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Factors predicting rehabilitation outcome in patients after unilateral transtibial amputation due to peripheral vascular disease

Prediktivni faktori ishoda rehabilitacije kod bolesnika posle jednostrane transtibijalne amputacije zbog periferne vaskularne bolesti

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Abstract

Background/Aim. The primary rehabilitation in the prosthetic phase after amputation of lower extremities is of great importance for the improvement of the activities of daily living (ADLs) of persons with amputation and their successful social reintegration. The aim of this study was to examine the influence of independent predictors (age, gender, duration of rehabilitation, time between the amputation and the mounting of the prosthesis) on the success of the primary rehabilitation in the prosthetic phase after amputation of lower extremities. **Methods.** This retrospective clinical study included patients who underwent the primary rehabilitation in the prosthetic phase at the Institute for Physical Medicine and Rehabilitation "Dr Miroslav Zotović", Banja Luka, in 2015. A total of 75 patients with unilateral transtibial amputation were included. Etiologically, these transtibial amputations occurred as a consequence of vascular complications of diabetes mellitus or peripheral occlusive arterial disease. Evaluation of the success of rehabilitation was performed at the end of the primary rehabilitation in the prosthetic phase and 3 months after the end of the treatment by means of K-levels classification system and Locomotor Capabilities Index (LCI) scale. Depending on the distribution of data, univariate and multivariate multiple regression analysis, *post hoc* Mann-Whitney test, Spearman's correlation coefficient and Wilcoxon test were used for statistical analysis. Statistical significance of the found differences was set at $p < 0.05$. **Results.** A total of 75 patients, 55 (73.33%) men and 20 (26.67%) women, were included in this clinical trial. Average age of all participants was 63.5 ± 9.06 years, 61.8 ± 9.34 years for males and 68.1 ± 6.4 for females ($p < 0.01$). Average duration of rehabilitation was 27.69 ± 7.39 days in men and 33.9 ± 6.89 days in women ($p < 0.01$). Male patients had better functional results compared to females obtained by all analysed outcome measures ($p < 0.01$). Younger patients achieved better results, with the degree of statistical significance ranging between $p < 0.05$ and $p < 0.001$. The time from the amputation to the mounting of prosthesis and the duration of rehabilitation had no influence on the rehabilitation outcome. **Conclusion.** The present study identified age and gender of patients as relevant independent predictors of the success of rehabilitation. Although it was initially expected, this clinical trial did not prove the importance of the time from the amputation to the start of the primary rehabilitation in the prosthetic phase. In the future research other independent predictive factors, such as comorbidities, first and foremost cardiovascular diseases, medication, laboratory parameters and mental status, should be taken into account.

Key words:
amputees; peripheral vascular diseases; prostheses and implants; prognosis; rehabilitation; treatment outcome.

Apstrakt

Uvod/Cilj. Primarna protetička rehabilitacija posle amputacije donjih ekstremiteta ima izuzetan značaj za poboljšanje samostalnosti u aktivnostima svakodnevnog života osoba sa amputacijom i za njihovu uspešnu društvenu reintegraciju. Cilj rada bio je da se ispita uticaj nezavisnih prediktivnih faktora (pol, starost, dužina trajanja rehabilitacije, dužina čekanja na početak primarne protetičke rehabilitacije) na uspešnost primarne protetičke rehabilitacije posle amputacije donjih ekstremiteta. **Metode.** Ovom retrospektivnom studijom obuhvaćeni su bolesnici koji su uspešno završili primarnu protetičku rehabilitaciju u Zavodu za fizikalnu medicinu i rehabilitaciju „Dr Miroslav Zotović“, Banja Luka, u 2015. godini. U studiju je bilo uključeno 75 bolesnika sa jednostranim transtibijalnim amputacijama. Etiološki,

