ACTA FACULTATIS
MEDICAE NAISSENSIS

UDC:
DOI: 10.5937/afmnai41-46106

Original article

Quality of life of patients with transtibial amputation and different periods of wearing prostheses

Vesna Bokan[1,2]

[1]*Center for Physical Medicine and Rehabilitation, Clinical Centre of Montenegro, Podgorica, Montenegro*
[2]*Faculty of Medicine, University of Montenegro, Podgorica, Montenegro*

SUMMARY

Introduction. Research into patients with lower limb amputation (LLA) reflects the growing emphasis on quality of life (QoL) and its increasing use as an outcome measure. The aim of this study was to show which aspects of QoL are related to the duration of wearing a prosthesis in patients with transtibial amputation (TTA).
Methods. The study sample comprised 40 patients who used prosthesis for 1 - 3year (group A), 4 - 7 years (group B) and > 8 years (group C). All patients completed Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES-R).
Results. Prosthesis wearing history was significant differently between groups: group A (2.2 ± 0.7 years), group B (5.5 ± 1.3 years) and group C (22.9 ± 13.6 years), $p < 0.001$. Patients in group B were significantly ($p < 0.05$) older compared to patients in group C, displayed significantly ($p < 0.05$) lower rate of employment and significantly ($p < 0.05$) longer duration of diabetes mellitus. Patients in group C displayed significantly ($p = 0.005$) lower rate of diabetes mellitus. TAPES-R showed that social adjustment was significantly lower ($p < 0.05$) in patients in group C compared to patients in group A, (3.14 ± 0.46 vs. 3.55 ± 0.41).
Conclusion. Although patients with TTA showed a good QoL the group with a long history of wearing a prosthesis differed significantly in social adjustment compared to patients with a short period of wearing a prosthesis. The age and etiology of amputation differed significantly between groups.

Keywords: **quality of life, transtibial amputation, prosthesis wearing**

Corresponding author:
Vesna Bokan
e-mail: vesnabokanmir@gmail.me

INTRODUCTION

The primary goals for patients with lower limb amputations (LLA) are to ambulate with a prosthesis and perform activities of daily living (1). The adjustment process after an amputation takes a long time, and includes physical and psychological adaptation to the loss of part of the limb and the use of a prosthesis (2). Restoring functional mobility in people with LLA has a positive effect on quality of life (QoL) and satisfaction (2, 3, 4). Greater use of the prosthesis during the day has a important impact on the level of independence and functionality in patients with LLA (4 - 7). In accordance with the above, patients with below-knee amputations have greater mobility and a better quality of life than patients with above-knee amputations (4). Adaptation to the prosthesis, satisfaction with the prosthesis and psychosocial well-being influence the patient's perception of QoL in patients with LLA (2, 3).

Currently, there is a growing need to examine the quality of life in people with LLA as a measure of the outcome of rehabilitation (6). Previous studies have noted an improvement in quality of life if patients live longer with an amputation (5). By analyzing the impact of the prosthesis on the patient's participation in activities, mobility, and psychological functioning, information on the quality of life can be obtained in this population group (7, 8). A relatively limited number of studies (5), focused on the analysis of the period (years) of use of the prosthesis as a factor affecting the QoL in amputees.

The aim of this study was to show which aspects of QoL are related to the duration of wearing a prosthesis in patients with transtibial amputation (TTA).

MATERIAL AND METHODS

Study design and sample

This is a cross-sectional study, conducted between March 2023 and July 2023 at Clinical Centre of Montenegro. We searched the electronic medical records of a local orthopedic company for patients with TTA who had an appointment for making a new prosthesis or correction of an existing prosthesis between January 1st, 2022 and March 1st, 2023. Forthy-five patients met our study's inclusion criteria, and forty of them consented to participate in this study. Inclusion criteria were patients having a unilateral transtibial amputation, use of prosthesis for more than 12 months, ability to walk with the help of prosthesis with or without aids, and age between 18 and 75 years. Patients were excluded if they had inadequate cognitive function, or they were nonambulatory for reasons related to complications of diabetes, musculoskeletal and neurological disorders.

