

ORIGINAL ARTICLE

Health Related Quality of Life in patients undergoing Lower Limb Amputation secondary to Peripheral Arterial Disease: A study from Karachi, PakistanRUBINA HASHIM^{1,2}, ZARMINA ISLAM³, WARYAM PANHWAR¹, ZIAD SOPHIE², FAHAD TARIQ BERLAS¹, AREEBA SALIM¹¹Department of Vascular and Endovascular Surgery, Shaheed Mohtarma Benazir Bhutto Institute of Trauma²Department of Vascular Surgery, Sindh Institute of Urology and Transplantation³Department of Medicine, Dow Medical College, Karachi, PakistanCorrespondence to Dr. Rubina Hashim, Email: Rubinahashim11@hotmail.com, Contact No: 03330664221**ABSTRACT****Aim:** To assess domains of health-related quality of life among patients undergoing major lower limb amputation secondary to peripheral arterial disease.**Study design:** Observational questionnaire-based study.**Place and Duration:** Data from 1st January to 31 December 2020 (collected from September 2022 to November 2022) was assessed out of which ninety-one patients fulfilled the inclusion criteria.**Methodology:** Twenty-three patients were interviewed after verbal consent over telephone using validated questionnaires: World Health Organization Quality of Life-BREF, Amputee Single Item Mobility Measure, Locomotor Capability Index-5. Independent sample t-tests and ANOVA were performed for demographics and domain scores. Pearson-Correlation tests were performed for relations between domains and mobility scores.**Results:** 12 (52.20%) of interviewed patients received below knee amputation, comprising mostly of males 16 (69.60%) with diabetes 18 (78.30%). Participants who used prosthesis had statistically significantly greater mobility scores compared to non-prosthesis users $t(21)=3.396$, $p=0.03$. Below knee amputees report better quality of life compared to above knee as these amputees had lower physical domain (mean difference -22.75, $p=0.027$) and environmental domain scores (mean difference -12.44, $p=0.009$). This study found that male participants had statistically significantly greater physical $t(21)=2.698$, $p=0.013$ and environmental $t(21)=2.771$, $p=0.011$ scores after a major lower limb amputation compared to females.**Conclusion:** Males and patients with prosthesis report significantly better quality of life compared to females and non-prosthesis users, owing to socioeconomic and cultural barriers.**Keywords (MeSH):** Amputation, Surgical, peripheral arterial disease, Artificial Limbs, Quality of Life**INTRODUCTION**

Peripheral Arterial Disease (PAD) is one of the leading causes of amputations in the developing world¹. It is due to occlusive changes in vessels of the lower extremity, and in its severe form may manifest as chronic limb-threatening ischemia (CLTI)². PAD affects over 230 million adults worldwide of which 12 million are Americans³ and 54.8 million Southeast Asians⁴ and further increasing. This amounts to costs as high as \$381 billion per year, including long-term costs^{2,3}. One year mortality varies from 9-49.6% depending on extent of amputation and level of care, indicating the need for appropriate management⁵. In the United States (US), cost of amputations range from \$10,103 to \$67,773 for minor and major amputations in Diabetics respectively⁶. Pakistan, a developing nation in South Asia where healthcare expenditure is not an easy undertaking keeping in view the socioeconomic status of patients, there are always challenges in management.

A 2010 cross-sectional study of 387 type II diabetic patients in Karachi detects PAD in 152(39.28%) patients⁷, prevalence of 31.6%, and 27.8% is reported by another study^{8,9} however prevalence of PAD in general population is not available. PAD has multiple risk factors predominantly Diabetes Mellitus, hence, majority of these limb amputations are performed on diabetics¹⁰. In Pakistan, of all amputations reported in one study of 135 patients, 67.4% patients present with poor glycemic control¹⁰. However, other risk factors include hypertension, hypercholesterolemia, obesity, and smoking¹¹.

PAD patients experience heightened amounts of pain, affecting their daily activities, and thus quality of life culminating into low physical activity, and poor walking endurance, velocity, and balance³. Lower extremity amputations, which eliminate the infective focus and alleviates pain experienced by patients, may possibly improve the quality of life of such patients however may also have profound negative impacts owing to the loss of a limb with real mental health concerns¹⁰. Health related quality of life is

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not commonly assessed in developing countries due to scarcity of resources, and poor research capacity. Moreover, prior socioeconomic disparities, unavailability of prosthesis and other challenges may exacerbate this experience, and further deteriorate quality of life^{1,10}. Amputations present a great economical, psychological, and social burden, severely affecting health related quality of life¹. Since majority of amputee patients are disabled for life, there is a growing need for interventions that evaluate the quality of life in such patients³. Providing such insights would allow surgeons to understand patient reported outcomes and create protocols that address the needs of their patient population regarding their rehabilitation.

