CHAPTER 3

PHYSICAL, MENTAL, AND SOCIAL PREDICTORS OF FUNCTIONAL OUTCOME IN UNILATERAL LOWER LIMB AMPUTEE PATIENTS

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Abstract

Objective: To study the value of physical, mental, and social characteristics as predictors of functional outcome of elderly amputee patients.
Design: Inception cohort study.
Setting: Main hospitals, rehabilitation centers, nursing homes, patients' own residence settings in the North of the Netherlands.
Patients: 46 patients older than 60 years, unilateral transtibial or transfemoral amputation or knee disarticulation due to vascular disease, living in one of the three northern provinces in the Netherlands.
Interventions: Measurement of physical, mental, and social predictors 2 and 6 weeks post-amputation.
Main Outcome Measures: Sickness Impact Profile (SIP68), Groningen Activity Restriction Scale (GARS), Timed “up & go” test (TUGT), prosthetic use.
Results: 15% died within the first year post-amputation. Seventy-percent of patients lived independently at home one year post-amputation. The functional level of the patients was low, as shown by high scores on the SIP68 (mean 23.6), the GARS (mean 41.2), and the TUGT (mean 23.9). Functionally prosthetic use as measured with the classification of Narang and Pohjolainen was reached by 49%. Of the SIP68-scores, age, comorbidity, one-leg balance, and the 15-Word test predicted 69%. The GARS-score prediction by age, one-leg balance, and the 15-Word test was 64%. Of the TUGT, age and one-leg balance predicted 42%. After correction for age, the only significant predictor for prosthetic use was one-leg balance.
Conclusions: Elderly patients with a leg amputation have a low functional level one year post-amputation. An important part of functional outcome could be predicted two weeks after amputation by age at amputation, one-leg balance on the unaffected limb, and cognitive impairment. Severe comorbidity probably also plays a role. The results may be used in the general policy concerning leg amputee patients.
**Introduction**

In the Netherlands 3,000 primary amputations of the lower limb are performed annually. Most patients are older than 60 years, and 80–90% of the amputations are performed as a result of vascular problems. The prediction of functional outcome is an important issue in rehabilitation medicine. The most important functional capabilities of elderly patients are in the field of personal care, household activities, and recreational activities.

Several predictors for functional outcome of amputee patients are mentioned in literature. In general, the functional capabilities of patients with a higher amputation level and a higher age are worse than that of younger patients with a lower amputation level. It is also generally accepted that the physical condition and the presence of comorbidity predict the functional possibilities after amputation. Especially cardiopulmonary diseases cause a lack of extra energy necessary for walking with a prosthesis. Other diseases affecting the locomotor system diminish the functional perspectives of amputee patients.

Characteristics of the stump are important for the success of prosthetic fitting. Persson and Liedberg and Pohjolainen reported a systematic description of the stump characteristics based on the Clinical Standard of Measurement and Classification of Amputation Stumps, defined at the ISPO (International Society of Prosthetics and Orthotics) congress in Bologna in 1980. Healing problems of the residual limb and restricted mobility in the joint proximal to the amputation cause a delay in prosthetic fitting and reflect a bad stump condition. In literature the negative relationship between stump pain and/or phantom pain and functioning is reported. However, it is not evident that the level of pain immediately after the amputation is predictive of a worse functional outcome.

Geurts described the problems people with an amputation have in maintaining their balance during the performance of dual tasks. Hermodsson showed an increase in lateral sway in a two-leg standing test of transtibial amputees, compared to healthy subjects. Standing balance is important in many daily activities and a good standing balance on the unaffected limb can be beneficial for the functional outcome of amputee persons, irrespective of prosthetic fitting.

Information about the predictive value of mental disturbances and cognitive impairments for the functional outcome after a lower limb amputation is scarce. Kashani et al described many amputee patients with depressive symptoms after an amputation. However, this was not confirmed by the studies of Frank et al and Furst and Humphrey. The relationship with functional outcome is unclear. Pinzur et al reported a relationship between the results of several psychological tests and the success of prosthetic fitting. Phillips et al found that amputee patients’ scores were lower for several neuropsychological tests, possibly due to the coexistence of peripheral vascular disease and cerebrovascular disease. In the study of Hanspal and Fisher there was a relationship between the mobility of the older amputee patient and the score on the Clifton assessment scale as a measurement for cognitive and psychomotor functions.

In clinical practice, rehabilitation specialists always stress the importance of the
social support of the family and friends in the functioning of the patient. This was also described in the study by Thompson and Haran.\textsuperscript{27} However, hardly any information about the predictive value for the rehabilitation outcome is available in literature. Helm et al\textsuperscript{5} and Nissen and Newman\textsuperscript{12} did not find a relationship between the social situation and the functional results of amputee patients.