Before participating in the study, all participants were informed about the purpose of the study and signed informed consent forms approved by institutional Ethics committee.

Sociodemographic and amputee-related characteristics

Out of 40 patients who were successfully fitted and ambulatory with a prosthesis at least twelve months, were included in the study. Prostheses for transtibial amputation were PTB (patellar tendon bearing) with dynamic feet. According to the index prosthesis wearing history patients were divided into three groups: a) Group A including 13 patients with short prosthesis wearing history from 1 to 3 years, b) Group B including 11 patients with medium prosthesis wearing history from 4 to 7 years, and c) Group C including 16 patients with long prosthesis wearing history for more than 8 years.

In Group A, cause of amputation was more commonly related to diabetes mellitus (8 patients) than trauma (3 patients). Peripheral arterial desease (PAD) was the cause of amputation in two patients. In Group B diabetes mellitus (DM) was the cause of amputation in most cases (9 patients), trauma in two patients. In Group C, the amputation was caused by trauma in the majority of patients (12 patients), DM in six patients.

Measurement instrument

The Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES-R)

We measured prosthetic function and satisfaction using the TAPES-R (8, 9). It includes 3 scales: a) psychosocial adjustment (general, social, and limitation adjustment) with a four-point rating scale (strongly agree, agree, disagree, and strongly disagree), b) activity restriction based on ten items

with a three-point rating scale (limited a lot, limited a little, and not at all limited), c) satisfaction with the prosthesis (aesthetically and functionally) using a 3-point rating scale (dissatisfied, satisfied, and very satisfied). A single overall index of satisfaction with the prosthesis was calculated using the Numerical Rating Scale (NRS) ranging from 0 to 10 ("not at all satisfied" and "very satisfied"). The TAPES-R contains a second section (Part II) that looks at experience of phantom limb pain and residual limb pain.

Statistical analysis

Data analyses were performed using IBM SPSS (version 25; IBM Corp.). Shapiro–Wilk tests indicated that diabetes mellitus duration (years) data and most items from TAPES-R (except social adjustement, adjustment to limitation, and activity restriction) were not normally distributed and therefore required nonparametric analyses. Chi-square tests were used to analyze differences in distribution of categorical variables [sex (male/female), employment status (yes/no), marital status (married/unmarried), residential location (urban/rural), diabetes mellitus dignosis (yes/no), stump ulcer (yes/no), peripheral arthery disease (yes/no), dominant side amputation (yes/no) and phantom limb pain (yes/no)] between groups. Post hoc procedures were conducted for Chi-square tests where appropriate, while adjusting for Type I error ($p < 0.017$). While a preliminary correlation analyses revealed a possible confounding influence ($p < 0.05$) of BMI on some items of TAPES-R (general adjustment, social adjustement, adjustment to limitation, activity restriction and overall satisfaction with prosthesis), this confouding influence was not controled as a covariate since there was no significant difference in BMI between groups. On other hand, no confounding influence of patients characteristics was observed on the remaining TAPES-R parameters. In this regard, differences between groups in TAPES-R were compared using the Kruskal Wallis test for non-normally distributed data, or one-way analyses of variance for normally distirbuted data.

RESULTS

General characteristics

General characteristics for patients with short, medium, and long prosthesis wearing history are presented in Table 1. Prosthesis wearing history was significant differently between groups: group A (2.2

Table 1. *General characteristics (mean ± standard deviation) in patients with short (Group A), medium (Group B) and long (Group C) prosthesis wearing history*

