University of Groningen

Adjustments to amputation and artificial limb, and quality of life in lower limb amputees

Sinha, Richa

[Link to publication in University of Groningen/UMCG research database](#)

SUMMARY

Amputation is a major life event for most individuals regardless of the cause of amputation. It affects physical and psycho-social functioning, body image, and social participation, thereby, influencing their quality of life (QoL). The study focuses on QoL in lower limb amputees. The study population has been derived from India. Although epidemiological data about amputation incidence in India is not available, it is believed that the incidence of lower level amputation is among the highest in the world, and that trauma is the main reason for lower limb amputation. Compared to the western countries, persons with lower limb amputation are relatively young. Additionally, there is scarce data on prevalence of (lower limb) amputation, and studies assessing QoL of lower limb amputees are lacking so far in India.

This study is an exploratory study, and intends to pave insights about the health and well-being of amputees, both at physical and mental level, as WHO defines 'health' as the state of complete physical, mental and social well-being. Prosthesis is an important aspect of an amputee's life, and therefore it is important to investigate the psycho-social adjustment to amputation and use and satisfaction with prosthesis.

The objectives of this study were to assess quality of life (QoL) in lower limb amputees, to study the adjustments to amputation and functioning and satisfaction with prosthesis, and to study the various factors influencing these in lower limb amputees, including the role of adjustment to amputation, and functioning and satisfaction with prosthesis on QoL.

In **Chapter 2**, the results of a systematic literature review (SLR) about QoL in lower limb amputees (LLA) are presented. Applying the standard methodology for conducting an SLR, 26 studies were identified. To evaluate the quality of these 26 relevant studies, the representativeness, reliability and validity of the studies were assessed. Gaps were found in the methodological and study population characteristics of most of the studies. Prospective longitudinal studies are envisaged to systematically study the events following amputation, and the change in QoL over time. To enable this, amputee specific standardized and validated QoL instruments are needed to capture the multitude of facets influencing QoL in amputees, and which would facilitate a direct comparison across studies.

QoL assessment to determine health outcomes is relatively a new research approach worldwide. Therefore, such research is limited in India and other developing countries. This means that instruments to assess QoL, which are used frequently in international research, have to be tested for reliability and validity in the Indian context. In **Chapter 3**, the psychometric analyses of the main outcome variable of this study 'QoL' are reported. The adapted and translated version of SF-36 (MOS Short-form health survey) in Hindi was used for assessment of QoL. Cultural adaptations were made to suit the Indian context, as is also done in other international validation

studies. The instrument was administered in the Indian general population, and its validity and reliability studied using item and scale level consistency methods. The prescribed internal consistency criteria were met at item and scale levels. The SF-36 scales demonstrated discriminant validity across different socio-economic groups. Two summary subscales, i.e. a physical component (PCS) and a mental component (MCS) were identified in line with the outcomes of international validation studies. Therefore, SF-36 can be advocated for use in the Indian general population to assess the quality of life, as well as can be used in different diseased populations. A study involving a larger sample size and repeated measures at different time points is envisaged to capture differences in quality of life.

Chapter 4 investigates the factors contributing to the adjustments to amputation and prosthesis. The study population (n = 368) comprised of prosthesis users and was derived from a larger sample of amputees (see **Chapters 5 and 6**). The Trinity Amputation and Prosthesis Experience Scale (TAPES) was administered along with background (socio-demographic and medical), amputation (time since amputation, reason of amputation, amputation level, phantom limb pain, residual stump pain, stump-skin condition), prosthesis use and assistive device use related information using face-to-face interviews. The TAPES is a multidimensional questionnaire assessing adjustment to amputation and prosthesis and is developed specifically for amputees. The TAPES subscales (ordered along psycho-social adjustment, activity restriction, and prosthesis satisfaction) showed overall internal consistency. Regression analyses were performed with TAPES subscales as the outcome variables. Being younger and employed, daily use of prosthesis and non-use of assistive device were the most important factors associated with positive adjustment to amputation and prosthesis (TAPES subscales), followed by being male, absence of comorbidity and lower amputation level. Employment contributed the most in influencing adjustment to amputation and prosthesis, followed by daily use of prosthesis although to a much lesser extent. The other background, amputation, prosthesis and assistive device use related variables were found not to affect amputees' adjustment to amputation and prosthesis.

