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Age and health-related quality of life, general self-efficacy, and functional level 12 months following dysvascular major lower limb amputation: a prospective longitudinal study

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**ABSTRACT**

**Aim:** This study investigates the effect of time and age on health-related quality of life, general self-efficacy, and functional level 12 months following dysvascular major lower limb amputation (LLA).

**Methods:** A prospective cohort study design with assessments at baseline and follow-up 3, 6, and 12 months post-amputation. Data were collected via in-person interviews using Short Form 36, the General Self-efficacy scale and Barthel Index 100. Out of a consecutive sample of 103 patients having dysvascular major LLA (tibia, knee, or femoral), 38 patients completed the study. Outcome at follow-up was compared with baseline and analyzed in age groups.

**Results:** All SF36 subscale scores were below population norms at baseline. At 12 months, two out of eight scores—physical function and role-physical—had not improved. Different patterns of change over the 12 months were detected among the subscales, and psychosocial problems persisted and fluctuated throughout the 12 months in all age groups. Large differences were identified between age groups in physical function with the loss of physical function almost solely evident among the oldest (aged 75+ years) patients.

**Conclusions:** Special attention should be given to the oldest patients' need for rehabilitation so that they gain higher quality of life.

**IMPLICATIONS FOR REHABILITATION**

- Psychosocial problems persist and fluctuate throughout the first 12 months after major LLAs in all age groups and rehabilitation services should include psychosocial support throughout the first year to all patients independent of age.
- Waiting for an unnecessarily long period of time for a prosthesis can negatively impact both physical and psychosocial aspects of health-related QOL, and interventions to reduce waiting time are warranted.
- Differences between age groups in functional level after 12 months exist, with the loss of function almost solely evident among the oldest patients (aged 75+ years). A special focus should be given to the oldest patients' need of everyday rehabilitation to regain basic physical functions.

**Introduction**

Vascular disease is the most common cause of major lower limb amputations (LLAs) in the western world with dysvascularity (peripheral artery disease, diabetes, and infection) being the underlying cause of more than 90% of the cases \cite{1, 2, 3}. Patients having dysvascular LLA are characterized by high age (mean age >70 years) and multi-comorbidity \cite{1, 2}. The incidence of this procedure is expected to rise in the coming years due to the rising prevalence of Type 2 diabetes and an increasingly aging population \cite{4}. Mortality is high with recently reported rates being 22%–30% thirty days post amputation and 44%–54% after one year \cite{5, 6}. Survival rate of 5 years is as low as 25% \cite{5}. Following LLA, the focus of rehabilitation is to optimize function with a special focus on walking \cite{7}. Considering this, it is interesting to note that the reported number of patients regaining indoor walking ability varies from 25% to 97% \cite{8, 9, 10, 11}. These differences could be explained by a difference in populations since the majority of studies included selected populations of patients referred for prosthesis rehabilitation which could mean that success rates are probably lower in unselected populations. Short life expectancy combined with the fact that regaining walking ability on a prosthesis is not a realistic option for a considerable proportion of patients after dysvascular LLA \cite{7} makes it vital to target rehabilitation and long-term care based on factors contributing to quality of life for the individual.

Although there are differences in definitions, the concepts of quality of life (QOL) and health-related quality of life (HRQOL) are used interchangeably in the literature \cite{12}. QOL is defined 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” \cite{13}. HRQOL is defined as “the functional effect of a medical condition and/or its consequent therapy upon a patient” \cite{14}. HRQOL is thus the subjective and multidimensional concept measured with self-reported
instruments and encompasses physical and occupational function, psychological state, social interaction, and somatic sensation. The only amputee-specific HRQOL measures available involve life with prosthesis [15].

Lower HRQOL has been found in individuals after dysvascular LLA when compared with LLA for other reasons such as trauma or cancer [16] and when compared with age- and gender-matched controls [17]. A recent systematic review of factors influencing QOL among patients after dysvascular LLA identified walking with a prosthesis as the most notable factor influencing QOL [18]. Other factors identified to influence HRQOL were age, gender, level of amputation, comorbidities, and social support. All these factors were described as influencing HRQOL indirectly through the ability to walk with a prosthesis [18]. These findings could be biased by the selected samples of individuals attending prosthesis fitting who were included in the studies and factors influencing HRQOL among those not attending prosthesis fitting is unknown.