General characteristics	Group A (n=11)	Group B (n=13)	Group C (n=16)	P
Age (yr)	62.7 ± 7.5	66.8 ± 5.9	58.0 ± 9.3	**0.024**
Body mass (kg)	96.6 ± 13.7	83.3 ± 10.5	80.5 ± 12.5	**0.004**
Height (cm)	180.3 ± 10.6	175.2 ± 7.1	176.42 ± 7.3	0.286
Body mass index	27.7 ± 3.8	28.2 ± 5.0	26.9 ± 3.1	0.672
Sex (Male/Female)	10/3	8/3	12/4	0.972
Employment status (Yes/No)	5/8	0/11	7/9	**0.037**
Marital status (Married, Unmarried)	9/4	8/3	11/5	0.973
Residential location (Urban/Rural)	10/3	10/1	11/5	0.399
Diabetes mellitus diagnosis (Yes/No)	8/5	9/2	4/12	**0.011**
Diabetes mellitus duration (yr)*	6.5 ± 6.6	13.1 ± 10.4	3.8 ± 7.5	**0.025**
Glycosylated hemoglobin	6.3 ± 0.5	6.4 ± 0.8	7.4 ± 0.4	0.104
Stump ulcer (Yes/No)	1/12	2/9	0/16	0.211
Peripheral artherial disease (Yes/No)	2/11	0/11	2/14	0.416
Dominant side (Yes/No)	9/4	4/7	7/9	0.224
Prosthesis wearing history (yr)	2.2 ± 0.7	5.5 ± 1.3	22.9 ± 13.6	**< 0.001**

Note: bolded p value indicates statistically significant differences at p <0.05, * data analyzed using Kruskal Wallis test

± 0.7 years), group B (5.5 ± 1.3 years and group C (22.9 ± 13.6 years), p < 0.001. Patients in group B were significantly (p = 0.022) older compared to patients in group C, 66.8 ± 5.9 vs. 58.0 ± 9.3 years. Body mass was significantly higher in patients with in group A compared to patients with patients in group B and (96.6 ± 13.7 vs. 83.3 ± 10.5, p < 0.05) and group C (96.6 ± 13.7 vs. 80.5 ± 12.5, p < 0.05) . Patients in group B displayed significantly (p < 0.05) lower rate of employment compared to patients with group A and group C. Patients in group C displayed significantly (p = 0.005) lower rate of diabetes mellitus diagnosis compared to patients with group A and group B. Diabetes mellitus duration (years) was significantly (p < 0.05) longer in patients in group B compared to patients in group C (13.1 ± 10.4 vs. 3.8 ± 7.5 years).

Trinity Amputation and Prosthesis Scales-Revised

The mean ± SD for each item of the Trinity Amputation and Prosthesis Scales-Revised (TAPES-R) are presented in Table 2. Social adjustment was

Table 2. *Differences between groups in Trinity Amputation and Prosthesis Scales-Revised (TAPES-R)*

TAPES-R	Group A (n = 13)	Group B (n = 11)	Group C (n = 16)	P
PART I				
Psychological adjustment				
General adjustment*	3.55 ± 0.45	3.53 ± 0.40	3.36 ± 0.48	0.482
Social adjustement	3.55 ± 0.41	3.42 ± 0.45	3.14 ± 0.46	**0.045**
Adjustment to limitation	3.15 ± 0.47	2.96 ± 0.48	3.09 ± 0.46	0.599
Activity restriction				
Activity restrition	0.87 ± 0.47	0.96 ± 0.48	0.89 ± 0.37	0.856
Satisfaction with prosthesis				
Aesthetic satisfaction*	8.54 ± 0.66	8.09 ± 0.83	8.13 ± 0.81	0.210
Functional satisfaction*	10.69 ± 2.21	12.45 ± 2.11	11.19 ± 2.37	0.075
Overall satisfaction with prosthesis*	7.77 ± 1.64	8.72 ± 1.55	8.25 ± 1.34	0.227
PART II				
General health*	3.85 ± 0.80	3.45 ± 0.93	3.38 ± 0.87	0.340
Prothesis wearing time per day (h)*	21.23 ± 6.81	16.36 ± 8.80	15.31 ± 8.04	0.172
Phantom pain				
Phantom limb pain (Yes/No)	7/6	7/4	11/5	0.709
Phantom pain per week (n)*	4.00 ± 2.31	4.14 ± 3.13	3.81 ± 0.87	0.676
Average length of episode pain*	3.29 ± 1.38	2.28 ± 0.76	2.63 ± 0.50	0.153
Average level of phantom pain*	2.29 ± 1.38	2.43 ± 0.79	2.45 ± 0.52	0.595
Lifestyle interference*	2.29 ± 1.28	2.43 ± 0.79	2.36 ± 0.50	0.635

Note: * data analyzed using Kruskal Wallis test

significantly lower (p < 0.05) in patients in group C compared to patients in group A, 3.14 ± 0.46 vs. 3.55 ± 0.41. Non-significant differences were observed between groups in other items of the TAPES-R.

