

## ORIGINAL RESEARCH

# Predicting successful prosthetic rehabilitation in major lower-limb amputation patients: a 15-year retrospective cohort study



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### KEYWORDS

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### Abstract

**Objective:** To determine and compare specific factors that could be associated and predictive with successful prosthetic rehabilitation in major lower-limb amputations.

**Methods:** A 15-year long (2000–2014) retrospective observational cohort study was conducted. Two different criteria were used to define successful prosthetic rehabilitation: (1) the ability to walk at least 45m, regardless of assistive devices; and (2) walking >45m without other ambulatory aids than one cane (if required). Age, gender, comorbidities, cause and level of amputation, stump characteristics, ulcers in the preserved limb, and time between surgery and physical therapy were examined as predictors of successful prosthetic rehabilitation.

**Results:** A total of 169 patients ( $61.60 \pm 15.9$  years) were included. Regarding walking ability with or without walking aids, the presence of ulcers in the preserved limb was individually associated with failed prosthetic rehabilitation ( $p < 0.001$ ), while being male (OR = 0.21; 95%CI = 0.06–0.80) and transtibial level of amputation (OR = 6.73; 95%CI = 1.92–23.64) were identified as independent predictors of failure and success, respectively. Regarding the criterion of successful rehabilitation, a shorter time until rehabilitation was individually associated with improved walking ability ( $p < 0.013$ ), while failure could be predicted by comorbidities (OR = 0.48; 95%CI = 0.29–0.78) and age groups of 65–75 years old (OR = 0.19; 95%CI = 0.05–0.78) and over 75 years old (OR = 0.19; 95%CI = 0.04–0.91).

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*Conclusions:* Regarding walking ability with or without walking aids, male gender and transtibial level of amputation are independently associated with failure and success respectively, whereas older age and comorbidities can predict failed prosthetic rehabilitation when assistive walking devices are considered. Future prospective cohort studies are needed to confirm these findings. © 2017 Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia. Published by Elsevier Editora Ltda. All rights reserved.

## Introduction

Major lower-extremity amputations have a great impact on the psychological and physical well-being, the mobility and the social life of individuals. Close monitoring of lower-limb amputee patients in multidisciplinary rehabilitation units plays an important role in the recovery or maintenance of function, as well as in the return to daily work, social, and sports activities.<sup>1</sup>

The ability to walk with a prosthetic limb is of paramount importance for major lower-limb amputees. From a physical health perspective, being unable to walk after a lower limb amputation can lead to physical deterioration and comorbidities, and be detrimental to overall health.<sup>2,3</sup> As far as psychological and social aspects are concerned, the inability to walk may have a negative impact on the individual's participation in daily life activities, on their body image perception, and on their degree of social reintegration, seriously affecting their quality of life.<sup>4,5</sup> Furthermore, prosthetic rehabilitation and the identification of prognostic factors are of great interest not only from a social and sanitary point of view, but also from the financial perspective of the cost of prostheses and rehabilitation processes.<sup>6</sup>

It is therefore essential, for patients and health-care teams alike, to be able to predict a patient's ability to walk with a prosthesis, since any incorrect estimation may lead to supplying patients with prostheses they will not be able to use, an undesirable situation for both patients and health services.<sup>7</sup> So far, studies on rehabilitation outcomes after lower-limb amputation have been performed on either relatively young patients or on the elderly. In other cases, research has been centered on specific causes or levels of amputation.<sup>6,8,9</sup> An important limitation affecting previous studies is the lack of a standard definition for successful prosthetic rehabilitation, which has led many authors to set their own criteria.<sup>10-13</sup>

The objective of this study was to analyze prosthetic rehabilitation and its effect on walking ability (according to two different definitions) in major lower-limb amputee patients treated in the outpatient service of a Prosthetics and Orthotics Rehabilitation Unit, and to determine and compare which specific factors are associated with walking ability and which are able to predict successful or failed prosthetic rehabilitation.

## Methods

### Design and participants

In this retrospective study we reviewed medical records from 335 major lower-limb amputees who took part in an outpatient rehabilitation program at the Prosthetics and Orthotics Rehabilitation Unit of the Virgen de las Nieves University Hospital of Granada (Spain), from January 1st 2000 to December 31st 2014. Prostheses for transfemoral amputations, in the case of patients between 60 and 65 years of age, were endoskeletal, with a resin- and carbon-fiber-laminated square socket, and fitted with locking knee and articulated foot. In younger patients, a dynamic, free-standing knee was used. In the case of transtibial amputees, PTB (patellar tendon bearing) or modified KBM (Kondylen Bettung Münster) with dynamic feet were employed for the last seven years. This study was approved by the ethics committee of the University of Granada (registration number: 323/CEIH2017), Granada, Spain and was conducted in accordance with the Declaration of Helsinki, good clinical practices, and all applicable laws and regulations.