This study aims to assess health related quality of life in patients at 12 months or more follow-up undergoing major Lower Limb Amputation at Vascular and Endovascular Surgery Department SMBBIT from the period of January 2020 to December 2020.

METHODOLOGY

This observational questionnaire-based study was conducted from June 2022 to December 2022. The study was approved by the institutional ethical review committee (ERC). We identified patients submitted to above-knee amputation (AKA) and below-knee amputation (BKA) due to peripheral arterial disease in the department of Vascular and Endovascular Surgery of a central referral hospital for vascular surgery in Sindh, Pakistan from January to December 2020.

Sample Size Calculation Method: Based on the study by Sarah et al, the mean +/- SD for Q1 of WHOQOL scale was 3.68 +/- 0.88. Keeping a margin of error of 0.4 and confidence interval of 95%, we estimated our sample size to be 21. This was calculated via Statulator Sample Size calculator for estimating a single mean^{13,14}.

Inclusion and Exclusion Criteria: Inclusion criteria were: All patients who have undergone major lower limb amputation secondary to PAD. Age above 18 years, amputation due to vascular disease with or without infection, including gangrene due

to arterial thromboembolism or acute exacerbation of chronic limb ischemia, and CLTI (according to definition in CLTI guidelines), and both prosthesis and non-prosthesis users.

Exclusion criteria includes amputations secondary to trauma or causes other than PAD for instance, patients with hip disarticulation, previous major amputation of the ipsilateral limb and patients with incomplete follow-up or records, and bilateral amputees with bilateral lower limb amputation separated less than 6 months in time and loss of consent.

Data Collection Procedure: The data of patients was retrieved from the hospital database via individual file study. Data related to patient demographics (age and gender), comorbidities, amputation type, smoking status and previous revascularization surgery was noted.

Quality of life of patients was assessed at 1 year post amputation by telephonic follow up after informed verbal consent. World Health Organization Quality of Life-BREF (WHOQOL-BREF)¹² was used to assess 4 domains of HRQOL: psychological, social, physical, and environmental. Amputee Single Item Mobility Measure (AMPSIMM) was utilized to assess mobility status. Locomotor Capability Index-5 (LCI-5) was used to assess the experiences of prosthesis users in daily living.

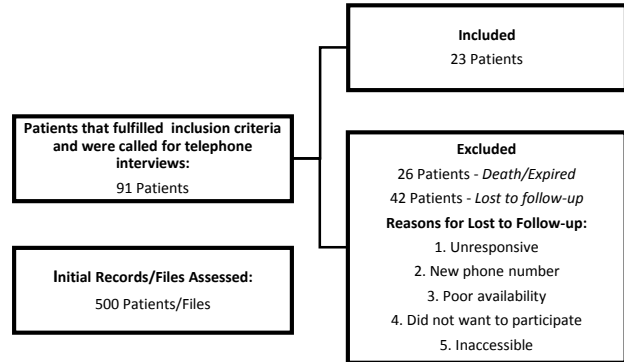
The World Health Organization (WHO) defines 'quality of life' as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. The significance of this questionnaire is to discover the individual's perceptions; a broad-ranging concept affected in complex ways by the person's physical health, psychological state, personal beliefs, social relationships, and relationships to salient features of their environment. The WHOQOL-BREF is a comprehensive research instrument containing 26 items rated on a 5-point Likert scale. A maximum score of 5 indicates a perception of a high quality of life, while a minimum score of 1 indicates a perception of a poor quality of life. Four domains comprise the following items: Physical Health (7 items); Psychological Health (6 items); Social Relationships (3 items); and Environment (8 items). The remaining two items, at the beginning of the questionnaire (coded Q1 and Q2), ask specifically about the participant's rating of their quality of life and satisfaction with their health. AMPSIMM is a 1 item instrument that rates mobility status of amputees with a score from 0 to 6 with 6 indicating excellent mobility, and 0 bedridden. LCI-5 is a 14-item instrument used specifically for prosthesis users to assess locomotor abilities and independence on a 5-point ordinal scale with a maximum score of 56; higher scores reflect greater locomotor capabilities.