DISCUSSION

The main findings of this study are that there are no significant differences in the quality of life among users of TT prostheses, which were assessed with the TAPES-R instrument, across the three categories of years reflecting time since amputation, with the exception of social adjustment. Also, the mean scores of TAPES-R suggest that the patients have reached their almost the best possible outcome in first three year since amputation.

In our study, patient in these three groups were significantly different in prosthesis wearing history. In Asano et al. (5) study, the period since amputation was categorized as: 0 - 3, 4-13 and 14+

years. Previus study (5) suggested that there is a difference in reported QoL across the three categories of years reflecting time since amputation. Fortington et al. concluded (6), that domain scores of QoL differed little from the population norm values after 6 – 18 months, with the exception of physical function.

Our patients with short prosthesis wearing history (group A) succesfully used prosthesis for 2.2 ± 0.7 years, mean age 62.7 ± 7.5 years, with mixed etilogy of amputation. The majority of patients were married, lived in an urban location and most of them were employed. Prosthesis wearing history in our study correlated with time points in other studies (6, 10). By evaluating values of TAPES-R, the average score for the general adjustment was 3.55 ± 0.45 and for social adjustment was 3.55 ± 0.41, with the maximum allowed being 4.0. Lower positive adjusment was on the Adjustment to limitation subscale (3.15 ± 0.47). No statistically significant differences were observed when comparing the adjustment scores to group B and group C, except for the social adjustment in group C (3.55 ± 0.41 vs. 3.14 ± 0.46). In multi-variable regression analysis of predictors of Qol, Asano et al. (5) categorized long period of using prosthesis as +14 years, and found that social support and social activity participation are important predictors of subjects' perceived QoL. Patients in group C, in our study, used prosthesis for 22.9 ± 13.6 years, with lower score for the social adjustment than patients in group A, and Asano et al. (5) suggested to test „the response shift hypothesis“ in patients who had their amputation for a longer period of time.

Patients with medium prosthesis wearing history (group B) wore the prosthesis for 5.5 ± 1.3 years. They were significantly older than group C (66.8 ± 5.9 vs. 58.0 ± 9.3 years). In this group, amputation were releated to vascular etiology with DM, in accordance with previous literature (1, 11). All patients in group B were unemployed. This suggests that amputation has an impact on employment status. Sinha et al. (12) found similiar results, compared to our respondents, the difference is in age (66.8 ± 5.9 vs. 43.7 ± 15.0 years). In our study, TAPES-R showed positive general adjustment and social adjustment, and lower score for adjustment to limitation (2.96 ± 0.48). The results of our study were in agreement with previous findings (4, 12, 13) which indicating worse men’s ability to deal with the limitation. Another possible explanation is duration of DM (13.1 ± 10.4 years), in acordence with other studies (14, 15).

Patients with long prosthesis wearing history (group C) used prosthesis for 22.9 ± 13.6 years. As mentioned above social adjustment was significantly lower in group C compared to group A. Kizilkurt et al. (16) reported that perceived social support was related to QoL. Patients in this group were youger than patients in group A and trauma were a cause of ampatation.

In the analysis satisfaction with prosthesis we found no significant differences in aesthetic, functional and overall satisfaction with prosthesis between three groups. According to our results overall satisfaction was lower in A group (7.77 ± 1.64). The evaluation of satisfaction with the prosthesis requires the analysis of several different factors (17). In the Baars et al. study (17), higher scores of satisfaction were associated with employment, sex, nonvascular reason for amputation and a longer period of time since amputation. Also, Baars et al. suggested that there is room for improvement in overall satisfaction with the prostheses (17).

We found that some patients suffer from phantom limb pain for years (group C), average level of phantom pain was 2.45 ± 0.52. Greater time since amputation is associated with less phantom pain (18, 19). Other factors such as satisfaction with prostheses, optimism, lower level of amputation, were also mentioned in the studies (18, 19).