The inclusion criteria were: having undergone major amputation at the transfemoral or transtibial level (either unilateral or bilateral), and being enrolled in the unit's rehabilitation program during the period under study. Patients were excluded if they had a lower-limb amputation at any other level (disarticulation of the hip or knee, or foot or toe amputation), mental deterioration to a degree that limited their cooperation, advanced neurological disorders, congestive cardiac failure, or advanced obstructive pulmonary disease.

### Outcomes measures

The following information was collected: age (patients were classified into four groups:  $\leq 55$  years, 55–65 years, 65–75 years, and  $\geq 75$  years old), gender, cause of amputation (vascular, traumatic, infectious, tumor, or other), and level (transfemoral, transtibial, and double amputation).

In order to assess lower-limb characteristics, stumps and preserved limbs were studied. Alterations in preserved limbs were classified as follows: no alterations, ulcers,<sup>14</sup>

or other (arthritis, weakness, fractures, or amputations of the foot, excluding toes). Stumps with a cylindrical shape, transversely scarred, scarred, with normal skin, and without adjoining joint contracture were classified as optimal, whereas those with irregular or square shapes, irregular scars, graft or infected scars, skin lesions, or adjoining joint contracture were classified as non-optimal stumps.

Diabetes mellitus, peripheral vascular disease, coronary disease, chronic respiratory conditions, neurological disease, dementia, diabetic retinopathy, and others (hepato-renal pathology, congestive heart failure, gastroduodenal ulcer, connective tissue disease, cancers, and hypertension) were used as comorbidity measures. Multimorbidity was the category used to describe patients with more than one comorbidity. In turn these were divided into three groups (zero, one, and more than one comorbidity). In addition, data were collected regarding the time elapsed between amputation and the start of physical therapy treatment (participants were divided into five groups according to the months elapsed until they started receiving physical therapy: <1, 1–2, 2–3, 3–6, and >6 months).

### Definition of successful prosthetic rehabilitation

The approach to patients with major lower-limb amputations was addressed by a rehabilitation specialist, an orthopedic technician who performed the adaptation and modification of the prosthesis, and a team of physical therapists who delivered the physical rehabilitation and who carried out weekly modifications of the treatment to fit the evolving needs of the patient. The use of assistive devices (walker, crutches, or one or two canes) was recorded at the moment of discharge, after completion of the rehabilitation program. Two different criteria were used to define successful and failed prosthetic rehabilitation. Criterion 1: patients were asked to walk at least 45 m at their most comfortable walking speed on a level surface. Use of any necessary ambulatory aids such as walkers, crutches or canes was permitted. Subjects were considered to be failed prosthetic users if they could not complete the 45-m walk, only used the prosthesis for transfers, did not use a prosthesis at the time of rehabilitation discharge, or were transferred out of rehabilitation because of medical instability.<sup>12</sup> Criterion 2: the use of assistive devices was included as a criterion of success,<sup>13</sup> so that patients who were able to walk at least 45 m without ambulatory aids or with only one cane were classified as successful prosthetic users (the use of two canes, crutches or a walker was considered a failure).

### Sample size calculation

For the calculation of sample size, the guidelines described by Peduzzi et al.<sup>15</sup> were applied. They considered that over ten events per predictive variable should exist in order to build a multiple logistic regression model. According to their criteria, the final number of participants included in our multiple regression analysis can be deemed sufficient, both for patients whose adaptation to the prosthesis was successful regardless of the use of walking aids ( $n=169$ ) and for those who employed walking aids ( $n=119$ ).

### Statistical analysis

A descriptive analysis of the data was performed by calculating measures of central tendency and dispersion for quantitative variables, and frequency distribution for qualitative variables. Chi-square test was used to compare continuous and categorical variables, and for quantitative variables we employed Student's *t* test, a one-way analysis of variance (ANOVA) when more than two groups were compared, and nonparametric analysis for variables that did not follow a normal distribution. Multivariate logistic regression was performed to calculate the odds ratios of the independent variables to explain successful or failed prosthetic rehabilitation. Stepwise multivariate logistic regression was used to analyze the independent effects of the significant variables in the prediction of successful or failed prosthetic rehabilitation. Results were considered statistically significant at a *p*-value below 0.05. All statistical analyses were performed with the Statistical Package for Social Sciences version 17.0 for Windows (SPSS Inc, Chicago, IL, USA) and MedCalc 13.1.