It has been suggested that the association between walking and HRQOL is due to the positive influence of walking abilities on social interaction [19] and that even small amounts of walking can result in greater HRQOL [20]. Further research, however, is needed to confirm this. Another suggestion is to evaluate HRQOL and functional outcome relative to the pre-morbidity levels to obtain a more detailed understanding of what makes goals of rehabilitation successful with each individual [20].

Having a LLA constitutes a major life-changing event [21] and adapting to the new life situation is found to be highly correlated with HRQOL [22]. The process of adaptation to life after leg amputation involves, among other things, symptoms of perceived loss, changes in body image, and social discomfort [23, 24] and has been found to be more strongly associated with decreased HRQOL than physical health among older people [25]. The process of adaptation may be different in individuals who are older than those who are younger. While both more, less and no difference in psychological disturbance, have been reported among older individuals when compared with younger individuals with LLA, it has been hypothesized that older people with more life experiences may have more ability to adapt psychologically in extreme adverse circumstances [25]. On the other hand, ageism may limit support for older patients and affect their ability to make successful psychological adjustments. HRQOL has been reported to change over time especially during the first 12 months post-amputation [17, 20]. To target rehabilitation and long-term care to person-centered needs, longitudinal studies, which include older patients, are needed to identify at what point which aspects of HRQOL change.

In the literature on HRQOL after dysvascular LLA, one unexplored element that could extend the understanding of the psychosocial consequences of amputation is measuring of self-efficacy. Self-efficacy originates from cognitive theory and refers to the extent to which an individual believes that she/he can perform in a specific situation [26]. Perceived self-efficacy is typically evaluated using self-reported instruments which focus on either one specific skill or more general instruments when a wider range of activities, skills, and conditions are of interest. An example of such a measure is the General Self-Efficacy (GSE) scale [27]. The GSE has recently been shown to correlate to measures related to daily activities, falls, functional disability, life satisfaction, and depressive symptoms in persons with Parkinson’s disease. Moreover, the GSE has been shown to be positively correlated to the number of hours a day prostheses were used among a sample of non-vascular amputees [28]. Given the relationship between self-efficacy, motivation, and improved coping, it is likely that an individual’s self-efficacy would affect their adaption and functional outcome and thereby their HRQOL.

This study aims to investigate the effect of time and age on HRQOL, GSE, and functional level 12 months following dysvascular major LLA.

**Methods**

**Design**

A prospective cohort study design was used with assessments at baseline and follow-up after 3, 6, and 12 months, respectively. This study is reported in concordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [29].

**Sample and setting**

Participants were recruited from a consecutive sample of patients who had primary major LLA (amputation at tibia, knee, or femoral level) due to complications of peripheral disease or diabetes in the orthopedic wards of two rural hospitals in Denmark from April 2015 to April 2016. Excluded were patients with a diagnosis of dementia documented in the record, severely deteriorated health lasting ≥ day 21, and patients who could not speak Danish as they were assessed not eligible for interviews.

**Data collection**

At baseline, patients were approached for consent to participate on days 3–6 post-amputation. Baseline assessments were performed whenever possible thereafter (at the latest on day 21) via in-person interviews and included measures of perceived HRQOL, GSE, and functional level the month preceding the amputation. HRQOL was measured using Short Form 36v2 (SF36) for interviews [30]. SF36 is a multipurpose short-form health survey which addresses eight domains that contribute to HRQOL: physical function, role-physical (how much physical problems is experienced to limit participation in, e.g., usual activities), pain, general health, vitality, social function, role-emotional (how much emotional problems is experienced to limit participation in, e.g., usual activities), and mental health. Each domain scale ranges from 0 to 100 with higher values representing better HRQOL. GSE was measured with GSE scale [27]. GSE scale measures GSE for 10 items and each of these items is rated on a four-point likert scale. Each item is formulated as positive statements such as “Thanks to my resourcefulness, I can handle unforeseen situations.” Possible responses include the following: (1) not at all true, (2) hardly true, (3) moderately true, and (4) exactly true. Scores range from 10 to 40 and a higher score equals better self-efficacy. Functional level was assessed with Barthel Index 100 [31] (hereafter referred to as Barthel). Barthel measures the level of assistance an individual needs to perform 10 activities of daily living: personal hygiene, bathing self, eating, toilet, dressing, bowel control, bladder control, ambulation or wheelchair (if no ambulation), chair/bed transfers and stair climbing. Overall scores range from 0 to 100. Each item is scored on a five-point likert scale (0–5, 0–10, 0–15, respectively) where the highest score represents independence in the activity. All baseline interviews started with the sentence: “In the following questions, I am asking you about the month BEFORE your amputation.”