In our study, subjects reported relatively high quality of life. Some authors (5, 6) discussed changes in the importance of the QoL domain in different periods of time since the amputation. In the period of wearing a prosthesis for up to 12 months, physical function is more important than in the later period when social adaptation takes precedence. Also, Fortington et al. suggested examining the social aspect in age-specific groups (6) .

The limitations of this study include the small number of patients, which limited the division into multiple time categories according to etiology; mixed cause of amputation; lack elderly person with traumatic amputation. Longitudinal studies are suggested for this population, as this will allow a better description of the variation in quality of life over time.

The practical implications are that our findings supported the claim that TAPES can be used to evaluate quality of life in rehabilitation

practice. Healthcare professionals should understand the importance in long-term support this population group.

CONCLUSION

This study showed that patients experienced a good quality of life after different periods of wearing a transtibial prosthesis. Patients with long prosthesis wearing differed significantly in social adjustment from group with short prosthesis wearing hystory. Different age and etiology of amputation were found in patients with long prosthesis wearing. This finding suggests the imortance of comparing age-specific groups when evaluating specific domains of QoL for prosthesis age wearing-related groups.

References

1. Fajardo-Martos I, Roda O, Zambudio-Periago R, et al. Predicting successful prosthetic rehabilitation in major lower-limb amputation patients: a 15-year retrospective cohort study. Braz J Phys Ther 2018; 22(3):205-14. https://doi.org/10.1016/j.bjpt.2017.08.002

2. Sinha R, Van Den Heuvel WJ. A systematic literature review of quality of life in lower limb amputees. Disabil Rehabil 2011; 33(11):883-99. https://doi.org/10.3109/09638288.2010.514646

3. Webster JB, Hakimi KN, Williams RN, et al. Prosthetic fitting, use, and satisfaction following lower-limb amputation: A prospective study. JRRD 2012; 49(10):1493-504. https://doi.org/10.1682/JRRD.2012.01.0001

4. Matos DR, Naves JF, de Araujo TCCF. Quality of life of patients with lower limb amputation with prostheses. Estudos de Psicologia 2020; 37:e190047. https://doi.org/10.1590/1982-0275202037e190047

5. Asano M, Rushton P, Miller WC, Deathe BA. Predictors of quality of life among individuals who have a lower limb amputation. Prosthet Orthot Int 2008; 32(2):231-43. https://doi.org/10.1080/03093640802024955

6. Fortington LV, Dijkstra PU, Bosmans JC, et al. Change in health-related quality of life in the first 18 months after lower limb amputation: a prospective, longitudinal study. J Rehabil Med 2013; 45(6):587-94. https://doi.org/10.2340/16501977-1146

7. Alessa M, Alkhalaf HA, Alwabari SS, et al. The Psychosocial Impact of Lower Limb Amputation on Patients and Caregivers. Cureus 2022; 14(11):e31248. https://doi.org/10.7759/cureus.31248

8. Gallagher P, Maclachlan M. The Trinity Amputation and Prosthesis Experience Scales and quality of life in people with lower-limb amputation. Arch Phys Med Rehabil 2004; 85(5):730-6. https://doi.org/10.1016/j.apmr.2003.07.009

9. Luthi F, Praz C, Léger B, et al. Cross-cultural adaptation and measurement properties of the

French version of the Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R). PLoS ONE 2020; 15:e0229084 https://doi.org/10.1371/journal.pone.0229084

10. Cox PSL, Williams SKP, Weaver SR. Life after lower extremity amputation in diabetics. West Indian Med J 2011; 60(5):536-40.

