

IMPACT OF LOWER LIMB AMPUTATION ON FUNCTIONAL STATUS AND QUALITY OF LIFE IN DIABETIC PATIENTS USING PROSTHESIS AN ANALYTICAL CROSS-SECTIONAL STUDY

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Abstract

Background: Diabetes mellitus is a major contributor to lower limb amputation throughout the world. Amputation, particularly in diabetics, has far reaching consequences in terms of daily activity levels and the general quality of life. This research paper explores the impact of lower limb amputations on the state of functioning and quality of life of diabetic patients who have adopted the use of prosthetics.

Material & Methods: An analytical cross-sectional survey was carried out in a period of 6 months at the Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar. It recruited 74 patients who were diabetic and were subjected to major lower limb amputations and had used prosthesis. Functional status was evaluated by locomotor capabilities index-5 (LCI-5) and quality of life was measured through WHOQOL-BREF tool. Independent t-test and Mann Whitney U test were used to test gender-based differences.

Results: Mean age of the participants was 46.81 ± 15.78 (mean $\pm$ SD) years. Among the 74 participants male participants were $n=57$ (77%), and female were $n=17$ (23%). Mean $\pm$ SD score for LCI was 34.54 ± 15.28 , 18.73 ± 6.8 , 15.81 ± 8.9 for total, basic and advanced ADLs locomotion. The mean $\pm$ SD for WHOQOL-BREF were 55.69 ± 8.48 (physical), 56.42 ± 8.34 , 49.74 ± 12.61 , 52.97 ± 8.01 for physical, psychological, social and, environmental domains respectively. For male vs female comparison ($n=17$ each), no statistical difference

was found in functional status ($p>0.05$) parameters and the quality-of-life domains ($p>0.05$).

Conclusion: Diabetic amputation of the lower limb compromises functional independence as well as the quality of life in various domains. These results were the same between both men and women indicating an objective to make rehabilitation gender-neutral, layered in physical functional rehabilitation and psychosocial support.

INTRODUCTION

Diabetes mellitus (DM) is a common metabolic disease that constitutes a major cause of morbidity all over the world especially through its long-term complications. Among them, one of the most severe and life changing is lower extremity amputation (LEA) that is induced mainly by the development of diabetic foot ulcers caused by peripheral neuropathy, ischemia, and poor wound healing (1-3). Diabetes is apportioned in over 85 percent of all lower limb amputations across the globe with an estimated amputation in every 30 seconds taking place in a diabetic patient (4,5). The situation remains particularly severe in Pakistan where the prevalence of diabetes nationally is approximately 14.6% and lower limb complications constitute the significant proportion of the number of disabilities associated with diabetes (6,7). Lower limb amputations, particularly, major ones, i.e., transtibial and transfemoral amputations, cause significant impairment to the walking, working, and social enjoyment of a person. It is also well documented that these physical impairments are formidable factors that in combination with psychological pressure, economic forces, and lessened self-esteem, are measured against a backdrop of decreasing quality of life (QOL) (8,9). It is possible that the use of prosthetic could enhance mobility; however, its success rates usually vary depending on the amputation level, rehabilitation services, and psychosocial support (10). Several studies have already been conducted to explore the effect of LEA in patients, especially in the domain of functional capacity and QOL. Still, results are not consistent. According to some studies, patients in the case of minor amputation (e.g., trans-metatarsal) are enjoying much better functional independence and quality of life than their counterparts with major amputation (11,13). Conversely, three other examinations managed to

detect no statistically significant difference in QOL scores between above and below-knee amputees, implying that age, comorbidities, or support systems may represent more substantial factors (14,15). Another issue is the fact that most of the literature available relies on study of heterogeneous population, where indications of amputation are vastly diverse, caused by trauma, cancer, and vascular diseases. Subsequently, the results of such studies cannot be fully applicable to the life of a diabetic amputee because they usually experience a completely different balance of physiological, functional, and social issues (16,18). In addition, gender disparities on post-amputation are not well known and especially in South Asian contexts where males and females have different social roles, mobility norms and access to expensive care in post-amputation (19,20). Majority of the existing research either lack gender comparison or they are too small to attempt to draw out gender trend analysis.