All alive patients with the above-mentioned inclusion criteria were contacted by telephone and the questionnaire was applied in Urdu. All ninety-one patients were called and asked for permission to conduct a survey interview over the telephone from September 1 to November 30th, 2022. Three researchers conducted the interviews. Patients who did not attend the phone call once were called an additional four times on separate days until patient was excluded and labelled as lost to follow up. When needed, a close family member or caregiver helped the patient answer the questions. Verbal informed consent was obtained from each participant and additional information relating to marital status, rehabilitation and prosthetic use was incorporated into excel sheets later integrated into SPSS. Patients were allowed to justify their answers whenever they wanted to.

Statistical Analysis: Statistical Analysis Statistical analyses were performed using SPSS version 24.0 statistical software package®. Frequencies in percentages were calculated for patient demographics including age, gender, comorbidities, smoking status, marital status, amputation type, previous revascularization surgery and prosthesis use. Patient characteristics, and domain scores were compared using student's t-test. Specifically, associations between gender and domain scores were assessed. One-way ANOVA tests were performed for amputation type and marital status, and domain scores. Pearson linear correlations were utilized to evaluate the strength of association between

domain scores, AMPSIMM and LCI-5. Sub-group analyses were performed in prosthesis users to further evaluate HRQOL and compare to non-prosthesis users. Data was calculated with a 95% confidence interval and significant value was set at P-value < 0.05. An estimation of the meaningful change of half standard deviation of the scores was used.

Figure 1: Flowchart for Patient Inclusion Process



RESULTS

In our study, 91 patients fulfilled the inclusion criteria out of which 69 (75.80%) were male, and 22 (24.20%) female patients (refer to Table 1 for demographics). Mean age of patients was 58.14 (SD 12.86) years. These patients were called for telephone interviews and 23 were included in final analysis. Among 91 patients, 26 patients had expired, and 42 were lost to follow-up (Figure 1). For expired patients, primary causes of death included natural, myocardial infarction, and stroke.

Interviewed Patients: Out of 23 patients, 16 (69.60%) were male, 7 (30.40%) were female. Mean age was 55.62 (SD 9.78) years. 12 (52.2%) received below-knee amputation (BKA), and 9 (39.1%) received above-knee amputation (AKA). 7 (30.40%) patients had previous revascularization surgery whereas 16 (69.60%) did not. The most common co-morbidity was Diabetes Mellitus, found in 18 (78.10%) of patients. Other comorbidities included hypertension 15 (65.20%), coronary heart disease 7 (30.4%).

17 (73.90%) patients were married, 5 (21.70%) divorced or widow, and 1 (4.30%) unmarried (refer to Table 1 for demographics). 11 (47.80%) patients were smokers in which 3 (13.0%) were current (all who were smoking for over 10 years) and 8 (34.80%) former, and 12 (52.20%) non-smokers. 7 (30.40%) were using a prosthesis, and 16 (69.60%) did not have one, out of which 6 (26.10%) were awaiting one. All patients that did not have a prosthesis expressed that they could not afford it, 16 (100.0%).

Prosthesis Users (n=7): Our study includes 7 prosthesis users, out of which 5 (71.40%) were male, and 2 (28.60%) were female. All mean scores reported in this group were higher than the mean scores for the overall sample (n=23). For prosthesis users, LCI-5 mean score was 47.28 (SD 11.10).

Gender and Quality of Life: An independent samples t test was done to assess the association between gender and different domains under quality of life (refer to Table 2). Males n= 16 (physical domain; 54.06 ± 20.22) (environmental domain; 49.62±10.35) and females n=7 (31.28 ± 13.86) (37.57±7.36) were compared for physical and environmental domain scores, respectively. This study found that male participants had statistically significantly greater physical $t(21)=2.69$, $p=0.013$ and environmental domain $t(21)=2.77$, $p=0.01$ scores after a major lower limb amputation compared to females. Other domain associations were insignificant, however being male was associated with greater health satisfaction in the global scale ($p=0.04$).

Amputation Type and Quality of Life: An analysis of variance showed that the amputation type had a significant impact on physical $F(2,20) = 4.79$, $p=0.02$, and environmental domain scores

F (2,20) = 8.29, p<0.01 (refer to Table 3). Post hoc analyses demonstrates that unilateral AKA has statistically significant lower physical domain (mean difference -22.75, p<0.01) score and environmental domain scores (mean difference -12.44, p<0.01) compared to BKA. Bilateral amputees demonstrate statistically significant higher scores in environmental (mean difference -21.94, p=0.01) domains compared to unilateral AKA.

