stick after rehabilitation program were classified into the group of successful prosthetic users. Age, gender, comorbidities, patency of the popliteal artery, wound healing complications, and presence of the phantom limb pain were used as predictive variables. Multivariate logistic regression analysis was used to identify predictive factors of successful prosthetic rehabilitation. The model included all variables explaining up to 59.8% of variance, however, only age, absence of functional patency of the popliteal artery and compromised wound healing made significant contribution to the model. In conclusion, good general condition of the patient and sustained patency of the popliteal artery reliably led to clinical improvement and realization of full capacity of rehabilitation after below-knee amputation.

Key words: *Amputation, transtibial; Lower limb; Rehabilitation, prosthetic*

Introduction

Amputation is defined as surgical removal or accidental loss of the entire limb or part of the limb[1]. Lower extremity amputation is a very common localization of surgical amputation and more than one million people undergo this kind of surgery every year[2]. Although amputation can be the final natural outcome of peripheral artery occlusive disease (PAOD) and failure of surgical treatment of critical limb ischemia (CLI), it is a procedure that can provide satisfactory functional results after successful rehabilitation[3,4].

According to the latest research, diabetes mellitus (DM) is one of the most significant contributing factors with a 20-30 times increased risk of lower limb amputation[5,6]. The level of amputation is a significant predictor of rehabilitation and prosthetic use since patients with more distal amputation (transtibial) achieve better walking ability compared to patients with more proximal level of amputation (transfemoral)[7]. Typical above-knee amputation is transfemoral amputation (TFA), while in the below-knee region (below-knee amputation, BKA), typical transtibial amputation (TTA) is done most often[8]. Numerous studies have documented an increased rate of successful prosthetic rehabilitation after TTA compared to TFA, with two-thirds of TTA patients and less than one-third of TFA patients being successfully fitted with the prosthesis[9], so the patient quality of life after lower extremity amputation is significantly in favor of BKA[10,11].

Investigation of predictive factors is needed to estimate the prosthetic rehabilitation potential more ac-

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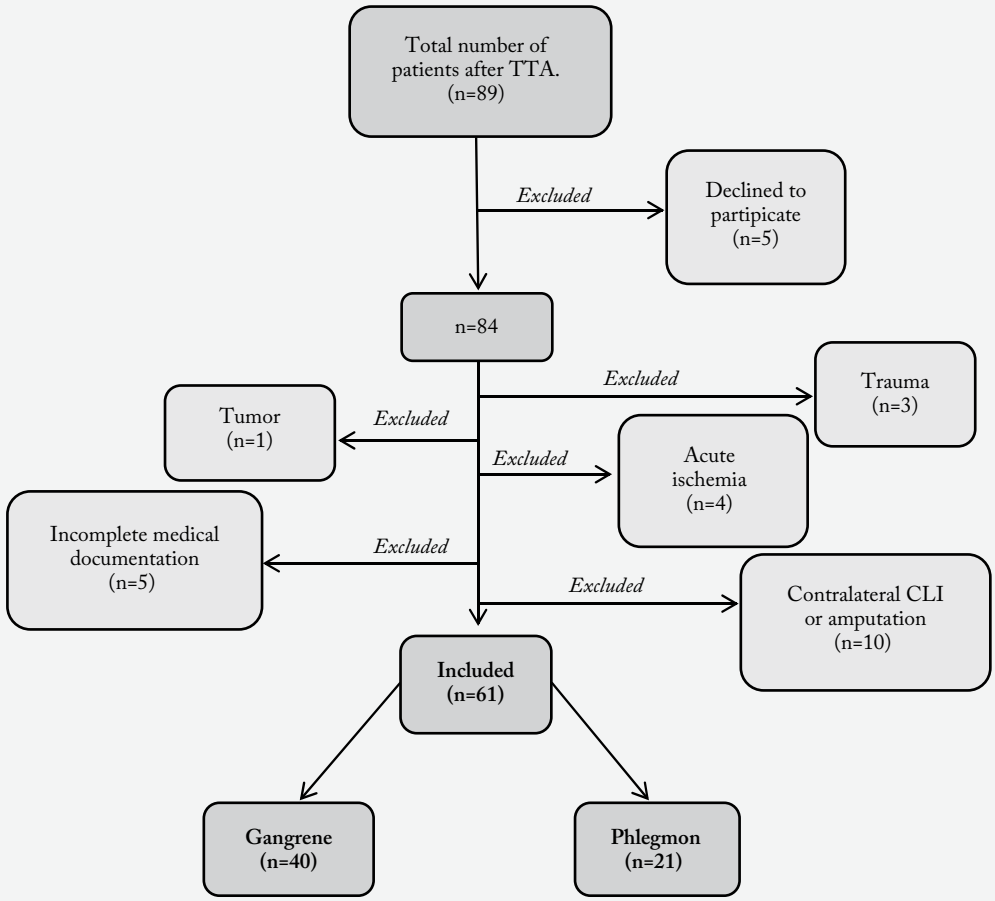