Most studies concerning predictors for functional outcome after a lower limb amputation, are retrospective in view. In addition, most studies are carried out only on patients who have been referred for limb fitting. Amputees are not all candidates for a prosthesis; therefore, a course in rehabilitation to learn wheelchair use and transfer activities may also be beneficial. Most of the literature defines functional outcome only in terms of prosthetic use, but general measures of functional outcome with or without a prosthesis are equally important.

The purpose of our research was to study physical, mental, and social characteristics just after amputation, the functional outcome one year after amputation, and the predictors for functional outcome of elderly patients with a unilateral lower limb amputation. It is important, for clinical practise, to predict the functional outcome as soon as possible after the amputation. Our first intention was to predict two weeks after amputation the functional outcome after one year. However, we realised that this early measurement may be greatly influenced by the disease process that lead to the amputation or surgery, and therefore, we also studied predictive factors six weeks after amputation to see if this differed from the early prediction.

\textbf{Methods}

\textbf{Patients}

Patients met the following inclusion criteria: older than 60 years, a unilateral transtibial or transfemoral amputation or a knee disarticulation due to peripheral vascular disease with or without diabetes mellitus, living in one of the three northern provinces in the Netherlands. Patients were excluded if they were not able to understand the test instructions, or if they were severely disabled without any walking ability before the amputation for reasons not related to peripheral vascular insufficiency. Patients were recruited from the main hospitals of the three northern provinces in the Netherlands. Patients were asked to participate by their surgeon or by their rehabilitation specialist and were informed by the researcher (TS) or a research nurse. The patients also signed an informed consent before participating in the study. Ninety-seven patients were recruited by the surgeons and rehabilitation specialists (fig. 3.1). Ten patients were presented too late to participate. Twenty-one could not participate because of severe cognitive impairment or severe physical impairment (dying or very bad condition), and in the case of 2 other patients multiple reasons played a role. Thirteen refused to participate. Three patients died between 2 and 6 weeks after amputation and 2 refused to participate further in the study after the first measurement. A total number of 46 patients participated in the study. Table 3.1 shows the patient characteristics. This table also shows that primary
rehabilitation took place in a rehabilitation center in 67%, whereas 26% went to a nursing home to rehabilitate and 7% received another kind of treatment, predominantly physiotherapy at home.

**Design**

We performed a prospective cohort study with the inclusion of patients from October 1997 till June 2000. Patients were followed from two weeks to one year after the amputation. When a patient had a second amputation of the same leg within two weeks after the first surgery (only 2 patients), the first measurement was done 2 weeks after the second amputation. When the patient underwent a second amputation during the rest of the follow-up period, this was noted as a complication during follow-up. We visited participants 4 times: 2 weeks after amputation, 6 weeks after amputation, 6 months after amputation, and one year after amputation. At 2 and 6 weeks after amputation we measured the physical, mental, and social characteristics. Six months after the amputation we looked at the development of functional capabilities, and one year after amputation we measured the functional
Table 3.1  Patient characteristics (n=46)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>men</td>
<td>32 (70%)</td>
</tr>
<tr>
<td>age at the time of amputation: mean (SD) (yr)</td>
<td>73.9 (7.9)</td>
</tr>
<tr>
<td>amputation level</td>
<td></td>
</tr>
<tr>
<td>transtibial</td>
<td>33 (72%)</td>
</tr>
<tr>
<td>knee disarticulation</td>
<td>8 (17%)</td>
</tr>
<tr>
<td>transfemoral</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>primary location for rehabilitation</td>
<td></td>
</tr>
<tr>
<td>rehabilitation center</td>
<td>31 (67%)</td>
</tr>
<tr>
<td>nursing home</td>
<td>12 (26%)</td>
</tr>
<tr>
<td>other</td>
<td>3 ( 7%)</td>
</tr>
</tbody>
</table>

outcome parameters. In this article the results will be presented of measurements 1 and 2 (two and six weeks after the amputation) and 4 (one year after the amputation). At measurement 3 (6 months after amputation), most subjects were still in their rehabilitation process, and their definitive functional outcome could not be assessed. The researchers visited the patients where they were staying at the moment of the visit, i.e. at the hospital, the rehabilitation center, the nursing home, or at their own home. The study was approved by the Medical Ethical Committee of the University Hospital Groningen.

**Potential predictors of functional outcome**

The instruments used to measure the predictors had to be easily transported, useful at all locations, and minimizing the efforts of the elderly patients. Below, we describe the predictors analyzed and their scoring systems.