Follow-up at 3, 6, and 12 months post-amputation was performed in participants’ homes using the same battery of instruments used at baseline (SF36, GSE, and Barthel). Additionally,
participants were asked whether they had received a prosthesis. The first author performed all interviews. Patients were encouraged to bring a relative to all occasions if preferred; an option taken by a total of 10 patients. Medical records were reviewed for clinical and demographic data on all patients having LLA during the study period by a specially trained physiotherapist and the first author. All data were documented directly into a trial software (http://www.easytrial.net).

**Statistical analysis**

To compare participants with non-participants, proportions of characteristics were calculated for “included vs excluded” and “completed study vs dropped out or deceased.” Differences were tested with the Chi square test of homogeneity or Fisher’s exact test for categorical variables and Mann–Whitney U-test for continuous variables.

To investigate changes in HRQOL, GSE, and functional level over time, mean values were calculated from the eight SF36 domains, the GSE and the Barthel overall score, as well as for each activity item individually: at baseline (1-month pre-amputation) and at 3, 6, and 12 months follow-up. A Wilcoxon signed rank test was used to test mean difference between scores at each follow-up with baseline scores.

To investigate whether HRQOL, GSE, and Barthel change in different patterns related to age, the sample was divided into three age groups: younger (<65 years), older (65–74 years), and oldest (75+ years). A Kruskal–Wallis H test was run to determine if there were differences in the SF36 median subscale scores, the GSE and the Barthel (overall and individual activities), respectively, from baseline and through follow-up between the three age groups. For statistically significant relations, pairwise comparisons were performed using Dunn’s (1964) procedure with a Bonferroni correction for multiple comparisons. Differences between age groups regarding decline in functional level at 12 months were tested by comparing differences in Barthel score (overall and individual activities) at 12 months compared with baseline using a Kruskal–Wallis H test.

Finally, multiple regression analysis was conducted to explore the potential predictive value of age and GSE at baseline on each of the outcome variables at 12 months (Barthel, SF36, and GSE) when controlled for gender, ASA score, level of amputation, and the outcome variable score at baseline.

Optum Smart Measurement System Scoring Solution was used to score SF36. As recommended, SF36 norm-based scores were used [32]. IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA) was used for the statistical analysis described. Descriptive data were reported as number and percentage and mean ± standard deviation as appropriate. Level of significance was set at a p value of <0.05 for all analyses.

**Ethics**

The study was conducted in accordance with the basic principles for research given in the Helsinki Declaration and the Northern Nurses’ Federation (2003). It was approved by the Danish Data Protecting Agency (Region Sjælland j.nr. 12-000179) and was presented to the Regional Ethics Committee whose secretariat did not find the project notifiable under Danish law (Region Sjælland j.nr. 12-000660).

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**Results**

Out of the 103 patients who were eligible for inclusion, 58 participated at baseline (Figure 1). Of the 45 patients not participating, 27 were excluded because of dementia, deteriorated health or confusion, nine were deceased before inclusion, three were identified too late to be included and six declined. Patients who participated were younger (69 vs 77 years, p < 0.001) (Table 1), more likely to be male (74 vs 53%, p = 0.037) and to have had a transfibial amputation (40 vs 7%, p < 0.001) than those not participating.

In all, 38 patients completed the study. There were no statistically significant differences in characteristics or how the patients reported their HRQOL (SF36), GSE, or functional level (Barthel) among those who completed the study and those who dropped out or were deceased (Table 1) except for how much emotional problems was experienced to limit participation in, for example, usual activities (SF36 subscale role-emotional). Patients who completed the study experienced less limitations because of emotional problems at baseline than those who dropped out or were deceased respectively (44.4 vs 41.3/33.5, p = 0.050).

In all, 28 out of the 38 patients who completed the study had got a prosthesis at 12 months follow-up (74%) with a mean time of 161 days (range: 34–313 days, ±79) from amputation to first time they had a prosthesis to use at home (data not shown).