### Results

A total of 169 patients met the inclusion criteria and were included in the study. The average age was  $61.60 \pm 15.9$  years, ranging from 15 to 91 years, and 82.84% were male. The most frequent causes of amputation were vascular (70.41%), followed by traumatological, infective, and tumoral etiologies (18.93%, 4.73%, and 5.33%, respectively). Comorbidities and lower-limb characteristics by cause of amputation are displayed in Table 1. Patients with amputations of vascular etiology were significantly older ( $p < 0.001$ ) and presented a significantly higher number of comorbidities than other patients ( $p < 0.001$ ). In addition, the number of female patients with ischemic and traumatological causes of amputation was significantly lower ( $p = 0.008$ ). Amputees with a vascular cause had a significantly higher prevalence of diabetes mellitus ( $p < 0.001$ ), peripheral vascular disease ( $p < 0.002$ ), and ischemic heart disease ( $p < 0.001$ ). The time elapsed between surgery and the start of physical therapy treatment (130.62 days) was significantly higher in patients with a vascular cause of amputation ( $p = 0.003$ ).

From the total sample, 88.17% of participants were able to walk longer than 45 m with a prosthesis by the time of discharge from rehabilitation services, either with or without using assistive devices. However, in three cases no information concerning the use of assistive devices could be collected (Table 2). As for the delay in the initiation of physical therapy treatment, no significant differences were observed. Regarding the level of amputation, significant differences were observed: transtibial ( $p < 0.020$ ) and transfemoral ( $p < 0.008$ ) levels of amputation were significantly associated with successful and failed prosthetic usage, respectively. Failure was also significantly related to the presence of ulcers in the preserved limb ( $p < 0.001$ ). No significant differences were observed for the other factors under analysis. The multivariate logistic regression model showed that, after adjusting for all covariates, only male gender (OR=0.21; 95%CI=0.06–0.80;  $p=0.022$ ) and transtibial level of amputation (OR=6.73;

**Table 1** Analysis of comorbidity and lower-limb characteristics according to cause of amputation.

|  | Total analyzed (n = 169) | Vascular (n = 119) | Trauma (n = 32) | Other (n = 18) | p-Value |
|--|--------------------------|--------------------|-----------------|----------------|---------|
| <i>Age (years)</i>                     | 61.60 (15.9)             | 67.64 (10.96)      | 45.92 (17.88)   | 49.50 (15.63)  | <0.001  |
| <i>Gender</i>                          |                          |                    |                 |                |         |
| Male                                   | 140 (82.84)              | 100 (71.4)         | 30 (21.4)       | 10 (7.1)       | 0.008   |
| Female                                 | 29 (17.16)               | 20 (69)            | 2 (6.9)         | 7 (24.1)       |         |
| <i>Level</i>                           |                          |                    |                 |                |         |
| Transfemoral                           | 76 (50.89)               | 55 (72.37)         | 11 (14.47)      | 10 (13.16)     | NS      |
| Transtibial                            | 86 (44.97)               | 59 (68.60)         | 20 (23.26)      | 7 (8.14)       |         |
| Bilateral                              | 7 (4.14)                 | 6 (85.71)          | 1 (14.29)       | 0 (0)          |         |
| <i>Number of comorbidities</i>         |                          |                    |                 |                |         |
| 0                                      | 24 (14.20)               | 1 (4.17)           | 18 (75)         | 5 (20.83)      | <0.001  |
| 1                                      | 53 (31.36)               | 34 (64.15)         | 10 (18.87)      | 9 (16.98)      |         |
| ≥1                                     | 92 (54.44)               | 84 (91.30)         | 4 (4.35)        | 4 (4.35)       |         |
| <i>Type of comorbidity</i>             |                          |                    |                 |                |         |
| Diabetes mellitus                      | 95 (56.21)               | 89 (93.68)         | 3 (3.16)        | 3 (3.16)       | <0.001  |
| PVD                                    | 30 (17.75)               | 29 (96.67)         | 1 (3.33)        | 0 (0.00)       | <0.001  |
| IHD                                    | 32 (18.93)               | 31 (96.87)         | 1 (3.13)        | 0 (0.00)       | <0.001  |
| CPOD                                   | 14 (8.28)                | 13 (92.86)         | 0 (0.00)        | 1 (7.14)       | NS      |
| Neurological disease                   | 14 (8.28)                | 13 (92.86)         | 0 (0.00)        | 1 (7.14)       | NS      |
| Dementia                               | 2 (1.18)                 | 2 (100)            | 0 (0.00)        | 0 (0.00)       | NS      |
| Retinopathy                            | 17 (10.06)               | 15 (88.24)         | 1 (5.88)        | 1 (5.88)       | NS      |
| Other complication                     | 89 (52.66)               | 65 (73.03)         | 13 (14.61)      | 11 (12.36)     | NS      |
| <i>Ulcers in the preserved limb</i>    |                          |                    |                 |                |         |
| No                                     | 137 (87.3)               | 94 (68.6)          | 27 (19.7)       | 16 (11.7)      | NS      |
| Yes                                    | 20 (12.7)                | 18 (90)            | 2 (10)          | 0 (0)          |         |
| <i>Stump</i>                           |                          |                    |                 |                |         |
| Optimal                                | 101 (59.76)              | 73 (72.28)         | 18 (17.82)      | 10 (9.90)      | NS      |
| Non-optimal                            | 68 (40.23)               | 46 (67.65)         | 14 (20.59)      | 8 (11.76)      |         |
| <i>Time to rehabilitation (days)</i>   | 130.62 (102.09)          | 148.16 (107.52)    | 90.96 (80.64)   | 78.33 (48.13)  | 0.003   |
| <i>Time to rehabilitation (groups)</i> |                          |                    |                 |                |         |
| <1 m                                   | 12 (0.08)                | 7 (58.3)           | 4 (33.3)        | 1 (8.3)        | 0.009   |
| 1–2 m                                  | 32 (0.21)                | 16 (50.0)          | 10 (31.3)       | 6 (18.8)       |         |
| 2–3 m                                  | 24 (0.16)                | 14 (58.3)          | 6 (25.0)        | 4 (16.7)       |         |
| 3–6 m                                  | 48 (0.32)                | 39 (81.3)          | 6 (12.5)        | 3 (6.3)        |         |
| >6 m                                   | 35 (0.23)                | 32 (91.4)          | 2 (5.7)         | 1 (2.9)        |         |