In the case of Pakistan, there is an exceptionally low evidence base. There is little access to context-specific data concerning the amputation and its consequences on the everyday functionality and general well-being among the diabetic population, especially when the level of amputation varies. The rehabilitation outcomes are also complicated by the culture, inaccessibility to healthcare and low knowledge regarding the use of prosthetics. This knowledge gap limits the process of building evidence-based, inclusive and culturally responsive strategies of rehabilitation. Considering an increasing trend in the diabetes related amputations and the dearth of locally based research, it is imperative to have an idea of how major lower limb amputation affects functional ability and quality of life of diabetic individuals in Pakistan. Also, the results show whether they vary based on gender to implement more effective and fairer clinical

action. The research indicates only diabetic amputees with prostheses under study that specific data on this specific population can be obtained which otherwise is less studied in the general studies of disability.

Although studies have shown the prevalence of amputation as a result of diabetes is very high in Pakistan, there is dearth of literature that examines the extent to which the amputation have influenced functional status and QOL among the local diabetic populations. Studies in the available literature are either hospital based or only examine the physical outcomes, disregarding the social and psychological aspects. To further add on this is that no study has so far given adequate attention to gender comparisons in this particular context with use of validated instruments like LCI-5, and WHOQOL-BREF. Therefore, the study covers a knowledge gap that is of great importance and offers context-sensitive evidence to clinicians, policy-makers, and rehabilitation professionals. This will be useful in determining the functional status and quality of life of diabetic patients with significant amputation of the lower limb with prosthesis and to compare the result in both sexes. The results will not only be able to provide a glimpse of reality surrounding the amputee and aid in the development of a more balanced, comprehensive program of rehabilitation.

Materials and Methods

The was an analytical cross-sectional study set up in six months (April 2021 to August 2021) at the Pakistan institute of Prosthetic and Orthotic Sciences (PIPOS), Peshawar, KP. The sampling technique was purposive and given a population 90 of which a sample size of 74 was selected in accordance with the calculated sample size of Rao soft in their online calculator of about 15 a month over a period of 6 months. The inclusion criteria were participants with a history of diabetes-related major lower limb amputation (defined as any amputation above the ankle), who have a prosthesis of at least six months, over 18 years of age, with cognitive ability, and who were willing to sign the informed consent were the inclusion criteria. The excluded persons were those who underwent amputation related to any condition other than diabetes (e.g. Trauma, malignant), those who were under 18 years, cognitively impaired or declined participation. The study has received ethical approval

by the KMU Research Ethical Committee (REC), and informed written consent was taken after all the participants had been explained of the research objectives and protocols regarding the research secrecy.

The process of collecting data was structured questionnaire and conducted face-to-face by trained personnel. It was performed as a questionnaire with questions on demographic, clinical data, and two well-established assessment measures. The first instrument was the Locomotor Capabilities Index-5 (LCI-5) that is a 14 items assessment tool measuring functional mobility in lower limb amputees. All of them are rated along a 5-point (0-4) scale, attributing higher scores to locomotor capacity. Advanced and basic activities of daily life (ADLs) are measured and the total range of the scale is 0-56. The second administered instrument was the World Health Organization Quality of Life-BREF (WHOQOL-BREF), a tool elaborated by the World Health Organization that assesses the quality of life within four different domains which are physical health, psychological well-being, social relationships and environmental context. The two domains contribute to the total score and the better the score the better quality of life. Analysis of the data was done using SPSS v.25. The respective participant characteristics and outcome variables were summarized by using descriptive statistics to form mean, standard deviation, count and percentages. The Shapiro-Wilk test was used to determine whether the data was normal. LCI Total and LCI Basic scores indicated a normal distribution, but thus Independent Samples t-test was conducted to make the comparison between the two groups: male and female participants. LCI Advanced and the scores of all dimensions of the WHOQOL-BREF failed to conform to a normal distribution, thus Mann-Whitney U test was used. The significance level was set to 0.05. Since gender distribution was not balanced (57 males,17 females), a random sample of 17 males was taken with the help of an online random number generator so it could be possible to compare the groups in an equal way.

Results

A total of 74 diabetic patients who had a major amputation of lower limb with the use of prostheses were included. The average age of study participants

was 46.81 ± 15.78 years. Majority of them were males comprising 57 (77%) as compared to 17 (23%) who were females. Figure 1 represents the gender distribution of the sample size with a majority of the

participants being male respondents this is in agreement with the fact that diabetic complication is more common in the male population in the region.