Changes in HRQOL, GSE, and functional level at 3, 6, and 12 months compared with baseline are presented in Table 2. Patients reported their HRQOL below population norms in all eight domains of SF36 at baseline (<47, Table 2), which means that the patients’ HRQOL the month before amputation was hampered in all domains. At 12 months, patients reported their HRQOL below population norms in two domains, physical function and experienced limitations because of physical function (role-physical). Patients reported different aspects of HRQOL changed in different patterns over the 12 months. The patients’ physical
function decreased from baseline to 3 months, increased to baseline level at 6 months, and then further increased at 12 months ending at a level not statistically significantly higher than baseline and still lower than population norm scores. A steady increase in HRQOL was seen in four domains (role-physical, pain, general health, and vitality) from baseline to 3, 6, and 12 months follow-up, respectively. Social function increased from baseline to 3 and 6 months and then dropped at 12 months though the difference from 6 to 12 months was not statistically significant (mean difference: −1.3, SD: 13.0, p = 0.779). The mental health and limitations caused by emotional problems (role-emotional) improved at 3 months, dropped at 6 months, and then increased again at 12 months. From 3 to 6 months, the mean difference was −1.4 (SD: 10.7, p = 0.257) for role-emotional and −2.1 (SD: 7.9, p = 0.240) for mental health. From 3 to 12 months, the difference was 1.9 (SD: 14.1, p = 0.460) for role-emotional and 1.6 (SD: 9.2, p = 0.155) for mental health. Thus, the observed changes were not statistically significant.
Table 3. Barthel index 100 scores 3, 6, and 12 months post-amputation compared with baseline.

<table>
<thead>
<tr>
<th></th>
<th>n = 38</th>
<th>Baseline mean (SD)</th>
<th>3 Months mean (SD)</th>
<th>Difference mean (SD)</th>
<th>p value*</th>
<th>6 Months mean (SD)</th>
<th>Difference mean (SD)</th>
<th>p value*</th>
<th>12 Months mean (SD)</th>
<th>Difference mean (SD)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal hygieneb</td>
<td>4.6 (0.9)</td>
<td>4.7 (0.7)</td>
<td>0.1 (0.8)</td>
<td>0.541</td>
<td>0.019</td>
<td>4.8 (0.5)</td>
<td>0.2 (1.0)</td>
<td>0.233</td>
<td>4.9</td>
<td>0.2 (1.0)</td>
<td>0.145</td>
</tr>
<tr>
<td>Bathing</td>
<td>4.2 (1.3)</td>
<td>4.0 (1.1)</td>
<td>−0.2 (1.5)</td>
<td>0.188</td>
<td>0.017</td>
<td>4.1 (1.0)</td>
<td>−0.01 (1.4)</td>
<td>0.314</td>
<td>3.9</td>
<td>0.3 (1.4)</td>
<td>0.052</td>
</tr>
<tr>
<td>Eatingc</td>
<td>4.9 (0.4)</td>
<td>5.0 (0.2)</td>
<td>0.1 (0.4)</td>
<td>0.257</td>
<td>0.107</td>
<td>5.0 (1.0)</td>
<td>0.1 (4.1)</td>
<td>0.102</td>
<td>5.0</td>
<td>0.0 (2.2)</td>
<td>0.414</td>
</tr>
<tr>
<td>Toiletf</td>
<td>9.6 (1.6)</td>
<td>8.1 (2.9)</td>
<td>−1.5 (2.9)</td>
<td>0.005</td>
<td>0.510</td>
<td>8.5 (2.8)</td>
<td>−1.0 (2.7)</td>
<td>0.028</td>
<td>8.2</td>
<td>−1.3 (3.1)</td>
<td>0.010</td>
</tr>
<tr>
<td>Clothing</td>
<td>9.1 (1.9)</td>
<td>8.6 (2.1)</td>
<td>−0.5 (2.1)</td>
<td>0.147</td>
<td>0.177</td>
<td>8.5 (2.1)</td>
<td>−0.6 (2.0)</td>
<td>0.117</td>
<td>8.7</td>
<td>−0.4 (2.0)</td>
<td>0.177</td>
</tr>
<tr>
<td>Bowel controlg</td>
<td>9.4 (1.6)</td>
<td>9.4 (2.0)</td>
<td>−0.1 (1.7)</td>
<td>0.862</td>
<td>0.314</td>
<td>9.6 (1.8)</td>
<td>0.2 (1.9)</td>
<td>0.579</td>
<td>9.3</td>
<td>−0.2 (2.2)</td>
<td>0.931</td>
</tr>
<tr>
<td>Bladder controlh</td>
<td>9.6 (1.8)</td>
<td>9.1 (2.2)</td>
<td>−0.5 (1.5)</td>
<td>0.068</td>
<td>0.721</td>
<td>9.4 (1.6)</td>
<td>−0.1 (1.9)</td>
<td>0.660</td>
<td>9.2</td>
<td>−0.4 (1.8)</td>
<td>0.221</td>
</tr>
<tr>
<td>Ambulationi</td>
<td>12.5 (4.1)</td>
<td>2.6 (5.4)</td>
<td>−9.9 (6.1)</td>
<td>&lt;0.001</td>
<td>0.004</td>
<td>5.7 (6.8)</td>
<td>−6.8 (6.4)</td>
<td>&lt;0.001</td>
<td>9.0</td>
<td>−3.6 (6.3)</td>
<td>0.004</td>
</tr>
<tr>
<td>Bed–chair transforder</td>
<td>14.8 (0.7)</td>
<td>13.1 (3.6)</td>
<td>−1.7 (3.6)</td>
<td>0.005</td>
<td>0.019</td>
<td>13.4 (3.7)</td>
<td>−1.4 (3.7)</td>
<td>0.026</td>
<td>13.2</td>
<td>−1.4 (4.0)</td>
<td>0.012</td>
</tr>
<tr>
<td>Climbing stairsj</td>
<td>5.8 (4.3)</td>
<td>1.6 (3.3)</td>
<td>−4.2 (4.9)</td>
<td>&lt;0.001</td>
<td>0.001</td>
<td>3.2 (4.3)</td>
<td>−2.6 (4.7)</td>
<td>0.003</td>
<td>4.7</td>
<td>−1.2 (4.7)</td>
<td>0.127</td>
</tr>
</tbody>
</table>