Chapter 5 studies the influence of background (socio-demographic, medical), amputation, prosthesis and assistive device use related variables on QoL. Apart from these variables, in **Chapter 6**, we introduced information on the adjustments to amputation and prosthesis (TAPES subscales). The analysis on the relationship between socio-demographic, medical and amputation related factors and QoL was based on a cross-sectional study involving (n=605) 18 years and above lower limb amputees. A convenience sample was taken from a limb fitting center, a rehabilitation center, and four limb fitting camps. Face-to-face interviews were conducted using

structured questionnaires, which included patient's socio-demographic (gender, age, education, employment, marital status), medical (co-morbidity) data, amputation related information (cause of amputation, type of amputation, use of assistive devices/prosthesis, stump problems, phantom pain) and quality of life (SF-36). Several amputation related factors were studied across different levels of amputees. QoL was assessed using PCS and MCS (physical and mental component summary) scores. Multivariate regression analyses were performed to study the influence of potential variables on QoL. Also the scores of QoL (PCS and MCS) of amputees were compared with the scores of a sample of the general population. SF-36 PCS and MCS scores were found to be significantly lower for amputees when compared to those for the general population. Employment status, use of an assistive device, use of prosthesis, lack of comorbidities, phantom limb and residual stump pain were associated with both better PCS and MCS scores. Younger age and a longer time since amputation were associated with better PCS scores. These variables explained 47.8% of the variance in the PCS and 29.7% in the MCS scores.

The influence of adjustment to amputation and prosthesis on quality of life (PCS and MCS) was investigated in a total of 368 amputees, i.e. those amputees who were using prosthesis (**Chapter 6**). Hierarchical regression analyses were performed by controlling for socio-demographic, medical, and amputation related factors in the analyses. The socio-demographic factors (being employed and being young), health related factor (absence of comorbidity), amputation related factor (absence of residual stump pain), and the TAPES subscales (less functional restriction, being more adjusted to limitation, increased social adjustment, and less restriction in athletic activity) were related to better PCS scores. The health related factor (absence of comorbidity) and amputation related factors (absence of phantom limb pain and non-use of assistive device), and the TAPES subscales (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, while assistive device use and phantom limb pain had a modifying influence on MCS scores. The independent variables explained 65.7% and 47% of the variance in PCS and MCS scores respectively, indicating the important role of adjustment to amputation and prosthesis on QoL.

In the general discussion (**Chapter 7**), the main findings of the study are discussed and recommendations presented. This study provides insight into adjustments to amputation and prosthesis in lower limb amputees, and the influence of varied socio-demographic, medical and amputation-related factors, and adjustment to amputation and prosthesis on QoL of LLA. To make this study possible, we used

two instruments which are important in rehabilitation research, i.e. assessment of QoL (using SF-36), and adjustment to amputation and prosthesis (using TAPES). The current study population of lower limb amputees differs as compared to most international studies, which are mainly from 'western countries'. The persons of our sample are younger and the main cause for amputation is trauma. Despite the relative young age of the study population, over half of the amputees are unemployed. It is also to be noted that phantom limb pain, stump skin problems and residual stump pain are less frequent as compared to 'western studies'. This finding demands further research to gain insights to explain these differences. Such differences might arise as a result of differences in the activity level between the amputee populations.

Employment is the most important factor not only related to QoL but also associated with psychosocial adjustment and activity restriction. People who are employed tend to be more physically active and more psychosocially adjusted. Coming to work and performing the job would require the amputees to perform some physical activity as compared to a non-working person. So here is the question what affects what. Longitudinal research is needed to unravel the relationship between employment, adjustments to amputation and artificial limb and QoL.

A longitudinal study with the study sample recruited from the primary source, like hospital(s) is envisaged, which will systematically provide information about QoL after amputation, adjustments to amputation and prosthesis, and changes in QoL over time. A study sample derived in such a way will also provide evidence about the cause(s) of rejection and non-use of prosthesis.