*Physical predictors:*
1. Age.
3. Healing of the stump: healed versus non-healed.
4. Extension of knee or hip: restricted versus unrestricted. Joint range of movement was measured in the joint proximal to the amputation with a goniometer. Normal knee extension is 0 to –10 degrees. Less knee extension was defined as restricted. Normal hip extension is 0 to –10 degrees. Less hip extension was defined as restricted.
5. Stump pain and/or phantom pain: none/little versus severe.
6. Standing balance on the unaffected limb: not possible, possible with support, possible without support ≤ 10 s, possible without support > 10 s. Detailed measurements, for example, on a balance platform, were not possible 2 weeks after the amputation and in all residence settings. The parameter we therefore used for standing balance was whether patients could stand on their unaffected limb, with or without support by a walking frame. The time they could stand on the unaffected limb was recorded with a stopwatch. During standing patients
were not allowed to hop and they wore their own shoe on the unaffected limb. The researcher was standing next to the patient, the walking frame before the patient, and a chair behind the patient to prevent them from falling.

7. Comorbidity: presence or absence of diabetes mellitus, cardiopulmonary disease, or other diseases/disabilities. Comorbidity was assessed using the combination of a structured self-report questionnaire and data from the medical records. In addition, the pulmonary function was measured with a portable spirometer. The Tiffinau index (i.e. the Forced Expiratory Volume/Forced Vital Capacity x 100%) is used as a measurement for obstructional disease.

Mental predictors:
1. Mood disturbances are measured with the Beck Depression Inventory (BDI). The BDI consists of 21 questions with 4 answer categories. The patient should report the feelings and emotions during the last week to assess the degree of depressive symptoms. A higher score indicates more depressive symptoms. The score ranges from 0 to 63.

2. The Cognitive Screening Test (CST) is a short questionnaire (20 items), based on the Short Portable Mental Status Questionnaire of Pfeiffer. It assesses orientation in time, place, and person, and general knowledge. A lower score indicates more cognitive impairment and the score varies from 0 to 20. An indication of severe cognitive impairment using the Cognitive Screening Test was defined as a score less than or equal to 15.

3. Memory. The 15-Word Test measures short term word memory and delayed recall after 15–30 minutes. The patient hears 15 words in 30 seconds on a tape recorder, and must reproduce as many words as possible. The words are repeated 5 times with reproduction of the subject. The score for the immediate reproduction varies from 0 to 75. In addition, decile scores can be calculated according to age and education level. After 15 to 30 minutes, the subject repeats all the words he still remembers without hearing the words again (delayed recall of 0 to 15 words). The delayed recall score can also be expressed as a decile score, related to the score of immediate reproduction.

4. Information processing and concentration. The Stroop Color-Word Test measures interference in cognitive functioning by color-word denomination. The patient reads 3 cards: one with 10 rows of 10 names of colors (printed in black), one with 10 rows of 10 rectangles of these colors, and one with 10 rows of colored words representing color names that were incongruent with the printed colors. The time score of the last card is taken in the analyses as an indicator of information processing. Decile scores can be calculated, related to the time necessary for the first two cards.

Social predictors:
1. Partner: present versus absent.

2. The Social Support Questionnaire-Interactions, 12 item version (SSL12-I), is a short version of the SSL-I. The questionnaire contains 12 questions with 4 answer categories, concerning everyday support, support in case of problems, and the degree of appreciation. The higher the score, the more support someone experiences. The score ranges from 12 to 48.
Functional outcome parameters

1. Sickness Impact Profile, 68 item version (SIP68). The SIP68 is a measure of "health-related changes in behavior associated with the carrying out of one's daily activities". The questionnaire consists of 68 items about behavior, subdivided into 6 categories: Somatic Autonomy, Mobility Control, Psychic Autonomy and Communication, Social Behavior, Emotional Stability, and Mobility Range. A total sumscore can be calculated in addition to the subscores on the different subscales.

2. Groningen Activity Restriction Scale (GARS). The GARS is a short questionnaire with 18 items assessing disability in the area of ADL (Activities of Daily Living including mobility) and also IADL (Instrumented Activities of Daily Living). It has a four-category response format:
   - 1 independent to perform the activity without any difficulty,
   - 2 independent to perform the activity with some difficulty,
   - 3 independent to perform the activity with great difficulty,
   - 4 unable to perform the activity independently.

   The score varies from 18 to 72. With a score of 18 the person can perform all the activities without any difficulty; with a score of 72 the person cannot perform any activity without the help of others.