*aWilcoxon signed-rank test, three, six and twelve months compared with baseline (one month pre amputation). bScore 0–5: 0 = not actively contributing in activity, 5 = performing the activity independently. cScore 0–10: 0 = not actively contributing in activity, 10 = performing the activity independently. dScore 0–15, 0 = not actively contributing in activity, 15 = performing the activity independently.

The patients reported their GSE improved from baseline to 3 months with a statistically significant difference of 1.4 (CI: 0.2–2.6, p = 0.04). This improvement in self-efficacy disappeared at 6 months and was not detected at 12 months (Table 2).

Functional level measured as level of independence in activities of daily living (Barthel overall score) decreased from baseline (84.79, SD: 12.86) to the lowest level at 3 months (69.55, SD: 16.31), a statistically significant mean difference of −15.2 (CI: −19.9 to 10.5, p = 0.001) (Table 2). At 6 months, patients’ functional level (Barthel) had improved to 74.6 (SD: 17.4) and at 12 months to 77.2 (SD: 20.4). However, with a statistically significant mean difference of −7.6 (CI: −13.2 to −2.0, p = 0.019) in Barthel score at 12 months compared with baseline, the patients as a group had not regained the level of independence in activities of daily living after 12 months they had before the amputation.

When looking at the Barthel activities one by one (Table 3), it was revealed that patients had statistically significantly lower function in 4 of 10 Barthel activities at 3, 6, and 12 months, respectively, compared with baseline (toilet, ambulation, transfer and stair-climbing at 3 and 6 months/toilet, bathing self, ambulation, and transfer at 12 months). The remaining six functions were unaltered compared with baseline at all three time points. The biggest decline, at 12 months (compared with baseline), was found in ambulation and bed–chair transfer. Changes over time followed almost the same pattern for all activities with the lowest scores observed at 3 months and then improving from there. One exception was the bed–chair transfer. Here, the lowest score was found at 3 months with a modest improvement at 6 months and a small decrease at 12 months (mean difference from 6 to 12 months −0.3, SD: 1.5, p = 0.357).

A Kruskal–Wallis H test was run to determine if there were differences in how patients reported their HRQOL (SF36 subscale scores), their GSE, and their functional level (Barthel individual activities), respectively, from baseline and through follow-up, between individuals in three age groups: younger (<65, n = 11), older (65–74, n = 18), and oldest (75+ years, n = 9).