Fig. 1. Flowchart of patient exclusion and inclusion criteria in the study.

CLI = critical limb ischemia; TTA = typical transtibial amputation

curately, targeting modifiable factors to optimize outcome after amputation. Ultimately, this would help establish successful prosthetic use, walking, and carrying out daily activities independently[12].

The aim of this study was to determine which factors affect the success of prosthetic rehabilitation after transtibial vascular amputation.

Material and Methods

This prospective study was conducted at the Department for Vascular and Endovascular Surgery, Clinical Centre of Vojvodina, between January 2018 and January 2020. The study included 61 patients having undergone TTA in 2018 due to PAOD and/or complications of diabetes[13]. Patients with CLI without the possibility to preserve the whole extremity (progressive foot gangrene or uncontrolled progressive infection, phlegmon) were included in the study. Exclusion criteria were as follows: patients whose lower extremity was amputated because of acute ischemia, tumor or trauma, patients with contralateral CLI or amputation, and patients with incomplete medical documentation (with no data on rehabilitation and follow-ups). Patients with TTA after acute CLI were not included in the study due to the lack of complete insight into the functional patency of the popliteal artery before amputation, as well as due to a different etiology of critical ischemia (embolization, thrombosis of popliteal aneurysm). These exclusion and inclusion criteria are shown in Figure 1, and were designed to homogenize the group of patients with better insight into the predictive factors for successful prosthetic rehabilitation.

Table 1. Patient caracteristics (N=61) before and after transtibial amputation and prosthetic rehabilitation outcome

Factor	Value
Age distribution (years):	
Youngest/oldest (years)	34/83
Mean (standard deviation)	64.2 (10.4)
Gender distribution:	
Male	50 (82%)
Female	11 (18%)
Comorbidity:	
Hypertension	45 (73.7%)
Diabetes mellitus	42 (68.8%)
Ischemic heart disease	18 (29.5%)
Smoking	19 (31.1%)
Chronic renal insufficiency	12 (19.6%)
Chronic obstructive pulmonary disease	2 (3.2%)
Functional patency of popliteal artery:	
Yes	40 (65.5%)
No	21 (34.4%)
Cause of amputation:	
Gangrene	40 (65.5%)
Phlegmon	21 (34.4%)
Amputated leg:	
Right	38 (62.3%)
Left	23 (37.7%)
Wound healing complications:	
Yes	15 (24.5%)
No	46 (75.4%)
Phantom pain:	
Yes	25 (40.9%)
No	36 (59.0%)
Successfully fitted with prosthesis:	
Yes	48 (78.6%)
No	13 (21.4%)

Table 2. Associations in successful (n=48) and failed (n=13) prosthetic rehabilitation and univariate analysis after rehabilitation of patients with transtibial amputation (χ^2-test)