Quantitative variables are presented as mean (standard deviation). Categorical variables are presented as frequency (percentage). PVD, peripheral vascular disease; IHD, ischemic heart disease; CPOD, chronic obstructive pulmonary disease. NS:  $p > 0.005$ .

95%CI = 1.92–23.64;  $p = 0.003$ ) remained as independent predictors of failure and success respectively, regardless of the use of assistive devices (Table 3).

Regarding the use of assistive devices (data not showed), the need for two canes, crutches or a walker for ambulation was significantly more frequent in individuals older than 65 years ( $p < 0.001$ ). Patients who required more technical assistance were those with a transfemoral level amputation ( $p < 0.41$ ), an amputation of vascular causes ( $p < 0.001$ ), and multimorbidity ( $p < 0.002$ ). The time elapsed between amputation and the initiation of treatment was also associated with a higher need for technical assistance ( $p < 0.01$ ). No statistically significant differences were observed for gender, stump characteristics and the presence of ulcers in the preserved limb.

When successful prosthetic rehabilitation included the use of assistive devices (Table 4), 41.18% of the participants

were classified as successful. Time between amputation and the start of treatment was significantly higher in the group of failed prosthetic users ( $p < 0.013$ ). Age was significantly associated with successful prosthetic rehabilitation ( $p < 0.001$ ), and an age of 55 years and younger was significantly linked to successful prosthetic rehabilitation ( $p < 0.001$ ). Meanwhile, participants 65–75 years old ( $p = 0.004$ ) had significantly higher rates of non-successful prosthetic usage, as did those with amputations at the transfemoral level ( $p = 0.004$ ) and with amputations of a vascular etiology ( $p < 0.001$ ). Regarding the number of comorbidities and the cause of amputation, patients without comorbidities ( $p < 0.001$ ) and a trauma etiology ( $p < 0.001$ ) showed a significantly higher association with successful prosthetic rehabilitation. On the other hand, having more than two comorbidities and an amputation of vascular etiology were significantly related to non-successful prosthetic rehabilitation ( $p < 0.001$  in both cases).