3. Timed “up & go” test (TUGT). The Timed "up & go" test is performed in the following way: the patient is sitting on a standard arm chair (seat height 46 cm, arm height 67 cm) with his back against the chair, arms resting on the chair's arms and his walking aid at hand. The patient wears his regular footwear and uses his customary walking aid. On the word "go" the patient has to get up, walk to a line on the floor 3 meters away (on a standard carpet), turn, walk back to the chair, and sit down again. The patient can choose his own comfortable and safe walking speed. A stopwatch is used to time the performance (in seconds). This test could only be performed by patients with a walking ability one year after the amputation.

4. Prosthetic use. We used the classification as described by Narang et al and Pohjolainen et al:
   I. Ambulating with a prosthesis but without other walking aids
   II. Independent at home, ambulating with a prosthesis but requiring one or two walking sticks or crutches for outdoor activities
   III. Independent indoors, ambulating with a prosthesis and one stick or crutch, but requiring two crutches outdoors and occasionally a wheelchair.
   IV. Walking indoors with a prosthesis and two crutches or a walker, but requiring a wheelchair for outdoor activities.
   V. Walking indoors only short distances, ambulating mostly with a wheelchair.
   VI. Walking with aids but without a prosthesis
   VII. Nonambulatory except in a wheelchair, patient possesses a prosthesis
   VIII. Nonambulatory except in a wheelchair, patient does not possess a prosthesis
Analysis

We calculated with the premise of an explained variance of 30 to 50% and a power of .80, that we needed 100 participants to assess a reliable prediction of functional outcome. Statistics were performed using the Statistical Product and Service Solutions (SPSS). The association between the predictors and the Sickness Impact Profile, the Groningen Activity Restriction Scale, and the Timed “up & go” test, was shown by using univariate linear regression analyses. The association between the predictors and prosthetic use was shown by using univariate logistic regression analyses. Prosthetic use was therefore dichotomized in “functional use” (score I–IV) and “non-functional use” (score V–VIII). The associations found in the univariate analyses were used for preselection of variables to be included in the multivariate analyses. Prediction models were assessed with forward multivariate regression analysis. Age at amputation was entered as a basic variable in all multivariate analyses. Secondly, other predictors were included in the multivariate regression analysis when their P-value in the univariate analyses in the relationship with the dependent variable was ≤.05. The significance level in the multivariate analyses of predictors was chosen as \( \alpha = .05 \).

The differences in functional outcome scores between the groups with different scores on the one-leg balance test was tested with analysis of variance, with a correction for age at amputation.

Results

Physical, mental and social characteristics two and six weeks after the amputation

Table 3.2 shows the characteristics of the patients two and six weeks after amputation. Physical and mental characteristics apparently improved between the two measurements. According to Bouman et al\(^3\) the Beck Depression Inventory scores could be divided into 7 severity categories. Nineteen and 11 percent of the patients had a score above average on the intensity scale for depression at two and six weeks post-amputation, respectively. In our study population 10 amputee patients fulfilled the criteria for severe cognitive impairment two weeks post-amputation and only 4 patients six weeks after amputation according to the scores on the CST. On the immediate recall of the 15-Word Test, most people scored in the lowest 5 deciles (90% and 73%). On the delayed recall, 50% and 59% scored in the lowest five deciles. The decilescores on the Stroop Color-Word Test were very low. Ninety-seven percent and 81% scored in the two lowest deciles, and only 1 patient at t=1 and 2 patients at t=2 scored in the highest decile. The sumscores on the Social Support Questionnaire of 28.3 and 27.9 respectively were slightly higher than that of a healthy reference population of 245 healthy people in the north of the Netherlands (26.4).
Table 3.2  Characteristics two and six weeks after the amputation (n=46)