Risk factor	Successful n (%)	Failed n (%)	p value
Age (years):			
<65	32 (66.66)	4 (30.76)	0.044
≥65	16 (33.33)	9 (69.23)	
Gender:			
Male	38 (79.16)	12 (92.30)	0.492
Female	10 (20.83)	1 (07.69)	
Hypertension:			
Yes	35 (72.91)	10 (76.92)	0.949
Diabetes mellitus:			
Yes	31 (64.58)	11 (84.61)	0.296
Ischemic heart disease:			
Yes	12 (25.00)	6 (46.15)	0.254
Smoking:			
Yes	13 (27.08)	6 (46.15)	0.910
Chronic renal insufficiency:			
Yes	7 (14.58)	5 (38.46)	0.127
Amputated leg:			
Right	30 (62.50)	8 (61.53)	0.107
Cause of amputation:			
Gangrene	31 (64.58)	9 (69.23)	0.987
Phlegmon	17 (35.41)	4 (30.76)	
Functional patency of popliteal artery:			
Yes	38 (79.16)	2 (15.38)	0.000
Wound healing complications:			
Yes	44 (91.66)	2 (15.38)	0.000
Phantom pain:			
Yes	16 (33.33)	9 (69.23)	0.044

All patients underwent duplex ultrasound scanning (DUS) preoperatively, and digital subtraction angiography (DSA) was performed in those patients (60%) considered for operative or endovascular revascularization. Accordingly, vascular procedures (endovascular and open revascularization) preceded amputation in some patients.

Physical examination before the surgery was carried out and data on gender, age, lateralization of the extremities, cause of amputation, medical history, and risk factors for vascular disease (arterial hypertension (AHT), DM, chronic renal insufficiency (CRI), chronic obstructive pulmonary disease (COPD), ischemic heart disease (IHD), and smoking status) were collected. IHD included myocardial infarction, angina pectoris and ischemic cardiomyopathy assessed by cardiologists. For this analysis, patients were divided into patients younger than 65 and those older than 65 years. Patients were considered smokers if they reported smoking "every day" or "some days" prior to amputation, and non-smokers if they reported the remaining category "not smoke at all"[13]. "Functional patency of

Table 3. Multivariate analysis of patients successfully fitted with prosthesis after transtibial amputation (binary logistic regression analysis)

	Coefficient	t Stat	p-value	Lower 95%	Upper 95%
Intercept	0.0681457	0.2881	0.774553	-0.408	0.5446
Age	0.155743	1.9233	0.0609234	0.0074	0.3189
Gender	-0.11203	-1.1366	0.2618408	-0.310	0.0866
Hypertension	0.047338	0.5366	0.5941942	-0.130	0.2251
Diabetes mellitus	-0.08738	-0.9869	0.3290459	-0.265	0.0910
Ischemic heart disease	-0.1006	-1.2156	0.2306043	-0.267	0.0661
Smoking	-0.08237	-1.0272	0.3099258	-0.243	0.0792
Chronic renal insufficiency	-0.03197	-0.3316	0.7417545	-0.226	0.1623
Gangrene/phlegmon	0.053554	0.6409	0.5248873	-0.114	0.2219
Functional patency of popliteal artery	0.337708	3.8782	0.0003474	0.1622	0.5132
Wound healing complications	0.456739	4.3978	0.0000683	0.2474	0.6660
Phantom pain	0.004165	0.0485	0.9615188	-0.168	0.1771

the popliteal artery" was assessed by DUS and in some cases by DSA, and it implied that the popliteal artery flow examined by DUS was triphasic or sufficiently biphasic and with no evidence for proximal or popliteal artery stenosis greater than 50%.

After the operation, if there were no complications, patients were discharged from the hospital and follow-ups were scheduled in two weeks, then at 1, 3 and 12 months after TTA. During the follow-up period, data on the presence of phantom limb pain, wound healing complications (defined as wound infection, hematoma, or tissue necrosis) were collected. After the first follow-up visit, all patients were referred to the rehabilitation team of the Department of Medical Rehabilitation, Clinical Centre of Vojvodina, and the inpatient program of prosthetic fitting and training was completed at the Department of Medical Rehabilitation. In case of complications due to which the rehabilitation program had to be deferred, the patients were reassigned to the Department of Vascular and Endovascular Surgery for further treatment.