**Table 2** Characteristics of the population under study regarding successful prosthetic use as assessed through their ability to walk regardless of the use of assistive devices after the rehabilitation program.

|                                 | Able to walk more than 45 m |                 | p value |
|---------------------------------|-----------------------------|-----------------|---------|
|                                 | Yes (n = 149)               | No (n = 17)     |         |
| Age (years)                     | 61.06 (16.20)               | 67.94 (13.05)   | NS      |
| Age (groups)                    |                             |                 |         |
| ≤55 y                           | 40 (95.24)                  | 2 (4.76)        | NS      |
| 55–65 y                         | 31 (88.57)                  | 4 (11.43)       |         |
| 65–75 y                         | 53 (91.38)                  | 5 (8.62)        |         |
| ≥65 y                           | 25 (80.65)                  | 6 (19.35)       |         |
| Gender                          |                             |                 |         |
| Male                            | 127 (92.03)                 | 11 (7.97)       | NS      |
| Female                          | 22 (78.57)                  | 6 (21.43)       |         |
| Level                           |                             |                 |         |
| Transfemoral                    | 60 (82.19)                  | 13 (17.81)      | <0.001  |
| Transtibial                     | 82 (95.35)                  | 4 (4.65)        |         |
| Double                          | 7 (100.0)                   | 0 (0.00)        |         |
| Cause of amputation             |                             |                 |         |
| Vascular                        | 102 (87.18)                 | 15 (12.82)      | NS      |
| Trauma                          | 30 (93.75)                  | 2 (6.25)        |         |
| Other                           | 18 (100.0)                  | 0 (0.00)        |         |
| Number of comorbidities         |                             |                 |         |
| 0                               | 23 (95.83)                  | 1 (4.17)        | NS      |
| 1                               | 47 (90.38)                  | 5 (9.62)        |         |
| ≥1                              | 79 (86.81)                  | 12 (13.19)      |         |
| Ulcers in the preserved limb    |                             |                 |         |
| No                              | 125 (93.28)                 | 9 (6.72)        | 0.001   |
| Yes                             | 13 (65)                     | 7 (35)          |         |
| Stump                           |                             |                 |         |
| Optimal                         | 91 (91.92)                  | 8 (8.08)        | NS      |
| Non-optimal                     | 58 (86.57)                  | 9 (13.43)       |         |
| Time to rehabilitation (days)   | 128.50 (90.82)              | 132.22 (103.36) | NS      |
| Time to rehabilitation (groups) |                             |                 |         |
| <1 m                            | 10 (90.91)                  | 1 (9.09)        | NS      |
| 1–2 m                           | 28 (90.32)                  | 3 (9.68)        |         |
| 2–3 m                           | 22 (91.67)                  | 2 (8.33)        |         |
| 3–6 m                           | 46 (95.83)                  | 2 (4.17)        |         |
| >6 m                            | 31 (88.57)                  | 4 (11.43)       |         |

Quantitative variables are presented as mean (standard deviation). Categorical variables are presented as frequency (percentage). y, years; m, months; NS:  $p > 0.005$ .

In the statistical regression model which predicted successful or failed prosthetic rehabilitation according to Criterion 2 (Table 5), raw analysis showed a significant effect for the cause-of-amputation variable ( $p < 0.001$ ), with the odds of successful prosthetic rehabilitation being 9.67 times higher for trauma causes than for amputations of a vascular etiology. Similarly, when the level of amputation was transtibial, the odds of success were 2.58 times higher ( $p = 0.017$ ). Comorbidities had a strong effect ( $p < 0.001$ ), with each comorbidity reducing by 58% the odds of success ( $p < 0.001$ ). Finally, the effect of age was also strong, as it reduced the odds of success by a factor of 0.62 in the second

group (although this did not reach statistical significance;  $p = 0.444$ ), of 0.12 ( $p < 0.001$ ) in the third group, and of 0.14 in the fourth group ( $p = 0.001$ ).

In the multivariate model, after adjusting for all variables with a significant effect, the cause effect disappeared, as did that of the level of amputation. However, a significant predictive effect remained for comorbidities (OR = 0.48; 95%CI = 0.29–0.78;  $p = 0.003$ ) and age in age groups 65–75 years old (OR = 0.19; 95%CI = 0.05–0.78;  $p = 0.021$ ) and over 75 years old (OR = 0.19; 95%CI = 0.04–0.91;  $p = 0.038$ ), which explains all other effects (Table 5).