11. Nehler MR, Coll JR, Hiatt WR. Functional outcome in a contemporary series of major lower extremity amputations. J Vasc Surg 2003; 38(1):7-14. https://doi.org/10.1016/S0741-5214(03)00092-2

12. Sinha R, van den Heuvel WJA, Arokiasamy P. Factors affecting quality of life in lower limb amputees. Prosthet Orthot Int 2011; 35(1):90-6. https://doi.org/10.1177/0309364610397087

13. Demet K, Martinet N, Guillemin F, et al. Health related quality of life and related factors in 539 persons with amputation of upper and lower limb. Disability and Rehabilitation 2003; 25(9):480-6 https://doi.org/10.1080/0963828031000090434

14. Spasić A, Radovanović RV, Đorđević AC, et al. Quality of life in type 2 diabetic patients. Acta Facultatis Medicae Naissensis 2014; 31(3):193-200. https://doi.org/10.2478/afmnai-2014-0024

15. Quigley M, Dillon MP, Duke EJ. Comparison of quality of life in people with partial foot and transtibial amputation: A pilot study. Prosthet Orthot Int 2016;40(4):467-74. https://doi.org/10.1177/0309364614568414

16. Kizilkurt OK, Kizilkurt T, Gulec MY, et al. Quality of life after lower extremity amputation due to diabetic foot ulcer: the role of prosthesis-related factors, body image, self-esteem, and coping styles. J Psychiatry Neurosci 2020; 33(2):109-19 https://doi.org/10.14744/DAJPNS.2020.00070

17. Baars E, Schrier E, Dijkstra P, et al. Prosthesis satisfaction in lower limb amputees: A systematic review of associated factors and questionnaires. Medicine (Baltimore) 2018; 97(39):e12296. https://doi.org/10.1097/MD.0000000000012296

18. Kaur A, Guan Y. Phantom limb pain: A literature review. Chin J Traumatol 2018; 21(6):366-8. https://doi.org/10.1016/j.cjtee.2018.04.006

19. Horgan O, MacLachlan M. Psychosocial adjustment to lower-limb amputation: a review. Disabil Rehabil 2004; 26(14-15):837-50. https://doi.org/10.1080/09638280410001708869

Article info
Received: August 22, 2023
Revised: October 4, 2023
Accepted: October 10, 2023
Online first: January 25, 2024

Kvalitet života pacijenata sa transtibijalnom amputacijom i različiti periodi nošenja proteze

Vesna Bokan[1,2]

[1]*Centar za fizikalnu medicine I rehabilitaciju, Klinički Centar Crne Gore, Podgorica, Crna Gora*
[2]*Medicinski fakultet, Univerzitet Crne Gore, Ljubljanska bb, 81000, Podgorica, Crna Gora*

SAŽETAK

Uvod. Istraživanje pacijenata sa amputacijom donjih ekstremiteta (LLA) odražava se na sve veće naglašavanje na kvalitet života (KoL) i njegovu sve veću upotrebu kao mere ishoda. Cilj ovog istraživanja bio je da pokaže koji aspekti kvaliteta života su povezani sa trajanjem nošenja proteze kod pacijenata sa transtibijalnom amputacijom (TTA).
Metode. Uzorak studije obuhvatao je 40 pacijenata koji su koristili protezu 1 - 3 godine (grupa A), 4 - 7 godina (grupa B) i > 8 godina (grupa C). Svi pacijenti su kompletirali Triniti skalu za amputaciju i iskustvo sa protezom-revidirana (TAPES-R).
Rezultati. Period nošenja proteza bio je značajno različit između grupa: grupa A (2,2 ± 0,7 godina), grupa B (5,5 ± 1,3 godine) i grupa C (22,9 ± 13,6 godina), p<0,001. Pacijenti u grupi B bili su značajno (p < 0,05) stariji u odnosu na pacijente u grupi C, imali su značajno (p<0,05) nižu stopu zaposlenosti i značajno (p < 0,05) duže trajanje dijabetes melitusa. Pacijenti u grupi C su imali značajno (p = 0,005) nižu stopu dijabetes melitusa. TAPES-R je pokazao da je socijalno prilagođavanje značajno niže (p < 0,05) kod pacijenata u grupi C u poređenju sa pacijentima u grupi A, (3,14 ± 0,46 prema 3,55 ± 0,41).
Zaključak. Iako su pacijenti sa TTA pokazali dobar kvalitet života, grupa sa dugom istorijom nošenja proteze značajno se razlikovala u socijalnom prilagođavanju u poređenju sa pacijentima sa kratkim periodom nošenja proteze. Starost i etiologija amputacije značajno su se razlikovali među grupama.

Ključne reči: kvalitet života, transtibijalna amputacija, nošenje proteza