CHAPTER 6

Influence of adjustments to amputation and artificial limb on quality of life in lower limb amputees

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ABSTRACT

Objective: The objectives of this study are to investigate the relationship between adjustments to amputation and artificial limb, and quality of life (QoL), and to analyze the influence of socio-demographic, medical, and amputation-related factors on this relationship.

Methods: Unilateral and non-congenital lower limb amputees who were using artificial limb were interviewed (n=368) using structured questionnaires. The Trinity Amputation and Prosthesis Experience Scales (TAPES) were used to assess adjustments to amputation and artificial limb, and MOS Short-Form Health Survey (SF-36) was used to assess the physical (PCS) and mental (MCS) components of QoL.

Results: Absence of comorbidity and residual stump pain, being employed, young age, less functional restriction, being more adjusted to limitation, increased social adjustment, and less restricted in athletic activity were related to better PCS scores. Absence of comorbidity and phantom limb pain, non-use of assistive device, being more adjusted to limitation, increased social adjustment, and being less functionally restricted were related to higher MCS scores. Comorbidity had a modifying effect on both PCS and MCS scores. Additionally, age, being employed, and residual stump pain had a modifying influence on PCS scores, while assistive device use and phantom limb pain had a modifying influence on MCS scores.

Conclusions: Our findings show that associations between several socio-demographic and amputation characteristics, and QoL (PCS and MCS) are modified by TAPES subscales, which indicate that adjustments to amputation and artificial limb are the key determinants of QoL in lower limb amputees.

Keywords: Rehabilitation; Amputation; Lower extremity; Leg; Artificial limbs; Adaptation, Psychological; Quality of life.

INTRODUCTION

The use of prosthesis can have a significant impact on mobility, participation and psycho-social functioning of the amputees, thereby influencing their quality of life (QoL).[1-3] According to Pell et al.,[3] mobility was the only significant independent variable affecting QoL as compared to the control group selected from the register of general practise matched for age and sex. Similarly, as found by van der Schans et al.,[4] walking distance was the most important amputation-related determinant of health-related QoL. Successful prosthetic users perceive their function, mobility, psycho-social response, overall well-being and satisfaction quite favorable.[5] So, physical functioning and independence is an important aspect of their life and will shape their perception about their life and well-being. It is imperative that the amputees get adjusted to the amputation[6] and use their artificial limb on an everyday basis for performing the activities of daily living, as well as other functional and social activities. Not getting used to the use of the artificial limb may have negative influence on QoL of the amputees.

Several other factors influence QoL in people with an amputation as well. Comorbidity has been reported to be a significant predictor influencing QoL negatively.[1, 7, 8] Being older and unemployed have also been found to negatively influence the physical component of QoL.[7, 9, 10] Absence of residual stump pain, phantom pain and ability to walk longer distances were found to have positive influence on QoL.[4] Gallagher et al.[11] reported the presence of residual stump pain to have a negative influence on physical health, and Sinha et al.[7] reported the presence of residual stump pain to negatively affect both the physical and the mental component of QoL, and phantom pain to affect the mental component of QoL.

Matsen et al.[1] found strong and significant positive correlations between the comfort of the residual limb; the condition of the contralateral limb; comfort, function and the appearance of the prosthesis; social factors and the ability to exercise recreationally, and QoL measured using a visual analog scale. Harness et al.[5] studied health-related QoL in dysvascular transtibial amputees using the Prosthetic Evaluation Questionnaire, which measures prosthesis function, mobility, psycho-social response, well-being, and satisfaction. Patients' perception of their social burden was strongly associated with their ability to walk with their prosthesis. More satisfaction was positively related to a lesser amount of pain and the ability to ambulate. The ability to be independent or being able to transfer was positively related to satisfaction and decreased social burden.[5]

Less is known about the role of adjustments to amputation and artificial limb on QoL of amputees, and the role of socio-demographic, medical, and amputation related factors on the relationship between the adjustments to amputation and artificial limb and QoL. The objectives of this study are to investigate the relationship between adjustments to amputation and artificial limb and QoL, and to analyse the role of socio-demographic, medical, and amputation related factors on this relationship.

METHODS

Participants

Lower limb amputees aged 18 years and above from a limb fitting center and a rehabilitation center based in Mumbai, and four limb fitting camps in and around Mumbai participated in the study. The study was cross-sectional, and conducted during 2005-2006 following convenience sampling. The subjects were included if they were willing to participate, did not have hearing or speech impairment, and were not mentally incapacitated resulting in a total of 622 subjects; 17 subjects refused to participate or were excluded because of the exclusion criteria.