During the 12 months after TTA, the success of prosthetic rehabilitation was monitored. Patients who were able to walk at least 45 meters without aids or with only one walking stick after rehabilitation program were classified into the group of successful prosthetic users. This group also included patients who had surgical correction of operative wound at the infrapopliteal level during the period of rehabilitation. Contrary to the group of successful prosthetic users, the group of failed prosthetic users included patients who were not completely able to use prosthesis or who needed two sticks, crutches or medical walkers for walking, and patients who required additional transfemoral amputation for wound complications[14].

The results were processed using descriptive and comparative statistical methods. Relative ratios (percentages), measures of central tendency (arithmetic mean), minimum and maximum interval values of the characteristics observed were determined. Univariate analysis was performed, as well as multiple variable analysis (multivariate analysis) by binary logistic regression. The t-test was used to determine differences in numerical variables. The significance of differences was defined at $p<0.05$ level.

The study was approved by the Ethics Board of the Clinical Centre of Vojvodina. All subjects signed an informed consent form before enrolment in the study.

Results

A total of 61 transtibial amputees (mean age 64.2±10.4 years) were included in the study. Functional patency of the popliteal artery was confirmed in 40 (65.5%) patients, including eight patients after endovascular treatment of the femoropopliteal (FP) arterial segment and one patient after open FP revascularization. Out of 21 (34.4%) patients who did not have functionally patent popliteal artery (occlusion or significant stenosis of popliteal or proximal arteries),

three patients had undergone endovascular and nine patients open FP revascularization (occluded femoropopliteal bypass). During the 12-month period, 48 (78.6%) patients were successfully fitted with the prosthesis, i.e. 14 (22.9%) patients within <90 days, while 34 (55.7%) patients completed rehabilitation program >90 days after amputation. The pre- and post-prosthetic wound healing complications occurred in 15 (24.5%) patients with TTA. More details are shown in Table 1.

Out of the 61 amputated patients, prosthetic rehabilitation failed in 13 (21.4%) patients. These patients were followed-up for 1-12 (mean, 10.1) months. One (1.6%) patient underwent revision and reamputation of the stump at the tibial level due to chronic ulceration on the stump, while three (4.9%) patients underwent transfemoral amputation due to wound infection. During the follow-up, 11 (18.03%) patients died. Two of these patients were successfully fitted with a prosthesis and death occurred in the 10th and 11th month, respectively, whereas nine of the deceased patients previously were not successfully fitted with the prosthesis and they were included in the group of patients with failed prosthetic rehabilitation. Postoperative mortality after TTA within the first 30 days after amputation was 3.3%. Univariate analysis of variables related to preoperative characteristics and pre-prosthetic complications with regard to successful prosthetic use is shown in Table 2.

It was found that age, functional patency of the popliteal artery, wound healing complications, and presence of phantom pain were significantly different between the patients who were able to use their prosthesis and those that were not. Logistic regression was performed to assess the factor impact on the likelihood of successful prosthetic rehabilitation. The variables included in this model are shown in Table 3. The model was statistically significant ($p<0.05$) indicating that it was possible to distinguish patients who were able to walk with prosthesis from those that were not. The full model explained up to 59.8% of variance. Three variables contributed to the model significantly (age, functional patency of the popliteal artery, and wound healing complications). More details are shown in Table 3.

Discussion

In case of progressive gangrene or infection and when there is no option for limb preservation, decision on limb amputation is made by vascular surgeon. It is frequently performed as a surgical emergency, when there is not enough time for detailed examination by a physiatrist, and decision on the level of amputation is made by taking in consideration the limited patient data, most of them being analyzed in this paper. Decision on the level of amputation is made with the aim to provide a functional stump and short rehabilitation period until prosthetic use. It is preferable to avoid complications that would result in dysfunctional stump and additional surgical procedures, delayed prosthetic use, or even raise the amputation level. At the same time, a lower level of amputation (BKA) provides significantly better functional results compared to the above-knee amputation[9].