No differences were detected between the three age groups in seven of eight domains at any time point when the eight SF36 domains were tested. The difference detected in the eighth domain (physical function) is illustrated in Figure 2. Physical function at 12 months was found to be statistically significantly different between age groups (χ²(2) = 8.478, p = 0.014). Subsequently, pairwise comparisons were performed using Dunn’s (1964) procedure with a Bonferroni correction for multiple comparisons. The adjusted p value is presented. This post hoc analysis revealed a statistically significant difference in physical function between the younger (36.52) and the oldest (23.09) (p = 0.001), but not between the older (31.71) and any other group combination.

When tested in a multiple regression analysis; however, age was not found to predict lower physical function when controlled for gender, ASA score, level of amputation, and physical function at baseline. It should be noted that not all requirements for performing multiple regression analysis were fulfilled. One-third of the sample had leverage values >0.2 which could reduce the predictive accuracy of the results as well as statistical significance. This reservation applies to all the multiple regression analyses performed.

As mentioned above, no differences were detected among the three age groups in how they reported their HRQOL in the other seven SF36 domains (role-physical, pain, general health, vitality, social function, role-emotional, and mental health (data not shown)). Similarly, the Kruskal–Wallis test did not reveal any differences in how patients reported their GSE between the three age groups at any time point (data not shown).

A multiple regression analysis was performed to explore the potential predictive value of age and GSE on HRQOL at 12 months. This analysis confirmed the results described above by not revealing any correlations between age and six of these seven SF36 domains or the level of GSE at 12 months. One found exception was that higher age was related with more experienced limitations because of physical function (SF36 role-physical) (F(2,35) = 8.893, p = 0.001, adj R² = 0.299).

Lower GSE at baseline was only related to the level of GSE at 12 months F(1,36) = 17.389, p < 0.001, adj R² = 0.307.

At baseline, there were no differences in functional level between the three age groups, either measured as Barthel overall or in any of the 10 activities of daily living measured with Barthel. This is illustrated in Figure 3. At 3 months, the oldest patients had
a higher need of assistance in bathing, dressing, and ambulation than younger and older patients. Stair-climbing was observed to be harder to the oldest patients than younger patients compared with their baseline scores. These differences were statistically significant ($p < 0.05$). At 6 months, the oldest patients had a higher need of assistance in dressing than the younger patient and were also in more need of assistance in self-bathing than both younger and older patients ($p < 0.05$). At 12 months, the oldest patients had a higher need of assistance in personal hygiene, self-bathing, and dressing than the younger and older patients. Furthermore, they were in more need of assistance in toileting than younger patients and had more difficulties in stair-climbing than older patients ($p < 0.05$). No difference between the age groups was detected in eating, bowel, and bladder control.

When functional level among the three age groups at 12 months was compared with functional level at baseline, the oldest had the biggest decline of all three age groups in Barthel overall score with a mean difference for the younger, older, and oldest of $-0.5$ (SD: 9.7), $-3.7$ (SD: 14.5), $-24$ (SD: 19.4), $\chi^2 (2)=9.676$, $p = 0.008$, respectively. This result was confirmed in a multiple regression analysis when controlled for gender, ASA score, level of amputation, GSE, and functional level at baseline. Here, higher age at baseline statistically significantly predicted lower functional level at 12 months ($F(6,31)=15.525$, $p < 0.001$, adj. $R^2=0.440$).

**Discussion**

The aim of this study was to investigate the effect of time and age on HRQOL, GSE, and functional level 12 months following dysvascular major LLA.
Based on prospectively longitudinal collected data, this study shows that patients having dysvascular LLAs have better HRQOL 12 months after amputation in all domains except physical function when compared with 1 month prior to amputation and are significantly more dependent on assistance in activities of daily living measured at group level. When looking at individuals, significant differences exist in functional level achieved. The physical, social, and mental domains of HRQOL (SF36) change in different patterns over the first 12 months. All SF36 domains, being below population norms at baseline, reflect the vulnerability of patients having major dysvascular amputations, at time of surgery. In line with our findings, Fortington et al. [17] reported HRQOL scores below population norms at time of amputation though not in the general health and mental health subscales in a longitudinal study of HRQOL after dysvascular LLA. That study included 35 patients up to 5 days post-amputation who filled in the HRQOL questionnaire at three times points. The difference might be explained by differences in study design: the present study recruited patients from a consecutive sample of patients having dysvascular amputations until day 21 after amputation and administered the HRQOL measures as interviews and were thus able to include more vulnerable patients who would have been otherwise excluded.