Table 1 Patients Demographics

Category	Sub-category	Frequency
Age	Mean	46.81 ± 15.78 years
Gender	Male	57 (77%)
	Female	17 (23%)

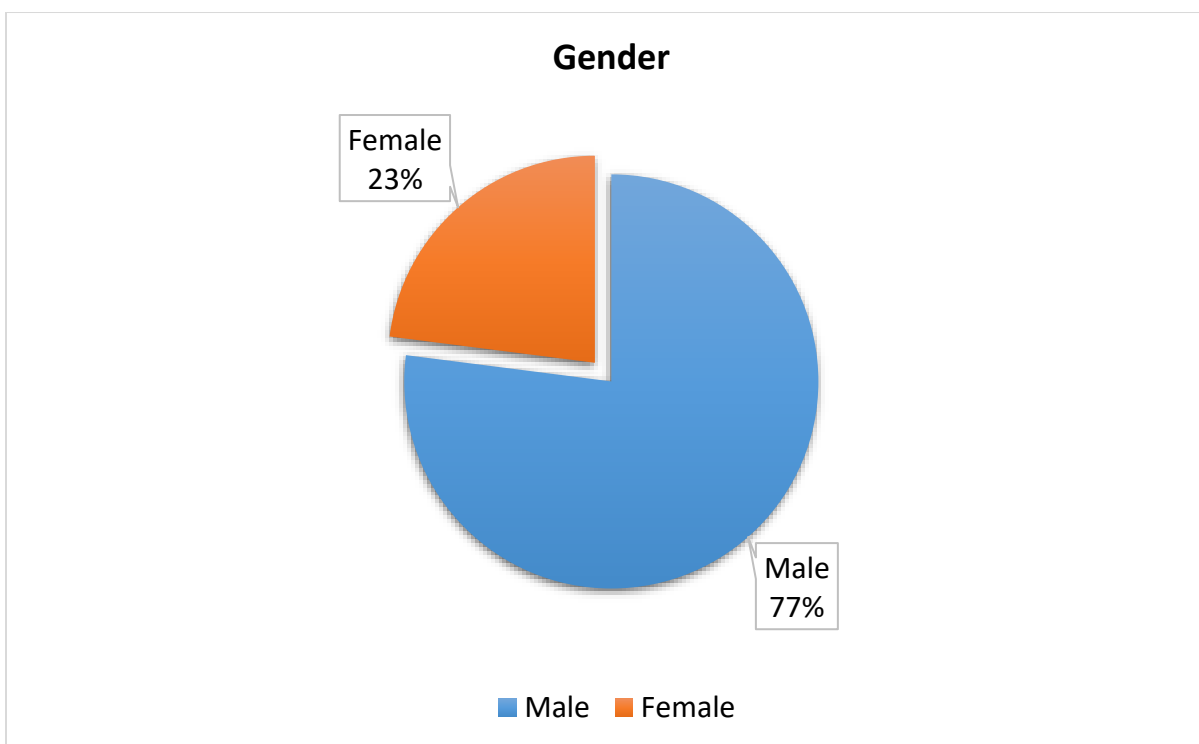


Figure 1 Pie Chart of Patients' Demographics

Locomotor capability The Locomotor Capabilities Index-5 (LCI-5) was used to determine locomotor capability among the participants. The overall mean LCI was 34.54 ± 15.28 , basic activity mean score was 18.73 ± 6.80 and advanced activity mean score was

15.81 ± 8.90 (Table 2). These values show an improvement in simple mobility functions over complex ones which is consistent with common functional constraints identified after amputation.

Table 2 LCI-5 scores for Functional Status

Domain	Mean $\pm$ SD
Total LCI Score	34.54 ± 15.28
Basic ADLs	18.73 ± 6.80
Advanced ADLs	15.81 ± 8.90

The quality of life of the individuals was measured through the WHOQOL-BREF questionnaire. The mean results of the four domains were as follows, the physical health (55.69 ± 8.48), the psychological (56.42 ± 8.34), the social relationships (49.74 ± 12.61), and the environmental factors (52.97 ± 8.01). There were no values above the threshold of 60 and thus, it

can be concluded that the quality of life fell in a moderately compromised range in all aspects. The lowest mean score was recorded in the social domain implying that interpersonal relationships and community involvement could be a problem (Table:3).

Table 3 WHOQOL-BREF Domain Scores for Quality of Life

Domain	Mean $\pm$ SD
Physical Health	55.69 ± 8.48
Psychological	56.42 ± 8.34
Social Relationships	49.74 ± 12.61
Environmental	52.97 ± 8.01

Normality of continuous variables was evaluated with Shapiro-Wilk test, to identify the suitable statistical tests. The total and basic LCI scores were normally ($p > 0.05$) and the advanced LCI score was only marginally not normally ($p = 0.047$) distributed. Conversely, the scores of all the WHOQOL-BREF domains were not normally distributed ($p < 0.05$). (Table 4)

Table 4 Normality Assessment Using Shapiro-Wilk Test

Variable	p-value
LCI Total	0.113
LCI Basic	0.075
LCI Advanced	0.047*
WHOQOL Physical Domain	0.015*
WHOQOL Psychological Domain	0.001*
WHOQOL Social Domain	0.008*
WHOQOL Environmental Domain	0.001*

Note: Values marked with an asterisk (*) indicate non-normal distribution ($p < 0.05$).