Mobility and Quality of Life: Our study demonstrates that participants with a previous stroke were associated with significantly lower AMPSIMM scores compared to those without (3.80 ± 1.40), p<0.01. With respect to quality of life, those with a previous stroke were associated with significantly lower social (p<0.01), psychological (p=0.04) and physical domain scores (p=0.04).

A Pearson-Correlation test was performed to assess relationships between AMPSIMM and physical domain (refer to Table 4). Our study demonstrates mobility (AMPSIMM) scores (3.47±1.72) were positively correlated, r(23) = 0.62, p<0.01 with physical domain scores (47.13±21.12).

Other Tests: An analysis of variance to assess the impact of marital status, and smoking status on quality of life demonstrates insignificant results in our study. No significant correlations were found between age and different domains.

Prosthesis Use and its Impact on Quality of Life: An independent samples t-test was done to assess the association between prosthesis use and mobility scores (AMPSIMM). Prosthesis users N= 7 (5.00±0.81) and non-prosthesis N=16 (2.81±1.60) were compared. Our findings indicate that participants who used prosthesis had statistically significantly greater mobility scores after a major lower limb amputation compared to non-prosthesis users t(21)=3.39, p=0.03.

A Pearson Correlation test was performed to see relationship between LCI-5 scores among prosthesis users and change in quality-of-life domains (refer to Table 4). Our study demonstrates LCI-5 scores (47.28±11.10) were strongly positively correlated with physical (47.13±21.12) r(7) = .928, p<0.01, psychological (56.69±19.29) r(7)=0.830 p=0.02 and environment domain scores (45.95±10.96) r(7)=0.847 p=0.01.

Sub-Group Analysis of Prosthesis Users: An independent samples t test was done to assess the association between gender and different domains under quality of life for prosthesis users. Males N= 5 (Mean Age 71.40± 13.04) and females N=2 (Mean Age 34.50± 13.43) were compared. This study found that male participants with a prosthesis had statistically significantly greater physical t (5) =3.36 (p=0.02), psychological t(4)=2.79 (p=0.04), and environmental domain scores t(5)=3.71 (p=0.01) after a major lower limb amputation compared to females.

Table 1: Demographics

Variables		Interviewed patients (n=23)
Age (mean ± SD)		55.26±9.789
Gender	Male (mean ± SD)	16 (69.6%)
	Female (mean ± SD)	7 (30.4%)
Amputation Type	BKA	12 (52.2%)
	AKA	9 (39.1%)
	BKA+BKA	1 (4.3%)
	AKA+AKA	1 (4.3%)
If unilateral, which leg?	AKA+BKA	1 (4.3%)
	Right	11 (47.8%)
	Left	10 (43.5%)
	Variables	
Marital Status	Unmarried	1 (4.3%)
	Divorced/Widow	5 (21.7%)
	Married	17 (73.9%)
Smoking Status	Current	3 (13%)
	Former	8 (34.8%)
	Never	12 (52.2%)
Prosthesis Use	Yes	7 (30.4%)
	No	16 (69.6%)
If No, are you awaiting one?	Yes	6 (26.1%)
	No	10 (43.5%) *
If No, are you able to afford a prosthesis?	Yes	0 (0%)
	No	16(69.6%)**
Comorbidities	Diabetes Mellitus	18 (78.3%)
	Hypertension	15 (65.2%)
	Coronary Heart Disease	7 (30.4%)
	Stroke	2 (8.7%)
	Chronic Alcoholism	0 (0%)
	End-Stage Renal Disease	1 (4.3%)
Smoker	Chronic Obstructive Pulmonary Disease	1 (4.3%)
	Yes	11 (47.8%)
Previous Revascularization Surgery	No	12 (52.2%)
	Yes	7 (30.4%)
Revascularization Procedure	No	16 (69.6%)
	Fem-Pop	1 (4.3%)
	SFA-PTA	2 (8.7%)
	CFA-ATA	1 (4.3%)
	Fem-PTA	2 (8.7%)
	Fem-Peroneal	1 (4.3%)

*this is actually 62.5% since we did not account for the 7 that have a prosthesis already.
 **since we are not accounting for ones that do have a prosthesis, this is 100%
 Below Knee Amputation (BKA), Above Knee Amputation (AKA)
 Common femoral artery(CFA),Posterior tibial artery(PTA),Anterior tibial artery(ATA).