Already at 3 months, patients reported fewer problems with pain and had improved general health and vitality comparable to a stable level above population norms. In the above described study of Fortington et al. [17], this positive change was found at 6 months post-amputation; however, HRQOL was not measured from baseline until 6 months and it is therefore unknown whether the improvement was present already at 3 months.

Interestingly, patients reported less limitation caused by their physical health (role-physical) already 3 months post-amputation although their physical function had the lowest scores at that point. That less limitation was reported could reflect the fact that physical function is not the only impact on physical limitations experience. The high level of pain, low general health, and vitality patients reported at baseline could have been experienced as limitations that are no longer present after 3 months.

Another explanation could be that expectations and importance of different aspects of HRQOL might not be the same after experiencing life-changing events such as a LLA [21]. Such a response shift (a shift in the person’s self-evaluation of the construct rather than a change in the construct itself) has previously been reported in LLA populations [33,34].

Patients reported the psychosocial aspects of their HRQOL at below population norms at baseline. This is important to be aware of when caring for these patients both pre- and post-amputation [21]. Patients reported their social function, experienced limitations in life caused by emotional challenges (role-emotional), experienced problems with mental health, and GSE fluctuating throughout the first 12 months after the amputation. That these changes were not statistically significant could be because of the relatively small and heterogeneous sample which contained large differences in scores between individuals. Combined with the above-mentioned potential of response shift, it should also be kept in mind that people who report extreme values in studies with repeated measures sometimes try to equalize their answers in later assessments [35]. That being said, these changing patterns might reflect the process of psychosocial adaption to disability that patients go through after a LLA [22,23,24] which indicates a need for psychosocial support at this stage of rehabilitation [24,38]. Six month post-amputation has been suggested as appropriate time for counseling to relieve the common emotional and mental problems of depression, distress, sleeplessness, and anxiety [38]. Support groups could be another appropriate intervention that patients prefer [39]. Not all patients need of counseling as some experience few if any psychological problems [37]. Some patients report having psychological gains when amputation results in less pain, less restrictions in mobility, and better general health and vitality [40]. This was also found among our participants. With limited resources available, it becomes crucial to identify those patients in most need for such psychosocial interventions. This should be further explored.

Whether older people adapt differently to leg loss than younger people has been debated and which age group is more or less psychosocial affected has also been discussed [25]. In this longitudinal study, we found no difference among younger, older, or oldest patients regarding how they reported the level of any of the psychosocial sub-scales of SF36 or the GSE scale. This finding contrasts with a study which suggests that activity restrictions cause older people less distress because of lower expectations about functional capacity [36]. It also contrasts with a large study of HRQOL among patients having upper- and lower-limb amputations which found better HRQOL including emotional responses are independently associated with younger age [41].

Our findings are in line with other studies which report depression and adjustment to amputation is independent of age [37,42]. The above-mentioned differences could be attributed cross-sectional design and study limitations excluding the oldest people. Reporting problems with psychosocial aspects of HRQOL is not the same as wanting healthcare interventions, and future appropriate designed studies should investigate whether the need for psychosocial interventions differ between age groups.

Measuring physical function with both SF36 (physical function subscale) and Barthel revealed some interesting details. Patients had the poorest physical function 3 months post-amputation in both measures. At 12 months, the patients’ physical function (SF36 subscale) had increased yet it was no different from baseline. Nonetheless, patients had a clinically significant decrease in functional level at 12 months when measured with Barthel. This loss of physical function, whether it was measured with SF36 (physical function subscale) or Barthel, was unevenly distributed among age groups.

All age groups had equal scores at baseline with the lowest scores coming after 3 months, but the oldest group reported only small gains in functional level and was carrying the biggest loss of physical function at 12 months. This contrasted with the younger and older patients who regained their level of physical function from 1 month before the amputation or even improved. Although it is well documented that age influences physical function after LLA [7,8,18], comparisons of these results are difficult because of diversity in outcome measures [15], populations studied [18,43] and the fact that the majority of studies in HRQOL are performed more than 12 months post-amputation [18]. More studies are required to find out whether the oldest physical potential is exhausted or other factors, such as differences in the extent and type of rehabilitation provided, provide accounts for some of these differences in achieved functional outcome.