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radilo se o potkolenim amputacijama nastalim kao posledica vaskularnih komplikacija dijabetes melitusa ili periferne okluzivne arterijske bolesti. Procena uspešnosti primarne protetičke rehabilitacije vršena je na otpustu (po završetku rehabilitacije) i na kontroli, tri meseca posle protetisanja, a kao mere uspešnosti korišćeni su K-nivoi funkcionalnog klasifikacionog sistema i *Locomotor Capabilites Index* (LCI) skala. Shodno distribuciji podataka izvršene su odgovarajuće statističke analize: univarijantna i multivarijantna multipla regresiona analiza, *post hoc* Mann-Whitney test, Spearmanov koeficijent korelacije i Wilcoxonov test. Nivo statističke značajnosti nađenih razlika utvrđen je za verovatnoću $p < 0,05$. **Rezultati.** Studijom je obuhvaćeno 75 bolesnika, 55 (73,33%) muškaraca i 20 (26,67%) žena, prosečne starosti 63,5 ± 9,06 godina. Prosečna starost bolesnika muškog pola iznosila je 61,8 godina, a bolesnika ženskog pola 68,1 godinu ($p < 0,01$). Prosečno trajanje rehabilitacije kod muškaraca iznosilo je 27,69 dana, a kod žena 33,9 dana ($p < 0,01$). Bolesnici muškog pola ostvarili su bolje funkcionalne rezultate, u odnosu na žene, kroz sve analizirane merne instrumente ($p < 0,01$). Mlađi bolesnici ostvarili su bolje rezultate, a utvrđena je statistička značajnost u rasponu od $p < 0,05$ do $p < 0,001$. Analizirana uspešnost rehabilitacije posmatrana kroz faktore vremena početka protetisanja u odnosu na amputaciju, kao i trajanje rehabilitacije nisu pokazali statističku značajnost. **Zaključak.** Studija je identifikovala pol i starost kao relevantne nezavisne prediktore uspešnosti protetičke rehabilitacije. Iako je bilo očekivano, ova studija nije pokazala značaj koji ima vreme od amputacije do započinjanja primarne protetičke rehabilitacije. U narednim istraživanjima treba uzeti u obzir i uticaj drugih nezavisnih prediktivnih faktora kao što su pridružene bolesti, pre svega kardiovaskularna oboljenja, medikamentna terapija, laboratorijski parametri i mentalni status.

Ključne reči:
amputacija; krvni sudovi, periferni, bolesti; proteze i implantati; prognoza; rehabilitacija; lečenje, ishod.

Introduction

The primary rehabilitation in the prosthetic phase, as part of the rehabilitation medicine, is not sufficiently present in Bosnia and Herzegovina. It is a complex treatment, the realization of which is stipulated by the existence of the multi-professional and well-coordinated prosthetic team. This work is based on the experience in prosthetic rehabilitation of the personnel of the Institute for Physical Medicine and Rehabilitation "Dr Miroslav Zotović" in the City of Banja Luka, capital of Republic of Srpska, Bosnia and Herzegovina. The Institute is a referral tertiary institution that performs the primary rehabilitation in the prosthetic phase in patients after amputation of lower extremities in Republic of Srpska, the population of which is estimated at 1.5 million. Diabetes mellitus with its late complications, including the complications in peripheral blood vessels in the lower extremities, as well as the peripheral occlusive arterial disease (POAD), are main etiological causes of amputations, which was clearly confirmed in this investigation, and which is also corroborated by the world statistical data [1–3]. Besides, our experience, as well as some international studies [4, 5], show that amputations are more frequent among the male diabetic patients.

Adequate estimate of the prosthetic potential and influence of the analysed independent predictive factors (gender, age, time after start of prosthetic rehabilitation after amputation and the duration of the primary rehabilitation in the prosthetic phase) is very important for the outcome of the prosthetic management of patients. Besides, existence of the adequate outcome measures is necessary for the evaluation of success of the primary rehabilitation in the prosthetic phase.

This is the first clinical trial in the Republic of Srpska to analyse prosthetic rehabilitation as means of medical rehabilitation aimed to improve the quality of this segment of medicine on one hand, but also to enable adequate tracking and comparison of our results and methods with the results in other institutions engaged in prosthetic rehabilitation. Since this study was a retrospective one, we chose the four independent parameters as the ones available in the medical charts of patients, which does not mean that in the future, prospective studies, other independent predictors will not be analysed, too.

Majority of the other studies suggest worse outcome in patients of older age at the moment of the lower limb amputation [6–13]. Similar studies, however, in principle, do not identify patient gender as a relevant determinant of success of the prosthetic rehabilitation process [3, 14]. Minority of studies found different level of mobility between the patient of different gender and different success rates between the two genders – sometimes better results were found in men [15–17], and sometimes in women [18].