To analyze the gender differences, 17 men were chosen randomly to compare with the 17 women in the sample. The Independent Samples t-test was applied in LCI score comparison. There was a lack of a statistically significant difference between the male and female in any area of LCI scores. Specifically, males had an average total LCI score of 36.41 ± 16.35 and the same was 30.41 ± 14.77 in women ($p = 0.27$). Likewise, the respective independent group-wise comparison of the score of both the basic and advanced ADLs was similar (Table5).

Table 5 Gender-wise Comparison of Functional Status (LCI-5 scores)

LCI Domain	Males (n=17) Mean $\pm$ SD	Females (n=17) Mean $\pm$ SD	Mean Difference (95% CI)	p-value
Total	36.41 ± 16.35	30.41 ± 14.77	6.00 (-4.88 to 16.88)	0.27
Basic Activities	19.35 ± 6.84	16.76 ± 7.18	2.59 (-2.31 to 2.40)	0.29
Advanced Activities	17.05 ± 9.62	13.64 ± 8.31	3.41 (-2.86 to 9.69)	0.27

Considering the non-normality of the scores, Mann - Whitney U test was applied to compare genders on WHOQOL-BREF domains scores. There were no significant differences noted between males and females in all the four domains of quality of life. So take the example of the physical health domain where the mean rank was 19.03 and 15.97 in male and female respectively ($U = 118.5$, $p = 0.35$) (See Table 6). There were similar insignificant scores in the domain of psychology, social, and environment.

Table 6 Gender-wise Comparison of WHOQOL-BREF Domain Scores

Domain	Mean Rank (Males)	Mean Rank (Females)	Mann-Whitney U
Physical Health	19.03	15.97	118.5
Psychological	16.18	18.82	122.0
Social Relationships	19.38	15.62	112.5
Environmental	18.18	16.82	135.0

Discussion

The aim of the study was to determine the QOL of diabetic patients with major lower limb amputations using prosthesis and compare them by gender. The findings indicated that the functional mobility as well as QOL were mildly impaired in this group of people, and no statistically significant differences were observed between the two genders. The identified findings can serve as a valuable contribution to clinical rehabilitation practice, particularly in the environment with limited resources such as Pakistan, as the, amputations due to diabetes develop and local information is scarce. The functional status was determined with the help of Locomotor Capabilities Index-5 (LCI-5) that evaluates regular and advanced locomotion functions. The overall LCI average was 34.54 ± 15.28 showing lower scores in more advanced activities of daily living (ADLs) in this study. These findings have shown that even though the patients gained some mobility by using the prostheses, they still met some difficulties when it came to more complicated movement like climbing stairs or walking outside.

This follows the previous reports indicating diminished functional outcomes in both amputees (18,22). In a study by Paxton et. al., lower limb amputees with diabetes indicated significant reduction in the number of daily steps taken, were more sedentary and exhibited poor functional performance than non-amputees (21). In a similar manner Lin et al. (22) noted that severe locomotor activities were especially poor in persons who

transfemoral or transtibial amputations and continued on their posture with training on the prosthesis. Such restrictions tend to be correlated with the recuperation of the quantity of lost tissue and the number of the joints that are involved, which impact the amount of energy spent and the gait biomechanic. The score on WHOQOL-BREF was poor overall in regard to the four domains: physical, psychological, social, and environmental. The social relationships domain yielded the least-mean score, and it is an area indicating psychosocial vulnerability in amputees. Our study findings are consistent with several other international studies that reported that amputation does not only cause impairment of physical functioning but also results in lower self-esteem, social withdrawal, and mental health issues (23,24). Using the WHOQOL-BREF as well in a similar population, the existence of this issue is concerned about the lack of awareness of the steps to be taken in order to become healthy or healthy again. Similarly, Aleksandar et al. (25) found that the QOL scores were significantly reduced among both above-knee and below-knee amputees especially in terms of physical functioning and emotional well-being in contrast to non-amputees. These tendencies prove once again the necessity of integrated rehabilitation regimes that have to deal with the aspects of prosthetic appliance and the process of mobility education as well as with mental health issues, professional reintroduction, and the restoration of the social environment. Stimulatingly, a gender-wise comparison in this study had no significant difference in functional status or in

the domains of QOL. The above result is comparable with Sinha et al. (14) and Deans et al. (29) findings that male and female amputees experienced similar levels of impairment and psychosocial disturbances. Having found a higher percentage of male representation in the sample (77%), perhaps due to the fact that diabetes prevalence is higher in men in South Asia (30,31), the extent to which amputation is stressing their everyday functioning and life satisfaction did not differ per gender category.