<table>
<thead>
<tr>
<th>Physical predictors:</th>
<th>2 weeks post-amputation</th>
<th>6 weeks post-amputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidity (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>diabetes mellitus</td>
<td>54</td>
<td>54</td>
</tr>
<tr>
<td>cardiopulmonary</td>
<td>67</td>
<td>67</td>
</tr>
<tr>
<td>other</td>
<td>80</td>
<td>85</td>
</tr>
<tr>
<td>Pulmonary function (FEV1%VC): mean (SD)</td>
<td>80.4 (14.4)</td>
<td>82.8 (19.4)</td>
</tr>
<tr>
<td>Non-healed scar on stump (%)</td>
<td>71</td>
<td>52</td>
</tr>
<tr>
<td>Limited extension of proximal joint (%)</td>
<td>50</td>
<td>31</td>
</tr>
<tr>
<td>Stump and/or phantom pain (%)</td>
<td>41</td>
<td>28</td>
</tr>
<tr>
<td>One-leg balance (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>not able to stand on one leg</td>
<td>42</td>
<td>17</td>
</tr>
<tr>
<td>able to stand on one leg with support</td>
<td>20</td>
<td>37</td>
</tr>
<tr>
<td>able to stand on one leg without support ≤ 10 s</td>
<td>22</td>
<td>17</td>
</tr>
<tr>
<td>able to stand on one leg without support &gt; 10 s</td>
<td>16</td>
<td>28</td>
</tr>
<tr>
<td>Mental predictors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beck Depression Inventory: mean (SD)</td>
<td>12.7 (10.2)</td>
<td>11.5 (8.4)</td>
</tr>
<tr>
<td>Cognitive Screening Test: mean (SD)</td>
<td>16.8 (2.8)</td>
<td>17.6 (2.2)</td>
</tr>
<tr>
<td>15-Word Test: mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immediate recall</td>
<td>23.2 (9.9)</td>
<td>29.2 (12.6)</td>
</tr>
<tr>
<td>delayed recall</td>
<td>3.8 (2.6)</td>
<td>5.0 (3.4)</td>
</tr>
<tr>
<td>Stroop Color-Word Test: mean (median; SD) (s)</td>
<td>236 (188;111)</td>
<td>184 (138;95)</td>
</tr>
<tr>
<td>Social predictors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partner present (%)</td>
<td>59</td>
<td>59</td>
</tr>
<tr>
<td>Social Support Questionnaire: mean (SD)</td>
<td>28.3 (5.8)</td>
<td>27.9 (5.3)</td>
</tr>
</tbody>
</table>

Survival, comorbidity during follow-up, and loss during follow-up

Seven of the 46 patients included in this study died within the first year after amputation. One patient was too ill to perform the last measurement and one patient could not be traced anymore. Functional outcome data was available for 37 patients. Only one patient died out of the 31 subjects who went to a rehabilitation centre, whereas 6 patients died from the 15 patients who went to a nursing home or received other therapy. During the follow-up period, 1 patient needed a reamputation at a higher level and 3 patients became bilaterally amputated.
Functional outcome one year after the amputation

Living environment

Of the 37 subjects, 28 (70%) lived independently at home, 7 (19%) lived in a nursing home or home for the elderly, and 2 other subjects stayed in a rehabilitation center.

Sickness Impact Profile, 68 item version

The mean total score of amputee patients on the SIP68 was 23.6 (SD 13.0). This was much higher than the score of 10.5 (SD 9.6) of a reference group of 2387 patients with multiple pathology, meaning that amputee patients experience more restrictions in their daily functioning.

Groningen Activity Restriction Scale

On the GARS, our patient group showed more restrictions in daily activities than a reference population of healthy subjects in the north of the Netherlands. The mean score of the amputee patients was 41.2 (SD 15.4), whereas for the able-bodied reference group it was 22.1 (SD 7.6). Amputee patients showed more problems in Activities of Daily Living as well as in Instrumental Activities of Daily Living.

Timed “up & go” test

18 subjects were able to perform the Timed “up & go” test. The mean time score was 23.9 seconds (median 21.3 s) with a standard deviation of 13.2 seconds. This score was comparable with the scores of an amputee group in a previous study in which amputees on average took 25 seconds to perform the test (SD 22 s). In a study by Newton, the mean time on the Timed “up & go” test of 251 healthy elderly people was only 15 seconds.

Prosthetic use

One year after the amputation, 11 out of the 37 patients visited, did not possess a prosthesis (table 3.3). Of the remaining 26 patients, 7 were nonambulatory except in a wheelchair and 1 only used his prosthesis marginally at home. Functional prosthetic use was only reached by 18 patients (49%).

Table 3.3 Prosthetic use one year after a lower limb amputation (n=37)

| Ambulating with a prosthesis but without other walking aids | 4 |
| Independent at home, ambulating with a prosthesis but requiring one or two walking sticks or crutches for outdoor activities | 6 |
| Independent indoors, ambulating with a prosthesis and one stick or crutch, but requiring two crutches outdoors and occasionally a wheelchair | 6 |
| Walking indoors with a prosthesis and two crutches or a walker, but requiring a wheelchair for outdoor activities | 2 |
| Walking indoors only short distances, ambulating mostly with a wheelchair | 1 |
| Walking with aids but without a prosthesis | 0 |
| Nonambulatory except in a wheelchair, patient possesses a prosthesis | 7 |
| Nonambulatory except in a wheelchair, patient does not possess a prosthesis | 11 |
**Prediction of functional outcome 2 weeks post-amputation**

Table 3.4 shows the relationship between the potential predictors 2 weeks after amputation and the outcome parameters one year after amputation, tested with univariate linear and logistic regression analyses. Age at amputation was significantly related with the scores of the SIP68 and the GARS. Potential predictors significantly related with the SIP68 and the GARS were: diabetes mellitus, other comorbidity, one-leg balance, BDI, CST, 15-Word test, and the Stroop Color-Word test. Two potential predictors showed a relationship with the TUGT: one-leg balance and the BDI. One-leg balance was the only factor showing a significant relationship with prosthetic use.