For this study, two additional inclusion criteria were added, namely persons who were unilateral and non-congenital amputees, and who were using lower limb prosthesis. Amputees who were in the process of limb fitting, gait training (for new amputees), procuring a new artificial limb, etc., were not included. This led to 368 amputees meeting the study inclusion criteria. The mean age and the gender distribution of the amputees who were included in the study are similar to the overall group of 622 subjects[7] indicating that the subsample used in the study is representative of the overall group.

The Institutional Review Board of one of the co-author's institute approved the study. The purpose of the study was explained to the subjects, and a signed informed consent was requested prior to the study. Face-to-face interviews were conducted by three trained interviewers.

Measures

Data was collected using structured questionnaires. They included information about patient's socio-demographic and medical information (sex, age, marital, educational and employment status, and comorbidity, if any). Furthermore, they included amputation-related information, like time with prosthesis, cause, level and side of amputation, daily prosthesis use, residual stump pain, phantom limb sensation and

phantom limb pain, stump skin problem and assistive device use. To assess the adjustment to artificial limb, the Trinity Amputation and Prosthesis Experience Scales (TAPES)[12] was used, which is a validated instrument for use in amputees. Quality of life was assessed by MOS Short-Form Health Survey (SF-36),[13] which is an internationally validated instrument to measure QoL.

TAPES is a multidimensional questionnaire assessing adjustment to amputation and prosthesis use developed specifically for use with lower limb amputees[11] consisting of three psychosocial adjustment, three activity restriction, and three prosthesis satisfaction subscales. All the subscales of TAPES except two (aesthetic satisfaction and general adjustment) met the internal consistency criteria (Cronbach's alpha>0.7)[14] (article submitted for publication).

The SF-36 is a multi-purpose short-form health survey consisting of eight scales, which lead to two summary scores, namely physical (PCS) and mental (MCS) component summary scores.[15] A considerable number of studies in amputee population have assessed QoL by SF-36,[7, 16-21] and also used PCS and MCS scores[15, 16] to summarize QoL. In our sample, Cronbach's alpha for PCS and MCS were 0.93 and 0.92 respectively, thus meeting the internal consistency criteria (>0.7). [14]

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 15).[22] First, desciptive analyses were performed for the socio-demographic and amputation related factors. Next, bivariate correlation analyses were performed between the TAPES subscales (except aesthetic satisfaction and general adjustment as they did not meet the internal consistency criteria) and QoL (PCS and MCS) to assess the relationship between the adjustment to the artificial limb and QoL. Finally, with hierarchical regression,[23] we analysed the influence of the socio-demographic, medical, and amputation related factors (step 1), and the adjustments to amputation and the artificial limb (TAPES subscales - step 2) on the two summary scores of QoL: PCS and MCS. Binary coding was done for the categorical predictor variables.[24] The regression procedure resulted in a parsimonious model based only on the factors, which achieved statistical significance ($p<0.05$).

Table 1: Study population characteristics.

	n	%	Mean (SD)
Socio-demographic			
Age (years)	368		43.13 (14.8)
Sex			
Male	324	88.0	
Female	44	12.0	
Marital Status			
Single	70	19.0	
Married	264	71.7	
Others	33	9.0	
Missing	1	0.3	
Education			
No formal education	63	17.1	
Primary education	47	12.8	
Secondary education	213	49.2	
Tertiary education	43	20.3	
Missing	2	0.6	
Employment Status			
Non-working	152	41.3	
Working	216	58.7	
Medical			
Comorbidity incidence	367	28.9	
Comorbidities[a]			
Diabetes	56	52.8	
Hypertension	19	17.9	
Musculoskeletal/Neurological	32	30.1	
Others	22	20.7	
Amputation			
Time since amputation (years)	368		12.90 (10.1)
Time with prosthesis (years)	365		10.92 (9.3)
Daily prosthesis use (hours)	368		10.22 (3.7)
Amputation cause			
Trauma	280	76.1	
Diabetes	42	11.4	
Vascular	17	4.6	
Cancer	14	3.8	
Others	14	3.6	
Missing	1	0.3	
Amputation Level			
Above knee	76	20.7	
Through knee	11	3.0	
Below knee	281	76.3	
Side of amputation			
Left	177	48.1	
Right	191	51.9	
Stump skin problem			
Yes	68	18.5	
Missing	3	0.8	
Residual stump pain			
Yes	115	31.2	

	n	%	Mean (SD)
Phantom limb pain			
Yes	67	18.2	
Assistive device use			
Yes	150	40.8	

[a] Includes single as well as multiple comorbidities.