The insight is vital especially in the Pakistani context where the gender divide in access to healthcare is documented. This could mean that there is lack of measurable gender disparity of outcomes, showing a shared lack of opportunities around the prosthetic training, mobility accommodations, and available psychosocial resources to all patients, regardless of gender. This result, however, is also to be treated with caution, as female participants were rather a small sample (n=17), and future work is to be based on larger gender-balanced populations that will help in seeing whether these findings are universally applicable. It was quite a surprising result of this study not to be able to address the initial objective of the research: comparing major and minor amputations given the fact that no cases of minor amputations could be identified during the time the data was collected. This indicates a possible gap in service delivery, because patients with smaller amputations may not attend prosthetic or rehabilitation centers consistently, because they may not perceive a need to attend, due to lack of health literacy or inability to access those centers. Some studies like that by Quigley and Dillon (27) and NM Yosuf et al. (28) also revealed that persons with minor amputations tend to report improved results with regard to mobility and QOL. Future research ought to take into account community-based sampling methods in order to sample this subgroup and include predictive modeling that helps evaluate the connection between amputation level, years of living with diabetes, and the use of prosthetics on the long-term outcomes.

In general, the results of the present study prove the fact that major lower limb amputation associated with diabetes poses a considerable threat to functional status and quality of life irrespective of gender. These findings support the necessity of considering comprehensive rehabilitation programs, including

physical therapy, the training of using the prosthesis, the involvement of psychosocial assistance, and informing the patient. In addition, regular QOL assessments and functional goal-setting should be routine post-amputation elements in diabetic patients.

Conclusion

This study indicates that there is a severe influence in terms of functional status and the quality of life of diabetic people who use prostheses by responding to the significant effect of major lower limb amputation. The participants showed compromised locomotive abilities, especially involving complex undertakings in the day-to-day activities, and an early poor quality of life on symptoms assessed by each of the four regions of the WHOQOL-BREF. These results affirm the notion that despite the use of the prosthetics functional limitations and psychosocial issues are strongly apparent among the victims of amputation. Notably, no strong effects were found reflecting differences between male and female individuals participating in terms of their outcome in functional performance or in quality-of-life parameters, so the impact of amputation can be considered relatively even between genders. These findings make the need to have well-coordinated rehabilitation methods that deal not only with mobility, but also embrace the physical, psychological, and social needs of patients who are living with an amputation occasioned by diabetes quite urgent.

Limitations

This study had several limitations.

- First, comparison between the major and minor amputations could not be done since there were only a small number of eligible participants who had minor amputations. This restricts the inference that may be established about the influence of the level of amputation.
- Second, this research was conducted in one rehabilitation center, which can interfere with the ability of the results to reach the whole population of diabetic amputees in Pakistan.
- Third, the group of female participants is small and even though Random matching was applied to perform gender comparisons, given its

stability, that sample will create a definite statistical power.

- Finally, the factors of quality of the prosthesis used, the period of use and existence of support systems were not considered, which also can contribute to the cons of the functional and quality of life outcome.

Recommendations

- People with minor amputations and those from the community who might not have access to official rehabilitation facilities should be included in the more diverse and balanced sample that future studies seek to assemble.
- It is also advised to conduct longitudinal studies to monitor improvements in quality of life and functional capacity over time, especially following organized rehabilitation programs.
- To monitor changes in functional ability and quality of life over time, especially following organized rehabilitation programs, longitudinal studies are also advised.
- It is critical to incorporate psychological counseling and social reintegration measures into post-amputation treatment, as these aspects were significantly compromised in this population.
- Expanding access to prosthetic treatments and implementing gender-inclusive rehabilitation policies should be top priorities for health policymakers, particularly in neglected and rural areas.
- Lastly, routinely using standardized evaluation instruments such as WHOQOL-BREF and LCI in clinical practice can assist in tracking patient progress and customizing rehabilitation objectives.

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