**Table 3** Logistic regression model predicting successful or failed prosthetic rehabilitation regarding criterion 1.<sup>a</sup>

| Variable                            | Univariate analysis |            |         | Variable                            | Multivariate analysis |            |         |
|-------------------------------------|---------------------|------------|---------|-------------------------------------|-----------------------|------------|---------|
|                                     | OR                  | 95%CI      | p-Value |                                     | OR                    | 95%CI      | p-Value |
| <i>Gender</i>                       | 0.39                | 0.14–1.14  | 0.085   | <i>Gender</i>                       | 0.21                  | 0.06–0.80  | 0.022   |
| <i>Cause of the amputation</i>      |                     |            |         | <i>Cause of the amputation</i>      |                       |            |         |
| Vascular                            | 2.33                | 0.51–10.71 | 0.277   | Vascular                            | 1.28                  | 0.17–9.50  | 0.812   |
| Trauma                              | 2.64                | 0.33–21.23 | 0.361   | Trauma                              | 4.15                  | 0.29–58.51 | 0.292   |
| <i>Level</i>                        |                     |            |         | <i>Level</i>                        |                       |            |         |
| Transtibial                         | 5.04                | 1.59–15.95 | 0.006   | Transtibial                         | 6.73                  | 1.92–23.64 | 0.003   |
| Comorbidities                       | 0.71                | 0.47–1.05  | 0.089   | Comorbidities                       | 0.88                  | 0.51–1.49  | 0.627   |
| <i>Age (groups)</i>                 |                     |            |         | <i>Age (groups)</i>                 |                       |            |         |
| 55–65 y                             | 0.39                | 0.90–1.63  | 0.204   | 55–65 y                             | 0.64                  | 0.10–4.16  | 0.637   |
| 65–75 y                             | 1.01                | 0.21–4.78  | 0.987   | 65–75 y                             | 2.75                  | 0.38–19.65 | 0.314   |
| >75 y                               | 0.31                | 0.07–1.36  | 0.122   | >75 y                               | 0.55                  | 0.08–3.79  | 0.545   |
| <i>Ulcers in the preserved limb</i> | 0.99                | 0.81–1.28  | 0.949   | <i>Ulcers in the preserved limb</i> | 1.03                  | 0.83–1.29  | 0.778   |

<sup>a</sup> Walk more than 45 m regardless of the use of assistive devices. OR, odds ratio; CI, confidence interval; y, years.

## Discussion

The present study examined and compared the independent association between a number of critical factors and successful prosthetic rehabilitation by examining walking ability at the time of discharge (for two definitions of walking ability). Our results indicate that gender and level of amputation were independently associated with walking ability with or without walking aids, whereas older age and comorbidities were able to predict failed prosthetic rehabilitation when the use of assistive devices was considered.

In accordance with what has been previously described in the literature, the present study showed that vascular causes were the most frequent for amputation,<sup>16</sup> and that these patients were significantly older than those who underwent amputations for other reasons.<sup>17,18</sup> Our results also revealed that vascular-related amputations are significantly linked to increased comorbidities.<sup>19,20</sup> In addition, diabetes mellitus has been reported to be the most important cause of major lower-extremity amputations,<sup>21</sup> which is also in accordance with our findings (56.21%).

Several studies have analyzed prosthetic rehabilitation after lower-limb amputation, but their conclusions vary according to the factors considered by each, such as their selected sample or their definition of successful prosthetic rehabilitation. This introduces a high degree of variability in their reported rates of success and failure.<sup>22,23</sup>

When analyzing the association between level of amputation and prosthetic rehabilitation, it has been suggested that patients with a lower level of amputation achieve better outcomes than patients amputated at a more proximal level,<sup>24–26</sup> whereas other authors could not find significant differences regarding the surgical level of amputation when analyzing ambulation, be it independent or with assistance.<sup>12,27</sup> Our logistic regression model showed that transtibial level was an independent predictor of success with respect to Criterion 1 (OR=6.73), although a 95%CI (1.92–23.64) suggests that these results should be

interpreted with caution regardless of their statistical significance. This may be partly explained by the fact that, compared to those with transfemoral amputations, walking with a transtibial prosthesis requires a reduced energy expenditure.<sup>28</sup> When the use of walking aids was considered, transfemoral amputations were individually associated with failure as could be expected, since it has already been described that individuals with transfemoral amputations fall at similar rates to balance-impaired individuals,<sup>26,29</sup> and that patients with unilateral transtibial amputation retain sufficient sensory and motor capacity to maintain adequate dynamic stability while walking.<sup>30</sup> However, such differences did not appear in our multivariate regression analysis.