Table 3: ANOVA comparing Amputation Type and Domain Scores

Descriptive	N	Mean	Std. Deviation
			17.72710
Unilateral Below Knee	12	55.4167	19.15705
Bilateral Amputation	2	62.5000	9.19239
Total	23	47.1304	21.12152
Environment Domain (1-100)			
Unilateral Above Knee	9	37.5556	7.16085
Unilateral Below Knee	12	50.0000	9.58218
Bilateral Amputation	2	59.5000	4.94975
Total	23	45.9565	10.96058
Dependent Variable	(I) Amputation Type	(J) Amputation Type	Mean Difference (I-J)
Physical Domain (1-100)	Unilateral Above Knee	Unilateral Below Knee	-22.75000 [†]
Environment Domain (1-100)	Unilateral Above Knee	Unilateral Below Knee	-12.44444 [†]
		Bilateral Amputation	-21.94444 [†]
			.027
			.009
			.010

Table 4: Pearson Correlation test for 1) AMPSIMM and Physical Domain and 2) LCI-5 and Domains

Correlations		
	The Amputee Single Item Mobility Measure (AMPSIMM) Score	Physical Domain (1-100)
Pearson Correlation	1	.621**
Sig. (2-tailed)		.002
N	23	23

** . Correlation is significant at the 0.01 level (2-tailed).

Correlations				
	Locomotor Capabilities Index - 5 (LCI-5) Score	Physical Domain (1-100)	Psychological domain(1-100)	Environment Domain (1-100)
Pearson Correlation	1	.928*	.830*	.847*
Sig. (2-tailed)		.003	.021	.016
N	7	7	7	7
**. Correlation is significant at the 0.01 level (2-tailed).				
*. Correlation is significant at the 0.05 level (2-tailed).				

Table 2: Comparison of Males and Females for HRQOL

Gender	Male (n=16)	Female (n=7)	P-Value
Physical Domain	54.06 ± 20.22	31.28 ± 13.86	.013
Environmental Domain	49.62±10.35	37.57±7.36	.011

World Health Organization Quality-of-Life Scale (WHOQOL-BREF), Amputee Single Item Mobility Measure (AMPSIMM), Locomotor Capabilities Index-5 (LCI-5).

DISCUSSION

The quality of life of an individual, is a subjective appraisal of well-being, more important than an objective assessment of health. Worldwide, especially in the western world, studies have been conducted to evaluate the HRQOL in amputee patients, especially due to CLI¹⁵⁻¹⁸. Challenges in the field of health care faced by developing nations are distinctive due to a lack of knowledge regarding disease progression and the related costs, often unbearable for needy patients in rural areas¹⁶.

Our study concurred with it as 100% of our patients expressed that they could not afford a prosthesis. According to our knowledge and literature search, no study like ours exists in Pakistan to compare our findings with, making our study unique. Among patients who undergo amputation due to peripheral vascular disease, living without pain is a greater priority than mobility¹⁷. However, amputation still affects different domains of life, so much so that the psychological sequelae is affected even during the rehabilitation phase¹⁹.

This study found that male participants had statistically significantly greater physical (p=0.013) and environmental domain scores after a major lower limb amputation compared to females (p =0.011) as well as greater health satisfaction in the global scale (p=0.043). Similar findings exist in the prosthesis group. Male prosthesis users report statistically significant greater physical (p=0.020), psychological (p=0.049), and environmental (p=0.014) domain scores after a major lower limb amputation compared to females. Previous studies have already reported lower functional status in women in AKA and bilateral amputees^{20,21}, higher use of prosthesis and better prosthetic fit rates among men^{22,23}. Socioeconomic and cultural barriers in Pakistan may prevent women from seeking healthcare services that they need, especially in rural areas²⁴. In addition, socially deprived diabetics are 5.6–7.9 times more likely to develop CLI, which warrants the need for more awareness and education around CLI²⁵.

In our study, majority of participants had a BKA (52.2%). Moreover, our study demonstrates better quality of life in unilateral BKA compared to unilateral AKA within physical (p=0.027) and environmental domains (p=0.09). Amputation below the knee has been found to optimize the patient’s likelihood of learning to walk, as walking with a BKA requires less energy in comparison to an AKA²⁶.