Age at amputation and the other significant factors were included in the forward multivariate regression analyses (table 3.5).

**Sickness Impact Profile**

Age explained 18% of the variance of the scores on the SIP68. The most important other predictors were: presence of other comorbidity (besides cardiopulmonary or diabetes mellitus), one-leg balance, and the 15-Word test. These 3 predictors explained 51% of the variance in the SIP68-scores. The total explained variance was 69%.

**Groningen Activity Restriction Scale**

Thirty-one percent of the GARS-scores were explained by age at amputation. Another 33% could be explained by one-leg balance and the 15-Word test. The total explained variance of the GARS-score was 64%.

**Timed “up & go” test**

Age at amputation explained 10% of the scores on the TUGT. An additional 32% was explained by one-leg balance; the total explained variance was 42%.

<table>
<thead>
<tr>
<th>Table 3.4 Univariate relations between predictors two weeks after amputation (t=1) and functional outcome one year after amputation (t=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic predictor:</strong></td>
</tr>
<tr>
<td>Age at amputation</td>
</tr>
<tr>
<td><strong>Physical predictors:</strong></td>
</tr>
<tr>
<td>Amputation level</td>
</tr>
<tr>
<td>KD versus TT</td>
</tr>
<tr>
<td>TF versus TT</td>
</tr>
<tr>
<td>Comorbidity</td>
</tr>
<tr>
<td>diabetes mellitus</td>
</tr>
<tr>
<td>cardiopulmonary</td>
</tr>
<tr>
<td>other</td>
</tr>
<tr>
<td>Pulmonary function</td>
</tr>
</tbody>
</table>
Table 3.5 Predictors for functional outcome 2 weeks post-amputation, tested with multivariate regression analysis

<table>
<thead>
<tr>
<th>Predictor</th>
<th>SIP68</th>
<th>GARS</th>
<th>TUGT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at amputation</td>
<td>.25</td>
<td>.42</td>
<td>.19</td>
</tr>
<tr>
<td>Other comorbidity</td>
<td>.43</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>One-leg balance</td>
<td>-.33</td>
<td>-.40</td>
<td>-.58</td>
</tr>
<tr>
<td>15-Word test</td>
<td>-.26</td>
<td>-.32</td>
<td>NS</td>
</tr>
</tbody>
</table>

$\hat{\beta}$ coefficients and the explained variance of the relationship between significant predictors and outcome measures are presented. SIP68 = Sickness Impact Profile, 68-item version; GARS = Groningen Activity Restriction Scale; TUGT = Timed “up & go” test; NS = non-significant.
**Prosthetic use**

As we already showed in the univariate analyses, the only significant predictor for prosthetic use besides age, was one-leg balance. Of the 18 patients with functional use of their prosthesis one year after the amputation, 3 could not stand on one leg two weeks after the amputation, and 6 could stand without support for more than 10 seconds. Of the 19 patients without a functional prosthesis, 10 could not stand on one leg two weeks after the amputation and 1 could stand without support for more than 10 seconds (table 3.6).

**Table 3.6 Functional outcome scores for four categories of one leg-balance**

<table>
<thead>
<tr>
<th>One-leg balance</th>
<th>SIP68 mean (SD) (n=37)</th>
<th>GARS mean (SD) (n=37)</th>
<th>TUGT mean (SD) (n=18)</th>
<th>Functional prosthetic use (n/ntotal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>not possible</td>
<td>31.2 (10.1)</td>
<td>49.9 (12.5)</td>
<td>34.6 (17.2)</td>
<td>3/13</td>
</tr>
<tr>
<td>with support</td>
<td>31.9 (9.0)</td>
<td>50.4 (14.5)</td>
<td>27.3 (20.1)</td>
<td>2/8</td>
</tr>
<tr>
<td>without support ≤10 s</td>
<td>15.9 (9.8)</td>
<td>31.8 (11.3)</td>
<td>24.7 (8.7)</td>
<td>7/9</td>
</tr>
<tr>
<td>without support &gt;10 s</td>
<td>9.9 (7.5)</td>
<td>26.9 (7.2)</td>
<td>12.7 (5.1)</td>
<td>6/7</td>
</tr>
<tr>
<td>Total</td>
<td>23.6 (13.0)</td>
<td>41.2 (15.4)</td>
<td>23.9 (13.2)</td>
<td>18/37</td>
</tr>
</tbody>
</table>