A shorter time interval between surgery and admission for rehabilitation has been associated with better walking potential.<sup>31</sup> In addition, alterations in the preserved limb often hinder prosthesis fitting.<sup>8</sup> In the present study, the presence of ulcers in the preserved limb and a longer time interval between surgery and admission for rehabilitation have been shown to be individually associated with failure in prosthetic rehabilitation (Criterion 1), but no other independent associations were observed in the regression analysis. With respect to gender, previous studies failed to find any consistent association with walking ability following lower-limb amputation.<sup>32,33</sup> In our study we found that being male is a predictive factor for failure in prosthetic rehabilitation (OR=0.21) with respect to Criterion 1, but not Criterion 2. These results may be linked to the fact that women made up a small percentage of our sample (17.16%), although any such interpretation must be tentative given the 95%CI values (0.06–0.80), which are probably due to sample size.

Age has been widely reported to play an important role in prosthetic and functional determinations,<sup>3,34</sup> but there is disagreement on the extent to which age is a factor.<sup>7,35</sup> Regarding walking ability, controversial results have also been reported, and while Suckow et al.<sup>27</sup> found that an age of 70 and above was associated with poor functional outcomes at hospital discharge, other authors did

**Table 4** Characteristics of the population under study regarding successful prosthetic use after the rehabilitation program.

|  | Successful prosthetic rehabilitation |                 | p-Value |
|--|--------------------------------------|-----------------|---------|
|  | Yes (n = 49)                         | No (n = 70)     |         |
| <i>Age (groups)</i>                    |                                      |                 |         |
| <55 y                                  | 23 (69.70)                           | 10 (30.30)      | <0.001  |
| 55–65 y                                | 10 (58.82)                           | 7 (41.18)       |         |
| 65–75 y                                | 10 (22.22)                           | 35 (77.78)      |         |
| ≥75 y                                  | 6 (25.00)                            | 18 (78.00)      |         |
| <i>Gender</i>                          |                                      |                 |         |
| Male                                   | 42 (42.00)                           | 58 (58.00)      | NS      |
| Female                                 | 7 (36.84)                            | 12 (63.16)      |         |
| <i>Level</i>                           |                                      |                 |         |
| Transfemoral                           | 16 (31.17)                           | 35 (68.63)      | 0.004   |
| Transtibial                            | 33 (54.10)                           | 28 (45.90)      |         |
| Double                                 | 0 (0)                                | 7 (100)         |         |
| <i>Cause of the amputation</i>         |                                      |                 |         |
| Vascular                               | 24 (29.27)                           | 58 (70.73)      | <0.001  |
| Traumatological                        | 20 (80.00)                           | 5 (20.00)       |         |
| Other                                  | 7 (28.33)                            | 5 (41.67)       |         |
| <i>Comorbidity</i>                     |                                      |                 |         |
| 0                                      | 18 (90.00)                           | 2 (10.00)       | <0.001  |
| 1                                      | 15 (44.12)                           | 19 (55.88)      |         |
| ≥1                                     | 16 (24.62)                           | 49 (75.38)      |         |
| <i>Ulcers in the preserved limb</i>    |                                      |                 |         |
| No                                     | 41 (40.20)                           | 61 (59.80)      | NS      |
| Yes                                    | 4 (30.77)                            | 9 (69.23)       |         |
| <i>Stump</i>                           |                                      |                 |         |
| Optimal                                | 22 (41.51)                           | 31 (58.49)      | NS      |
| Non-optimal                            | 27 (40.91)                           | 39 (59.09)      |         |
| <i>Time to rehabilitation (days)</i>   | 108.80 (77.72)                       | 156.57 (121.51) | 0.013   |
| <i>Time to rehabilitation (groups)</i> |                                      |                 |         |
| <1 m                                   | 4 (44.4)                             | 5 (55.6)        | NS      |
| 1–2 m                                  | 11 (61.1)                            | 7 (38.9)        |         |
| 2–3 m                                  | 12 (54.5)                            | 10 (45.5)       |         |
| 3–6 m                                  | 11 (31.4)                            | 24 (68.6)       |         |
| >6 m                                   | 7 (25.0)                             | 21 (75.0)       |         |

Quantitative variables are presented as mean (standard deviation). Categorical variables are presented as frequency (percentage). Successful prosthetic rehabilitation: walk more than 45 m without ambulatory aids or with only one cane. y, years; m, months. NS:  $p > 0.005$ .

not find any age-related differences.<sup>13,32</sup> Our study showed modest differences with respect to age in the multivariate logistic regression model when the use of assistive devices was considered. Furthermore, being 65–75 years old (OR = 0.19; 95%CI = 0.05–0.78) and over 75 years old (OR = 0.19; 95%CI = 0.04–0.91) was independently associated with failed prosthetic rehabilitation, while no differences regarding age were observed regarding Criterion 1. One possible explanation is that age is linked to a loss in balance confidence in the performance of daily-life activities,<sup>36</sup> a normal trait in lower-limb amputees,<sup>37</sup> which may push even more patients to using walking devices. In any case, the 95%CI values suggest that a cautious interpretation of results is in order, particularly before any extrapolation is made to the general population.