In our research, we achieved success in prosthetic rehabilitation in 78.6% of patients within 12 months. Successful prosthetic rehabilitation was confirmed if patients were able to walk independently more than 45 meters. In the literature, this ratio ranges from 49%[14] to over 95%[15]. A similar time frame of 12 months was used in previous researches[2,13].

Age was an independent predictor of successful prosthetic rehabilitation and younger age implied successful rehabilitation[13]. Risk factors for occlusive PAOD accumulate in the elderly and PAOD remains the leading cause of lower limb amputation[1]. Younger persons have fewer comorbidities, stronger muscles and better coordination, which is of great importance for successful walk with prosthesis[16]. Older age has a negative impact on prosthetic potential, and some studies have reported that walking ability is more affected by age than by the present comorbidities[17].

In the absence of popliteal artery pulsations, evidence for insufficient blood flow or stenosis or occlusion of femoral or popliteal artery is the rationale to perform above-knee amputation. Regardless of that, our research was set up with hope that satisfactory results would be achieved even if such findings were present. Disappointingly, the patients who did not have functionally patent popliteal artery had almost 4 times less chance for successful prosthetic use, and it was not a surprise considering that adequate blood flow is necessary for satisfactory wound healing and stump formation. The importance of open or endovascular revascularization of the FP segment before TTA is also emphasized both in our paper and by literature data[18]. Wong *et al.* also found that indicators of poor

vascularization such as low ankle brachial index and absence of popliteal pulse were negative predictors of prosthetic rehabilitation[2]. Further investigation should identify factors which improve outcome after TTA in patients with insufficient flow in the popliteal artery.

Significantly better prosthetic use is observed in patients without wound healing complications. Healing complications could postpone or extend the rehabilitation process. Stump infection is a common postoperative complication after BKA with a potentially serious clinical outcome, including reamputation at a higher level, poorer functional outcome, and higher mortality. Kumar *et al*. found that the most common indications for revision and reamputation of BKA were inadequate stump formation and infection[1]. Sansam *et al*. found that stump problem was a significant predictor of poor results when it comes to prosthetic rehabilitation[19]. In the present study, wound complications were present in 24.5% of patients and 4.9% of patients underwent reamputation at the transfemoral level[20]. None of the patients with wound healing complications in combination with the absence of functionally patent popliteal artery fitted successfully with a prosthesis. It seems that such patients should undergo early above-knee reamputation in order to facilitate prosthetic rehabilitation instead of preserving below-knee amputation stump.

Association of hypertension, smoking, diabetes and cardiovascular diseases with PAOD has been widely investigated and documented[21]. Walking with prosthesis is energy demanding, and higher amputation level demands higher energy consumption[9]. Our research included only patients having undergone TTA who require minimally higher energy consumption compared to healthy persons for walk at self-selected speed. Cardiovascular requirements in these circumstances are low and that could be the reason why cardiac comorbidity was not a significant predictor of the ability to walk with prosthesis. Patients with DM reach up to 40 times higher incidence of lower limb amputations[22]. In these patients, the healing process is challenged by intrinsic factors such as neuropathy, micro- and macrovascular problems, as well as extrinsic factors such as wound infection[23]. Some authors found that diabetes was significantly associated with poor clinical outcomes after TTA[17]. In addition, patients who undergo lower limb amputation due to vascular disease have poorer walking potential than those with traumatic amputation[19]. However, DM was not a significant prediction factor in the present model. Smokers with DM are more likely to develop vascular disease and therefore have a higher risk of potential lower limb amputation[21]. However, smoking was not a significant predictor in our model. Most patients were fitted with a prothesis in more than 90 days after the amputation. Although this period was longer than some authors found as optimal[24], this variable was not a significant predictor of successful prosthetic rehabilitation. One of the reasons could be high correlation with stump complications, the variable which was a significant predictor of successful prosthetic rehabilitation. Additional subanalysis of the subgroups showed no significant factors predicting if prosthetic rehabilitation would be accomplished within 90 days or more, but these results are not shown.