**Comparison of prediction of functional outcome 2 and 6 weeks post-amputation**

Table 3.2 showed differences in the characteristics 2 and 6 weeks post-amputation. Despite these differences in characteristics, the predictors were very much alike at both measurement moments. Small differences existed in predicting the SIP–scores due to the fact that at six weeks, diabetes was somewhat more important than other comorbidity, and the CST became more important than the 15-Word Test. In predicting the GARS, the BDI became more important at six weeks than the 15-Word Test. No other differences existed. In addition, the percentage explained variance was only slightly higher at 6 weeks than at 2 weeks post-amputation. Because of these marginal differences, we only presented the prediction model at 2 weeks post-amputation as the most important for clinical purposes.

**One-leg balance and functional outcome**

As shown in our previous results, balance on the unaffected leg was the most important predictor for all 4 outcome measurements, after adjustment for age. The differences in functional outcome for the 4 groups of standing balance was shown in table 3.6. It is clear from this data that the most important differences in functional outcome after one year are predicted by a score on the one-leg balance of 0 or 1 (not possible or possible with support) in contrast with a score of 2 or 3 (possible without support). People who were not able to stand without support 2 weeks after
amputation had a score on the SIP68 and the GARS above the mean score one year after amputation. People who were able to stand without support 2 weeks after amputation had a score on the SIP68 and the GARS below the mean score one year after amputation. This difference was less evident in comparing the TUGT-scores, but this is probably caused by the small number of patients in each group; only 2 patients who could perform the TUGT were able to stand on one leg without support ≤10 seconds. One year after amputation there was also a marked difference in prosthetic use between people who could not stand without support on the unaffected limb 2 weeks post-amputation (only 5 of 21 with functional prosthetic use) and people who were able to stand on the unaffected limb without support (13 of 16 with functional prosthetic use). The group differences mentioned were significant (P=.000), when tested with analysis of variance after correction for age at amputation.

Discussion

The main problem in our research was the number of participating patients. During the study, the number of 100 participants was not attained. To resolve part of the problem, we restricted the number of predictors in the analyses. Factors with very skewed distributions or factors we judged as not reliably measured were not used in the analyses. Despite the restricted number of participants, it is one of the largest sample populations achieved in a prospective study and it gives a great deal information as a basis for further research about this topic.

Altman describes a framework for assessing the internal validity of articles dealing with prognosis. Many of these qualities are met in our research, but some problems could not be avoided. His first point concerns the correct sample of patients. We studied prognostic variables for all lower limb amputee patients and not only for those fitted with a prosthesis. However, patients with very severe cognitive or physical problems, not able to perform our tests, were excluded. Our results, therefore, cannot be generalized to amputee patients with very severe cognitive or physical disabilities. In clinical practice, however, there is no discussion about the lack of rehabilitation potential of these patients and their bad functional prognosis. The second criterion is a sufficiently long follow-up period. We feel that one year after an amputation the functional outcome can accurately be assessed. When we visited the patients 6 months after the amputation, most persons were still undergoing therapy or had not returned to their family residence. After a year, most people had finished their therapy programs and were living in their own homes or definitively in a nursing home or a home for the elderly. The third and fourth study features described by Altman concerned the prognostic variables and the outcome measures. The potential prognostic variables were available for most of the subjects. Some stump characteristics could not be measured because of bandages or plaster casts. We used four different instruments to measure functional outcome. The 2 self-report questionnaires (the SIP68 and the GARS) reflect the patients’ opinions about their functioning. While visiting the patients, we noticed a good correlation
between the subjects' functional capabilities and their report on the questionnaires. We used generic instruments because we wanted to obtain information about the patients' overall functioning, with or without a prosthesis. The Timed “up & go” test was shown before to be reliable and valid to test functional mobility of amputee patients. Only 18 patients with the ability to walk and no temporary problems with the stump or prosthesis could perform the test. Many scales for prosthetic use are available. We selected the classification described by Narang et al and Pohjolainen et al, because it gives detailed information about the functional use of the prosthesis in our study population. The last criterium about the standardization of treatment subsequent to inclusion in the cohort could not be fulfilled. The treatment was not standardized or randomized. The choice of a certain treatment was made by the rehabilitation specialist at the local hospital. Although this did not influence the prognostic factors two weeks after the amputation, it could have influenced the outcome measurements one year after the amputation. We were not able to study the influence of the therapy between 2 and 6 weeks and one year after amputation.