RESULTS

The average age of the prosthesis users was 43 years and 88% were males (Table 1). The majority was employed (59%) and reported at least one comorbidity (29%) with diabetes as the most frequent one (53%). The average time since amputees were using their prosthesis was 10 years, and the average time since amputation was 12 years. The main cause of amputation was trauma. Three out of four amputees had a below knee amputation. Besides the prosthesis 41% used an assistive device. Stump pain was mentioned by almost one third of the prosthesis users, while 18% reported stump skin problems and residual phantom pain.

The correlations between TAPES, and PCS and MCS scores were significant at 0.01 level. The activity restriction subscales were negatively correlated with both PCS and MCS, with the correlation being stronger with PCS. On the other hand, the psychosocial adjustment subscales were positively correlated with both PCS and MCS, and the correlation was stronger with MCS. The correlations between the prosthesis satisfaction subscales and PCS/MCS were found to be similar.

Table 2: Nonparametric correlations between TAPES, and SF-36 PCS and MCS summary scores.

TAPES	PCS	MCS
Prosthetic satisfaction		
Functional satisfaction	.292	.241
Weight satisfaction	.157	.179
Psychosocial adjustment		
Social adjustment	.348	.417
Adjustment to limitation	.434	.502
Activity restriction		
Functional restriction	-.671	-.448
Social restriction	-.576	-.380
Athletic restriction	-.645	-.459

All correlations significant at 0.01 level (2-tailed).

In the hierarchical regression analyses, four of the seven TAPES subscales used were found to be related to QoL; three (functional restriction, adjustment to limitation and social adjustment) were related to both PCS and MCS, and one (athletic activity restriction) only to PCS. Of all the variables, absence of comorbidity, being employed, young age, absence of residual stump pain, less functional restriction, being more adjusted to limitation, increased social adjustment, and less restriction in athletic activity were related to better QoL, as indicated by the PCS scores ($F[11, 336] = 58.46$, $R^2 = 0.657$, $p<0.001$). For MCS scores, lack of comorbidity and phantom limb pain, non-use of assistive device, being more adjusted to limitation, increased social adjustment, and being less functionally restricted were related to better QoL ($F[9, 338] = 33.33$, $R^2 = 0.470$, $p<0.001$).

Table 3: Hierarchical regression (final model) of adjustments to amputation and artificial limb (TAPES) and SF-36 PCS and MCS summary scores controlled for socio-demographic, medical and amputation related factors.

	B	SE B	β
PCS			
Constant	52.004		
Employment status	4.098	2.032	0.075*
Educational status	3.489	2.284	0.050#
Age	-0.232	0.073	-0.128§
Comorbidity	-12.379	2.223	-0.211†
Assistive device use	-2.590	2.026	-0.048#
Residual stump pain	-3.924	1.901	-0.068*
Cause of amputation	1.707	2.024	0.030#
Functional restriction	-4.240	0.587	-0.346†
Adjustment to limitation	0.792	0.203	0.151†
Social adjustment	0.513	0.178	0.104§
Athletic activity restriction	-1.580	0.646	-0.128*
MCS			
Constant	16.602		
Employment status	4.367	2.446	0.080#
Educational status	4.515	2.795	0.065#
Comorbidity	-9.165	2.618	-0.157§
Assistive device use	-5.426	2.372	-0.100*
Residual stump pain	-4.592	2.355	-0.079#
Phantom limb pain	-7.431	2.805	-0.107§
Functional restriction	-2.319	0.562	-0.189†
Adjustment to limitation	1.685	0.238	0.321†
Social adjustment	0.924	0.215	0.187†

PCS: $R^2 = 0.657$ ($p < 0.001$), MCS: $R^2 = 0.47$ ($p < 0.001$)
$p < 0.05$, § $p < 0.01$, † $p < 0.001$, # = Not significant

Being less functionally restricted and absence of comorbidity showed the strongest relation to higher PCS scores, while being more adjusted to limitation, functionally and socially less restricted, and absence of comorbidity did so to higher MCS scores. Comorbidity had a modifying effect on both the PCS and MCS scores, but education did not. Additionally, age, being employed, and residual stump pain had a modifying influence on the PCS scores, while assistive device use and phantom limb pain had a modifying influence on the MCS scores.

DISCUSSION

Our aim was to investigate the roles of adjustment to amputation and an artificial limb on QoL of amputees and the intervening role of socio-demoghraphic, medical, and amputation related factors. The results confirm that adjustments to amputation and artificial limb are important determinants of QoL. Functional restriction, adjustment to limitation and social adjustment were found to have a signicant influence on QoL. In the final model, less comorbidity, being more adjusted to limitation, being more socially adjusted and the absence of functional restrictions were found to be associated with both better physical and mental components of QoL. Employment status, younger age, absence of residual stump pain and lesser athletic activity restrictions were found to be associated with better PCS scores. Lesser assistive device use and absence of phantom limb pain were found to be associated with better MCS scores.