Phantom limb pain was present in almost half of our patients, which was similar to the findings reported by other authors[25]. The presence of phantom limb pain in our patients did not affect the success of prosthetic rehabilitation. The reason for this could be the duration of phantom limb pain. In communication with our patients we realized that most of them had phantom limb pain for a short period of time.

Mortality after TTA within the first 30 days after amputation was 3.3%, which is in agreement with literature data where mortality ranges from 0.9% to 14.1%[9]. In our study, mortality was up to 18% during the follow-up period of 12 months after amputation. According to the literature, the annual risk of fatal outcome after BKA is even higher than 25%[26]. Death was associated with failed prosthetic use (nine of the deceased patients had not been successfully fitted with a prosthesis during rehabilitation), which could be attributed to the accumulation of comorbidities and complications in such patients, and at the same time the absence of timely mobilization. This study did not analyze the effect of individual factors on fatal outcome after amputation. To accurately estimate the full percentage of successful prosthetic rehabilitation in all patients after TTA, we also included patients with fatal outcome during the 12-month follow-up period. Of those eleven patients, only two were successfully fitted with a prostheses, but unfortunately, fatal outcome occurred in the 10th and 11th month after amputation, respectively.

Some limitations warrant further consideration, and a major limitation was a relatively small number of patients. Secondly, amputations and prosthetic rehabilitation were performed by various physicians, which could put the reliability of these treatments in question. Thirdly, we did not collect data on cognitive and social factors, which could influence functional outcome in these patients.

Conclusion

The main purpose of patient management after amputation is to maintain the quality of life and to reduce the number of complications. Good general condition of the patient and sustained patency of popliteal artery reliably lead to clinical improvement and realization of the full capacity of rehabilitation after below-knee amputation.

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Sažetak

PREDIKTIVNI ČIMBENICI ZA USPJEŠNU PROTETSKU REHABILITACIJU NAKON VASKULARNE TRANSTIBIJALNE AMPUTACIJE

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Amputacija donjih ekstremiteta vrlo je česta amputacija, a uspješna protetska rehabilitacija je poželjan ishod. Cilj ovog istraživanja bio je utvrditi koji čimbenici utječu na uspjeh protetske rehabilitacije nakon transtibijalne vaskularne amputacije. U studiju je uključen 61 bolesnik podvrgnut transtibijalnoj amputaciji (srednja dob 64,2±10,4 godine; 50 (82%) muškaraca). Bolesnici koji su nakon programa rehabilitacije mogli prijeći najmanje 45 metara bez pomagala ili sa samo jednim štapom za hodanje svrstani su u skupinu s uspješnom protetskom rehabilitacijom. Kao prediktivne varijable primijenili smo dob, spol, subolesti, prohodnost poplitealne arterije, komplikacije zacjeljivanja rana i prisutnost fantomske boli udova. Multivarijatna logistička regresijska analiza korištena je za utvrđivanje prediktivnih čimbenika uspješne protetske rehabilitacije. Model je obuhvaćao sve varijable koje su objašnjavale do 59,8% varijance, međutim, samo su dob, nepostojanje funkcionalne prohodnosti poplitealne arterije i ugroženo zacjeljivanje rana dali značajan doprinos modelu. U zaključku, dobro opće stanje bolesnika i trajna prohodnost poplitealne arterije pouzdano dovode do kliničkog poboljšanja i ostvarenja punog kapaciteta rehabilitacije nakon potkoljenske amputacije.

Ključne riječi: *Amputacija, transtibijalna; Donji ekstremitet; Rehabilitacija, protetska*