**Functional outcome**

Fifteen percent of patients died in the first year after amputation. Mortality within one year ranges from 26% in the USA to 39% in Finland. Our percentage was somewhat lower, but that may be the result of the exclusion of severely disabled patients as previously mentioned. Fewer patients who went to a rehabilitation center died in the first year after amputation than patients who went to a nursing home after their initial hospital stay. This is probably due to the fact that patients selected for a rehabilitation center were patients with a better physical condition. The percentage of our patients (70%) returning to their homes after amputation, was somewhat lower than in the population of Rommers et al, that was also from the north of the Netherlands. This is caused by their inclusion of patients treated in a rehabilitation center as this creates a selection of better functioning patients. The number of amputee patients returning to home was comparable to the study of Stewart and Jain and somewhat higher than in the study of Larsson et al that only concerned diabetics.

Amputee patients on average have a low level of functioning, as indicated by the SIP88, GARS, and TUGT scores. This was also shown in previous studies. The functional prosthetic use was low in our study population (49%). In most other studies patients were only included when they went for prosthesis training, but this was not the case in our research. This may be the cause of the low prosthetic use. It was somewhat higher than in the study by Fletcher et al, who reported 36% of successfully fitted geriatric vascular amputee patients in an unselected population.

**Prediction of functional outcome**

The SIP88 and GARS scores showed that age at amputation was especially important for the general functioning. Standing balance on the unaffected limb 2 weeks after amputation was a significant predictor of all functional outcome parameters. The one-leg standing test was easy to apply and may reflect several physical conditions in one simple test. In addition to balance in general, it may reflect
the physical condition of the non-amputated leg, muscle power in the leg and thigh, presence or absence of comorbidity with disturbance of balance or power, and age-related balance problems. In amputee patients the role of the unaffected limb is very important for the functioning of all patients with or without a prosthesis. Table 3.6 shows that in predicting functional prognosis, it is important to test whether a patient can stand on the unaffected limb without support. The functional prognosis is less positive if a patient is not able to stand on the unaffected limb without support. We think that this test can be used soon after amputation for the prediction of functional outcome.

Memory seems to be the most important of the mental predictors for functioning with a leg amputation. The score on the 15-Word Test 2 weeks post-amputation was a significant predictor for the scores on the SIP68 and the GARS. A good memory may be important for relearning many daily tasks after the amputation. Six weeks after amputation, the importance of the CST and the BDI became more obvious (data not presented). The CST and the 15-Word Test both reflect cognitive impairments and will interact. The relevance of the BDI 6 weeks after amputation may partly be explained by the fact that this test was fulfilled by all patients, whereas some patients refused to do the 15-Word Test again because of a dislike of the test. In general, we think that in predicting functional prognosis, it is important to develop a simple test for memory function as well as a test that gives a quick impression of mood disturbances in an individual patient.

Comorbidity was only found as a predictor for the SIP68. Cardiopulmonary disease was surprisingly not a significant predictor in our research. This may partly be explained by an interaction with standing balance which may also reflect someone’s cardiopulmonary condition. It is also possible that, by coincidence, the severity of the cardiopulmonary disease was too low to influence functional outcome. A more sophisticated measurement of cardiac condition as was carried out by Cruts during rowing ergometry, may be necessary to study the influence on functional outcome. However, this kind of measurement is very difficult to apply so soon after amputation.

Amputation level described in literature as an important predictor was not found to be significant in our study. This may be caused by different reasons. The first may be a skewed distribution of the presented variable in our study population of mainly transtibial amputees. The second may be the interaction between this variable with the standing balance. Patients with a higher amputation level may have more difficulties in keeping balance on the unaffected limb because of a greater disturbance of their body scheme.

The mentioned variables explained a high percentage of the functional scores on the SIP68 (69%) and the GARS (64%) and a moderate percentage of the TUGT (42%). The remaining part may be explained by other variables such as the functional abilities before the amputation, personal traits, and motivation of the amputee. This was not measured in our present research because of logistic problems in seeing the patients before the amputation, and because of the restriction in the number of possible measurements in this elderly population.
Conclusions

In general, elderly patients with an amputation of the lower limb have a low level of functioning one year after their amputation. An important part of functional outcome could be predicted two weeks after the amputation by age at amputation, one-leg balance on the unaffected limb, and cognitive impairment. Severe comorbidity probably also plays a role. The results may be used in the general policy concerning leg amputee patients.
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