There are discrepancies in the current literature regarding the choice of basic instruments that would enable to estimate the rehabilitation potential in the pre-prosthetic phase and to adequately verify the success of the prosthetic rehabilitation. Some of the most frequently used outcome measures used in the evaluation of the patients with amputations are: Time Up and Go; 10 m walk test; 2-min walk test, mobility grades [such as Special Interest Group of Amputee Medicine (SIGAM) and K-levels], Barthel index, Functional Independence Measure (FIM), Locomotor Capabilities Index (LCI) scale, Houghton Scale, Prosthetic Evaluation Questionnaire-Mobility Scale (PEQ-MS) and Amputee Mobility Predictor (AMP) [19].

The aim of this study was to examine the influence of independent predictors (age, gender, duration of rehabilitation, time between the amputation and the mounting of the prosthesis) on the success of the primary rehabilitation in the prosthetic phase after amputation of lower extremities.

Methods

This was a retrospective clinical study including the patients underwent the primary rehabilitation in the prosthetic phase at the Institute for Physical Medicine and Rehabilitation

"Dr Miroslav Zotović", Banja Luka, Bosnia and Herzegovina, in 2015. A total of 75 patients of both genders were included.

Inclusion criteria were: patients of both genders with unilateral transtibial amputations caused by peripheral vascular disease as late complications of diabetes mellitus and POAD. Non-inclusion criteria were: patients in whom amputations were performed due to malignant diseases, injuries, patients with bilateral transtibial amputations, patients with transfemoral amputations and patients without adequate prosthetic potential.

All the patients signed the informed consent at the beginning of rehabilitation, in a form of a general document consenting to permit use of their medical data for the purpose of research. This is the routine procedure for all the admitted patients in the Institute and not the concrete study-oriented document, although it covered the present study, too. The primary rehabilitation in the prosthetic phase programme was not time-limited; each patient was treated for as long as the prosthetic team saw fit. Patients after amputation performed in the regional general hospitals or clinical centres received an information to report to the Institute after their sutures had been removed and following the complete healing of their postoperative wounds at the amputated limb. Our health insurance system cannot allow for all the patients to be directly transferred to our Institute – hence the wide range of times elapsing between the discharge after amputation and admission at the Institute.

Evaluation of the success of rehabilitation was at the end of the primary rehabilitation in the prosthetic phase and 3 months after the end of the treatment with K-levels classification system and LCI scale. LCI at discharge and on the control examination was not performed as interview; it was tested through the requested activities and it was performed by the same therapist at discharge and on the control examination in order to eliminate subjectivity.

K-levels classification system was developed in the USA in 1995 by the Medicare programme, as a functional classification system that makes a triage of all patients in one of the five levels of mobility, depending on their functional status. Marks were from 0 to 4, with higher mark meaning better patient functionality [20]. Use of K-levels classification system during the study enabled the monitoring of the mobility level of the patients without prosthesis, with prosthesis at the end of the prosthetic rehabilitation and during the control examination 3 months following the end of the treatment.

LCI scale consists of 14 questions, each question is scored on scale from 0 to 4. The questions are divided into two groups. Each group consists of 7 questions, the first covering the basic activities and the second one covering the advanced activities [21]. Maximum score, for basic and advanced activities alike is 28 points, depending on the performance of the tested activities.

Review of the clinical studies addressing the outcome analysis of prosthetic rehabilitation appraises the LCI scale as content-consistent, reliable during testing and re-testing, which recommends the test for clinical use and its usage as an investigational tool [14].

The calculated descriptive statistical parameters included mean value ± standard deviation (SD) as well as minimal and maximal values.

Based on the distribution of the obtained data that was checked by the Kolmogorov-Smirnov test, adequate statistical analysis was performed with Mann-Whitney and Wilcoxon test. Influence of certain predictors on the values of the used outcome measures at discharge was checked by means of the univariate and multivariate multiple regression analysis.

Statistical significance of the found differences was set at $p < 0.05$. Complete statistical analysis of the data was performed by use of the commercial statistical software SPSS Statistics 18.

Results

A total of 75 patients, 55 (73.33%) men and 20 (26.67%) women, with average age of 63.51 ± 9.06 years, were enrolled in this study. Average age of male and female patients was 61.84 ± 9.34 years and 68.10 ± 6.40 years, respectively. Average time from amputation to mounting of the prosthesis was 5.15 ± 2.08 months (range 2–11 months), (5.05 ± 2.24 months for men and 5.40 ± 1.60 month for women) while the average duration of the rehabilitation was 29.35 ± 7.68 days, range 11–53 days (27.69 ± 7.31 days for men and 33.90 ± 6.89 days for women). Duration of rehabilitation was significantly longer in women than in men ($p < 0.01$) and women were significantly older ($p < 0.01$).