Finally, although the negative effect of comorbid conditions on outcome effects has been already been pointed out,<sup>32,34,38</sup> for some authors these effects were simply not present.<sup>9,39</sup> In this respect, and as far as walking ability is concerned, Van Eijik et al.<sup>6</sup> found that multimorbidity was not independently related to successful ambulation with or without walking devices. We find our results to be in accordance with theirs: according to Criterion 1, no independent association was observed in the regression analysis. As for Criterion 2, we found an individual association between the presence of multimorbidity and the use of assistive walking devices, and the multivariate model showed that for patients with no comorbidities and with multimorbidity an independent association existed with greater rates of success and failure, respectively. These findings are also in

**Table 5** Logistic regression model predicting successful or failed prosthetic rehabilitation regarding criterion 2.<sup>a</sup>

| Variable                       | Univariate analysis |            |         | Variable                       | Multivariate analysis |           |         |
|--------------------------------|---------------------|------------|---------|--------------------------------|-----------------------|-----------|---------|
|                                | OR                  | 95%CI      | p-Value |                                | OR                    | 95%CI     | p-Value |
| <i>Gender</i>                  | 0.81                | 0.29–2.22  | 0.676   | <i>Gender</i>                  | 0.51                  | 0.13–2.05 | 0.346   |
| <i>Cause of the amputation</i> |                     |            |         | <i>Cause of the amputation</i> |                       |           |         |
| Vascular                       | 1.00                |            |         | Vascular                       |                       |           |         |
| Trauma                         | 9.67                | 3.25–28.73 | 0.000   | Trauma                         | 1.67                  | 0.32–8.65 | 0.542   |
| Other                          | 1.73                | 0.50–5.98  | 0.389   | Other                          | 0.36                  | 0.07–1.89 | 0.227   |
| <i>Level</i>                   |                     |            |         | <i>Level</i>                   |                       |           |         |
| Transtibial                    | 2.58                | 1.19–5.61  | 0.017   | Transtibial                    | 1.84                  | 0.70–4.87 | 0.218   |
| Other                          | 1.00                |            |         | Other                          | 1.00                  |           |         |
| <i>Comorbidities</i>           | 0.42                | 0.28–0.63  | 0.000   | <i>Comorbidities</i>           | 0.48                  | 0.29–0.78 | 0.003   |
| <i>Age (groups)</i>            |                     |            |         | <i>Age (groups)</i>            |                       |           |         |
| 55–65 y                        | 0.62                | 0.18–2.10  | 0.444   | 55–65 y                        | 1.09                  | 0.22–5.43 | 0.917   |
| 65–75 y                        | 0.12                | 0.04–0.35  | 0.000   | 65–75 y                        | 0.19                  | 0.05–0.78 | 0.021   |
| >75 y                          | 0.14                | 0.04–0.47  | 0.001   | >75 y                          | 0.19                  | 0.04–0.91 | 0.038   |

<sup>a</sup> Walk more than 45 m without ambulatory aids or with only one cane. OR, odds ratio; CI, confidence interval; y: years.

agreement with those described by Hamamura et al.,<sup>13</sup> who, after applying similar criteria, stated that a low number of comorbidities is a predictive factor for successful prosthetic rehabilitation.

Among the limitations of the present study, the most important derives from its retrospective character, which makes it impossible to contemplate any variable not included in the original protocol. Other limitations include our sample size and the fact that walking ability was evaluated only at the moment of discharge. Larger prospective studies should be performed to assess, at the medium and long term, other social and psychological factors and objective functional measurements, such as the degree of mobility and walking speed of patients, as well as subjective outcomes like health-related quality of life or satisfaction as perceived by patients.

## Conclusions

In summary, the results of this study showed that if walking ability is used as the only definition for successful prosthetic rehabilitation, the presence of ulcers in the preserved limb was individually related to failure, while male gender and transtibial level were independent predictors of failure and success respectively. However, when the use of assistive devices was taken into consideration, a shorter time to rehabilitation was individually associated with improved walking potential, while age (65 years and over) and the number of comorbidities were revealed to be independent predictors of failure in prosthetic rehabilitation. These findings may help detect poor prosthetic rehabilitation candidates, thus enabling multidisciplinary teams of health-care providers to focus on their particular needs in order to improve their condition.

## Conflicts of interest

The authors declare no conflicts of interest.

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