The results of the individual activities of Barthel add some notable details to the loss of function over time when compared to functional level at baseline. We found patients were more dependent on help than before amputation in four activities at all three time points measured and had significantly lower function in toilet, self-bathing, ambulation, and bed–chair transfer still present at 12 months. Big individual differences were detected though, and final decline was almost solely found among the oldest (age 75+ years). It is important to note that all age groups had the same level of scores at baseline. The biggest decline was found in ambulation. Being independent in ambulation after LLA
naturally depends on whether the patient has a prosthesis. In our study, 28 patients (74%) were provided a prosthesis and had the first prosthesis with them home within the mean time of 161 days with a wide range of 34–312 days. Depending on the population studied and criteria for assessment, the proportion reported having had a prosthesis differed from 5% to 100% [44]. Having a prosthesis is not the same as walking successfully; yet being provided with a prosthesis is a prerequisite to ambulate, and the time spent waiting for the prosthesis explains part of the loss of ambulation skills at 3 and 6 months in our study.

The second biggest decline was found in bed–chair transfer. Again, the oldest were the ones most affected with decline already evident at 3 months and no signs of improving from that point. Although early mobilization is possible even among the heterogeneous population of patients having vascular amputations [46], it is known that hospitalized older people lose basic functions due to immobilization during their in-hospital stay [45]. A short, early pre-prosthetic rehabilitation intervention can result in independence in bed–chair transfer for 80% of a sample comparable to ours [47]. From the same cohort as the present study, it has been reported that 40% of the sample were dependent on assistance in bed–chair transfer on day 21. Independence in bed–chair transfer was positively associated with lower age and physiotherapy initiated after discharge [48]. The authors conclude that short-term functional outcome is modifiable by care provided. They highlight the need of increased focus on postoperative care to maintain independence in activities of daily living as well as to establish and provide everyday rehabilitation in the general population of patients having vascular LLA with special focus on older patients. These findings, however, need to be tested in experimental research.

Although some limitations must be considered, this study provides unique prospectively collected longitudinal data on the effect of time and age on HRQOL, GSE, and functional level the first 12 months after a vascular LLA. We managed to recruit 57% (n = 58) of a consecutive sample of which 34% (n = 45) of those eligible for the study were too ill to participate. Of those recruited, 63% (n = 38) completed the study. These numbers correspond with other studies on the dysvascular LLA population [17,49], but the relatively small sample represents a limitation especially when considering the heterogeneous population. This highlights the methodological difficulties of doing research in this field and highlights the need for attention to vulnerable patients having vascular amputations who are too ill to participate in research. Our analysis include those surviving until 12 months and though only small differences were found in characteristics of those completing the study and those who dropped out or were deceased, it is not reasonable to generalize the findings to the general patient population having dysvascular LLA.

We chose to perform all data collections as interviews and were thus able to collect complete data from even the frailler patients. One researcher performed all interviews minimizing the risk of difference in assessments. By measuring baseline HRQOL, GSE and functional level 1-month pre-amputation after amputation, there was a risk of recall bias. We considered recruiting patients pre-amputation but found that it was not feasible in the acute setting. Nonetheless, high compliance in recording this kind of data up to 6-week post-amputation has previously been documented [49]. Letting patients bring relatives to the interviews could affect their answers. This approach was chosen based on former studies in this population, where patients expressed preferred preference for having a relative present to support and help with memory. It has been found that even if the presence of a relative influences patients‘ answers, responses could still be close to the patients’ own answers. When relatives act as proxy and grade experiences of the patient, the difference in scoring between patient and proxy tends to be small with tendency for relatives to score slightly lower in function and higher in symptoms [50].

The SF36 is a generic HRQOL questionnaire and results can therefore be compared across different populations. The use of generic measures, however, does not identify issues that are of specific importance to the LLA population. The amputation-specific measures available are developed for individuals with prosthesis [15] and are thus not relevant to a significant proportion of patients having LLA due to vascular disease. Development and use of patient-recorded outcome measures (PROMs) [51] could be a solution for future studies.

This study reports unique prospective longitudinal data on patients after dysvascular LLA who survive 12 months and documents that significant improvement in more aspects of HRQOL can be achieved as soon as 3 months post-amputation. Psychosocial problems persist and fluctuate throughout the first 12 months in all age groups indicating the need for psychosocial support as part of the rehabilitation services provided. The patients reported their physical function causing them less limitation although the physical function never became better than the poor level at baseline. Differences were identified between age groups in physical function with loss of physical function almost solely evident among the oldest patients after 12 months. There is a need for more studies to determine whether the oldest patients’ physical potential is exhausted or if they could benefit from further rehabilitation to regain basic physical functions, thereby gaining higher QOL.

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