Majority of our patients did not have a prosthesis even 2 years post amputation, in contrast to other literature where patients received prosthesis by 14 months²⁷. Poverty and rehabilitation center accessibility constituted major factors for avoiding prosthesis and ultimately affecting HRQOL. Of all patients, sadly only 30% used prosthesis in our study. Encouragingly all mean scores reported in prosthesis group were higher than the mean scores for the overall sample. Moreover, participants who used prosthesis had statistically significant greater mobility scores after a major lower limb amputation compared to non-prosthesis users (p=0.03) which would contribute to improved quality of life, also evidenced in other studies^{18,23}. Interestingly, one study highlights that prosthesis users who walked had the largest HRQOL improvement, giving them a sense of independence²³.

While half of the patients were smokers, ironically 13% were still smoking despite misery. Cui et al. found that smoking was associated with a loss of health-related quality of life (HRQOL) and presented an economic burden²⁸. However, our study did not find any significant associations regarding smoking.

Interestingly, only thirty percent of interviewed patients had a secondary amputation indicating delayed presentation to medical facilities demonstrating the paucity of awareness regarding vascular diseases. This is concerning since delayed revascularization has been associated with a higher chance of postoperative amputation²⁹. A cohort study of limb ischemia from Aga Khan University demonstrates that non-referral by primary physician is the main reason for late presentation³⁰.

We propose multiple reasons for a large lost to follow-up in our study. First, the data collection process in this study was very comprehensive, as reaching out to primary patients entailed interviewing multiple intermediaries. This was mainly due to poor socioeconomic status of patients who had therefore provided contact numbers of people who did not directly belong to them, and additionally because patients mostly lived in rural areas resulting in connectivity issues. Flooding in Sindh also played its part as patients had been displaced and were not reachable on available contact numbers. Owing to prevalence of multiple languages being spoken, often an interpreter was required.

A generous prescription of prostheses and rehabilitation after amputation will give the patient a chance to improve his/ her HRQOL³¹. This shall be achieved via institution of individualized postoperative physiotherapy and exercise programmed, easy access to rehabilitation centers and preoperative training of amputee patient for successful rehabilitation after surgery. Amputees with capacity to wear a prosthesis should receive it earlier after amputation to improve HRQOL, shall be provided free of cost, should be lighter and adapted to each individual patient. Rehabilitation and prosthetic care teams should be included sooner in the process and have close association with the surgeons. Efforts should be made to set up Rehabilitation centers in rural areas as majority of our affected patients abide there, social awareness regarding PAD should be emphasized and disease-specific questionnaire formulated for ischemic amputees.

Our study has several limitations. Firstly, we were only able to recruit 23 patients, a small sample which limits the generalizability of our results. Second, we had an unequal distribution of males and females, which may be due to our sampling method. An equal distribution of male and female participants may help in assessing challenges each group face. Other barriers that limit our findings include language barriers, and poor connectivity. For future studies, an emphasis on semi-structured interviews to gain an in-depth understanding of patient experiences should be done. Additionally, researchers should evaluate the caretaker’s perspective to assess whether differences exist among reported HRQOL scores about the patient between patients themselves and their caretakers. Lastly, it is vital to compare experiences of those in rural areas versus urban since availability of ease of healthcare access and transport services is sure to have an impact on HRQOL.

CONCLUSION

In conclusion, our study explores unique experiences of patients with PAD undergoing major lower limb amputation in Pakistan. Males as well as patients with prosthesis report significantly better quality of life compared to females and non-prosthesis users, which may be attributed to socioeconomic and cultural barriers.

Patients using a prosthesis report better physical, psychological, and environmental domain scores. This study is a steppingstone for clinicians and policymakers trying to understand patient reported outcomes to better support amputee patients with access to prosthesis across Pakistan.

Author Contributions: **RH:** Conceived the idea, designed, and wrote the synopsis, collected data, wrote discussion, and conclusion, critically revised the manuscript, **ZI:** Assisted in data collection, data analysis, results, and introduction writing, **WP:** Mentored throughout the project, helped with the data analysis and critically revised the manuscript for important intellectual content, **ZS:** Reviewed research proposal and approved it. Critically revised manuscript, **FTB:** Reviewed research proposal and approved it. Assisted with sample size calculation and result interpretation, **AS:** Assisted in data collection. All authors have reviewed and approved the final manuscript.

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