A significant difference between the genders was found for all the outcome measures at discharge, with all parameters being better in men than in women ($p < 0.01$ to $p < 0.001$) and also a significant difference among men between the results obtained at the control and at discharge. In women the same could be applied for LCI basic and advanced activities, while no significant difference could be found regarding the K level values (Figure 1).

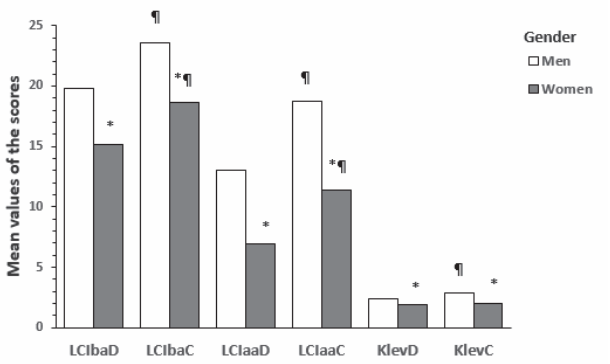

Fig. 1 – Mean values of the scores at discharge and at the control examination in patients with transtibial amputation. LCI – Locomotor Capabilities Index; LCIbaD – LCI basic activities at discharge; LCIbaC – LCI basic activities at control; LCIaaD – LCI advanced activities at discharge; LCIaaC – LCI advanced activities at control; KlevD – K-levels at discharge; KlevC – K-levels at the control examination.
***$p < 0.01$ – difference between mean values of the outcome measures in women compared to men (Mann-Whitney test).**
¶$p < 0.01$ – difference between mean values of the outcome measures at the control examination compared to the corresponding discharge values (Wilcoxon test).

Table 1
Summary of univariate/multivariate multiple regression analyses with the Locomotor Capabilities Index (LCI) activities at discharge as dependent variable

Variables	Standardized coefficients β	*t*-value	*p*
Basic			
Univariate analyses			
gender	-0.519	5.186	0.001
age	-0.376	3.472	0.001
time (amputation-prosthesis)	-0.044	0.377	0.708
duration of rehabilitation	-0.232	2.040	0.045
Multivariate analyses			
gender	-0.440	4.067	0.001
age	-0.237	2.282	0.025
duration of rehabilitation	-0.018	0.166	0.868
Advanced			
Univariate analyses			
gender	-0.477	4.633	0.001
age	-0.354	3.232	0.002
time (amputation-prosthesis)	-0.003	0.022	0.983
duration of rehabilitation	-0.169	1.466	0.147
Multivariate analyses			
gender	-0.406	3.850	0.001
age	-0.229	2.176	0.033

Basic/advanced – influence of independent variables on LCI basic/advanced activities.

Table 2
Summary of univariate and multivariate multiple regression analyses with the K-levels at discharge as dependent variable

Variables	Standardized coefficients β	*t*-value	*p*
Univariate analysis			
gender	-0.369	-3.388	0.001
age	-0.404	-3.769	0.001
time (amputation-prosthesis)	-0.074	-0.634	0.528
duration of rehabilitation	-0.190	-1.650	0.103
Multivariate analysis			
gender	-0.270	-2.481	0.015
age	-0.321	-2.947	0.004

The influence of important demographic and clinical parametres as independent variables on values of the LCI basic activities was determined at discharge from the hospital by means of the univariate and multiple regression analyses (Table 1).

Among the parametres investigated, the important factors were gender, age and duration of rehabilitation. Time from amputation to mounting of the prosthesis was not a significant independent variable (Table 1).

The mutual influence and importance of the individually significant parameters, analysed together, on the values of the LCI basic activities was analysed by the multivariate multiple regression analysis (Table 1).

Based on the multivariate regression analysis, gender and age remained significant predictors of the LCI basic activities values, while the duration of rehabilitation lost importance in interaction with the gender and age (Table 1).

Gender and age were defined as important predictors for the LCI advanced activities at discharge (Table 1).

Gender and age were defined as significant predictors of K-levels at discharge, too (Table 2).

A negative, highly significant correlation was found between the age and the values of all the used outcome measures. Older age of patients was associated with smaller values of the outcome measures at discharge ($p < 0.001$) (Table 3).