Residual stump pain and phantom limb pain can be postulated to affect the physical and mental components of QoL respectively. Residual stump pain was found to be associated[11] with the physical health domain, and not the mental health domain of WHO-QoL.[25] Phantom pain did not influence the physical health domain, but was found to be negatively associated with the mental health domain to a great extent. Van der Schans et al.[4] found stump pain to be a significant predictor for eight out of nine scales of RAND-36 DLV,[26] and did not find phantom pain to influence QoL of amputees. However, QoL of amputees with phantom pain was found to be worse than the amputees without phantom pain after correcting for sex, age, level of amputation and bilateral amputation. Also, phantom pain was significantly and negatively associated with walking distance. The study did not analyze the mental and physical health domains separately, but studied it as a composite score. In a qualitative study,[27] the direct influence of phantom pain on well-being was found to be small. However, the study sample comprised of only 16 amputees.

Functional restriction is significantly and negatively associated with both PCS and MCS scores, however more strongly associated with PCS, whereas social adjustment is significantly and positively associated with both PCS and MCS scores, however it has a stronger association with MCS. Gallagher et al.[11] found similar association between TAPES and QoL i.e. functional restriction was significantly and negatively associated with the physical health domain of WHO-QoL. In a similar study by Deans et al.,[28] functional restriction was found to be significantly and negatively associated with the physical, psychological and social health domains of WHO-QoL.

The athletic activity restriction scale was also found to have a negative impact only on the physical component of QoL. The study by Deans et al.[28] also reported the athletic activity restriction to negatively affect the physical health domain of WHO-QoL in a significant manner. Similarly, according to a study by Weiss et al.,[29] ability to perform activities of daily living was found to be the most important predictor of QoL.

Social adjustment affected the mental component of QoL more strongly than the physical component. Similarly, it was found to be significantly and positively related to the psychological and social domain of WHO-QoL.[11] However, it was not associated with the physical domain of WHO-QoL, whereas in our study, it was found to be associated with the physical domain of QoL, which is a new finding. In its real meaning, social adjustment scale of TAPES pertains to the feeling of comfort level of the amputees in the society with respect to their amputated limbs. In congruence to the findings, studies have also demonstrated the influence of positive body-image on the psychological well-being of the amputees.[2, 19]

Aspects related to the adjustments to amputation and prosthesis are crucial determinants of QoL, followed by co-morbidity. Functional restriction, adjustment to limitation and social adjustment were found to be contributing the most to QoL, whereas functional satisfaction, social restriction, and to a much lesser extent athletic activity restriction had an influence on QoL, which is in line with the findings of Gallagher et al.[11] However, their study did not find the comorbidity to be influencing any domain of QoL. The study was conducted in Ireland and this could have been linked to the quality and accessibility of health care system in Ireland.

Strengths and limitations

One of the study strength is a reasonably larger sample size considering the aim of the study from three different sources. Also, a very high participation in the study was noticed, as only eight amputees were not willing to participate in the study. Therefore,

this eliminates the chance of selection bias to a great extent. However, the study sample was not derived randomly from a primary source, like hospitals; therefore there is a possibility that the study population comprised of those people who were motivated and interested in their health and well-being, and therefore visited the center to procure an artificial limb.

Aesthetic satisfaction and general adjustment subscales of TAPES were not included in the regression analyses, since they did not meet the internal consistency criteria. Therefore, the effect of these on QoL cannot be reliably estimated, at least in this study. However, Gallagher et al.[11] had found aesthetic satisfaction and general adjustment to be linked with psychological and physical health domains of WHO-QoL respectively.

The study was cross-sectional in design, which limits the interpretation between the meaning of the association between adjustments to amputation and artificial limb, and QoL. As the questionnaires were self-reported by the amputees, the chance of recall bias for amputation-specific questionnaires cannot be entirely excluded.

CONCLUSIONS

Our findings show that associations between several socio-demographic and amputation characteristics and QoL (PCS and MCS) are modified by introducing information on the adjustments to amputation and artificial limb. Adjustments to amputation and artificial limb – and therefore use of an articial limb – are key determinants of QoL. This finding has important consequences for rehabilitation and health care, namely, to enable, stimulate and train the use of prosthesis. To further unravel this connection, a longitudinal study with the study population taken from the primary source is envisaged to provide an in-depth knowledge of the adjustments to amputation and prosthesis, and their impact on QoL.

The use of TAPES to assess the adjustment and appreciation of the artificial limb in clinical practise is strongly recommended. It will not only assist in an objective assessment of adaptation of the amputees to amputation and artificial limb, but also indicate the extent to which QoL in amputees might be improved.

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