Table 3
Correlation parameters of LCIbaD, LCIaaD and KlevD with patient's age

Score	*ρ*	*p*
LCIbaD	-0.448	< 0.001
LCIaaD	-0.408	< 0.001
KlevD	-0.404	< 0.001

LCI – Locomotor Capabilities Index;
LCIbaD – LCI basic activities at discharge;
LCIaaD – LCI advanced activities at discharge;
KlevD – K-levels at discharge;
***p* – Spearman's correlation coefficient.**

Discussion

In this study the influence of several factors as predictors of the outcome of the prosthetic rehabilitation were analysed: patient age, gender, time between the amputation and the mounting of the prosthesis, and duration of rehabilitation. The initial hypothesis that the predictive factors mentioned above have a significant influence on the outcome of rehabilitation was partly confirmed, i.e., for two independent variables – gender and age of patients. However, for the time elapsed from the amputation to the mounting of the prosthesis and the duration of rehabilitation, a significance was not confirmed. A possible explanation of this result would be that the duration of rehabilitation was set on an individual basis and the patients used to finish their treatment after reaching the maximum level of functionality, which was ascertained by the prosthetic team.

Mean age of patients was 63.5 ± 9.06, which is in accordance with the mean age of patients at the Institute during the latest five-year period. It was also confirmed that the success of rehabilitation decreased with age. Better results in younger patients were maintained at the control examination three months after the rehabilitation. The aim of the control testing was to obtain a more adequate estimate of the improvement functionality in activities of daily life.

This study included patients of both genders. Male patients were dominant (73.33%), which is in accordance with the gender structure of lower limb amputees rehabilitated at the Institute over the last five years, as well as with the data from other countries that were available in the literature [3, 22]. Male patients had much better rehabilitation results than the female ones. This difference could be explained by the fact that men were on average 7 years younger than women. This is why better results obtained in men in the present study could be primarily ascribed to their younger age, although the significant levels obtained in the univariate and multivariate multiple regression analyses indicate that gender of patients may be an age-independent predictor of the success of rehabilitation in amputees. This result could have been attributable to the insufficiently large sample that could not allow for a more adequate analysis of the rehabilitation success within the same age groups between male and female patients.

In the present study, time from the amputation to the mounting of the prosthesis and the duration of rehabilitation were analysed as possible predictors of success of the prosthetic rehabilitation. Although some studies report worse results in patients with a delayed start of rehabilitation, the results of the present study did not confirm the importance of time from the amputation to the mounting of the prosthesis. This factor was considered relevant in some clinical trials, which probably indicates the adequate triage of patients during their rehabilitation [23].

The patients were evaluated by LCI scale and K-levels classification system. Relevant publications from this field report on use of a larger number of tests, but warn to the absence of clear guidelines on the choice of the optimal outcome measures [3, 19]. The choice of the outcome measures in the present study was made based on their content, practicability of their implementation and capability of the monitoring of the registered results.

The experience with use of K-levels classification system were according to the other reports that justified its use during the prosthetic rehabilitation [19].

Single use of the K-levels test as a predictor of the success of the prosthetic rehabilitation does not offer the detailed estimate of the capabilities of the patients, which is a consequence of the general character of its content. Some other publications also did not recommend use of the K-levels alone [24]. A more complete estimate of the patient's capabilities would be obtained by a combined use of outcome measures, based on complementarity of their content. The present study confirmed the content consistency and analytical usefulness of the LCI scale in the continuous follow-up of the monitored results. It makes the LCI scale an adequate outcome measure during the rehabilitation phase with a prosthesis.

A limitation of this research could be a small number of outcome measure used for the evaluation of patients and for this reason in the future research a special attention will be paid to the inclusion of more measurable and mutually complementary outcome measures.

Future studies should also include a larger number of potential predictive factors, since in this study, due to its retrospective nature, we did not have an access to any additional predictors, other than the four ones mentioned above.

Conclusion

Success of the prosthetic rehabilitation is based on the adequate estimation of the rehabilitation potential of patients. Measurement of the success of rehabilitation at the end and at the control examinations is possible by using the adequate outcome measures.

The present study identified age and gender of patients as relevant independent predictors of the success of rehabilitation. Although this study failed to show statistical significance of the time elapsing from the amputation to the start of the primary rehabilitation in the prosthetic phase on the rehabilitation success, this factor should be paid attention in the forthcoming prospective studies. In the future clinical studies other independent predictive factors should also be taken into account, such as comorbidities, first and foremost cardiovascular diseases, medication, laboratory parametres and mental status.

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