DEVELOPMENT OF A SCORING TOOL (BLARt SCORE) TO PREDICT FUNCTIONAL OUTCOME IN LOWER LIMB AMPUTEES

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ABSTRACT

Purpose: To develop a valid pre-operative scoring tool that predicts the probability of walking with a prosthetic limb after major lower limb amputation.

Methods: A retrospective review of 338 patients who had undergone lower limb amputation was conducted to identify characteristics that affected the success of rehabilitation with a prosthetic limb. These data were used to devise an assessment tool (the BLARt score), which was then tested and validated in 199 patients planned to undergo lower limb amputation in two UK regional centres. Functional rehabilitation outcomes were recorded at 12 months after surgery using the SIGAM mobility grading.

Results: At 12 months after amputation, no patient with a BLARt score ≥13 was able to walk independently (good functional outcome, SIGAM grade E or F); no patient with a BLARt score ≥22 and only 6 patients with a BLARt score ≥17 were able to walk to any degree ('functional' outcome: SIGAM grade C or greater). The area-under the ROC for predicting inability to walk (poor functional outcome, SIGAM A or B) was 0.914 (SE 0.2) (95% confidence intervals 0.87-0.95).

Conclusions: In the patient cohorts studied, the BLARt assessment tool was a strong predictor of patients' inability to walk with a prosthetic limb after surgery. It is simple to administer and could be useful in clinical practice to inform expectations for patients and clinicians.

IMPLICATIONS FOR REHABILITATION

- Patients undergoing lower limb amputation face major physical and psychological challenges after surgery that have a considerable impact on rehabilitation and their ability to walk independently.
- Many amputees are unable able to walk with a prosthetic limb, but there are no validated tools to predict this before surgery.
- The BLARt is a potentially valuable measure that can predict the likelihood of being unable to walk after amputation.
- It is simple to use and could be useful to inform patients’ and clinicians’ expectations before surgery

INTRODUCTION

Recent estimates suggest that approximately 5000 people in the UK and 50,000 in the USA undergo major lower limb amputation each year.[1, 2] It is difficult to quantify precise numbers worldwide because many countries do not keep accurate data. Most lower limb amputations (80%) are performed for peripheral vascular disease; 40% of these are performed in diabetics.[3] Other common indications are trauma, malignancy, congenital deformities and in extreme cases, chronic pain.

Major lower limb amputation has a huge impact on a patient's physical capabilities, quality of life and requires many adjustments to daily life.[4] The importance of being able to estimate an individual's potential to walk with a prosthesis after amputation has been recognised.[5] Effective rehabilitation to achieve independent walking with a prosthetic limb is physically and mentally challenging. The ability to walk independently with a prosthesis is determined by several factors, including patient age, physical fitness, the presence of associated injuries or co-morbidities, patient motivation, social circumstances and the availability of support.[6] The reliability, comfort, ease of use and functionality of the prosthesis are also important. [2]

Accurate and informed information should be at the heart of decision-making before amputation.[7] However, it is difficult to predict before surgery whether a patient will be able to walk independently after lower limb amputation .[5, 8] Several pre-operative [9-12] and post-operative factors [13-22] have been associated with the likelihood of being able to walk with a prosthetic limb, but there are no validated methods of predicting this before amputation surgery .

Best practice should ensure that patients are informed in detail before surgery about what type of prosthesis may be suitable, and that they are counselled about their likely prognosis.[23] This can help manage expectations as well as plan for environmental changes at home or at work, returning to driving and attending social activities.[6] However, these discussions do not always occur, partly because of the urgent nature of many lower limb amputations.[7] When pre-amputation discussions do occur there is evidence that patients' expectations of being able to walk independently with a prosthetic limb are often unrealistic [24] and this is borne out by our own clinical experience. This may relate to the prominent media profile of some amputees including war veterans and disabled athletes. Alternatively, advice from surgeons that patients will be suitable for prosthetic rehabilitation after amputation may be over-optimistic, based on a lack of knowledge or available evidence in predicting longer term outcome in different patient groups, or a reluctance to emphasise negative outcomes before surgery.

Therefore the aims of this study were to identify pre-operative factors associated with the ability to walk with a prosthetic limb after major lower limb amputation. These would inform the development of a predictive assessment tool that could be used to predict the likelihood of walking with a prosthesis after surgery.

METHODS

We conducted a service review of mobility outcomes of all patients (n=350) referred for prosthetic rehabilitation after trans-tibial and trans-femoral amputation between 1st April 2000 – 31st March 2008 in the tertiary referral vascular and orthopaedic unit at University Hospitals of Leicester NHS Trust. Research ethics committee was not required as this study was a retrospective analysis of routinely collected clinical data. Data were recorded as part of routine care during 2000-2008 by clinicians from the prosthetic rehabilitation service. The use of anonymised patient information was approved by the institutional review board and individual patient consent was not required Functional outcome was determined using the NHS prosthetic activity coding classification in use at the time (A0L- non limb user, A1L- limited household/cosmetic user, A2L – limited community/household user, A3L – active adult, A4L – very active adult or athlete).[25] Variables included sex, age, body mass index, medical co-morbidities, cause of amputation, level of amputation and impaired cognitive capacity. This creation dataset was limited to those variables collected as part of routine care.

Selection of variables

Data were entered into an SPSS for Windows version 22 (IBM, Armonk, NY, USA) spreadsheet for analysis. Univariate binary logistic regression analysis of the creation dataset was used to identify potential variables that were predictive of the level of function (ability to walk with prosthetic limb) after amputation. Our primary aim was to identify the likelihood of walking independently with a prosthetic limb. A successful functional outcome was defined as an activity level of A2L or greater at 12 months. Patients with A0L or A1L grade at 12 months were deemed to have an unsuccessful rehabilitation outcome. All potential predictors that had an odds ratio >1, and a p-value<0.1 were analysed using multinomial logistic regression analysis, with walking after amputation as the dependent variable, and independent predictors as covariates.

Development of the BLARt scoring system

Following consensus discussion amongst the research team based on regression analysis of the significant variables identified from the creation dataset and previously published literature,[4, 6, 9, 11, 12, 16, 23, 26-37] eight preoperative variables were identified as potentially affecting the success of rehabilitation and having a significant impact on ability to mobilise independently after amputation . The eight variables were:

1: *Age*. The elderly are more likely to be frail with less strength and can find learning new skills more difficult. [12, 23, 27-29]

2: Sex. There is conflicting evidence regarding the effect of sex on mobility outcomes.[5] The creation dataset and previous studies[19, 38] have shown that women are less successful in rehabilitation.

3: *Body mass index (BMI).* BMI has an impact on the effective fitting and functioning of a prosthesis.[30] Obesity can indicate a lower level of fitness and can make socket fitting challenging. Low BMI can also be associated with frailty, lack of physical fitness and affect the socket comfort because of bony prominences.

4: *Level of amputation.* Walking ability is reduced with more proximal amputations, particularly hip disarticulation, and bilateral amputation; trans-tibial amputees are much more likely than trans-femoral or through-knee amputees to achieve a functional level of A2L or greater. [4, 26, 27, 29]

5: *Indication for amputation.* Patients undergoing amputation for vascular disease have poorer mobility related outcomes than amputees related to trauma. [4, 6, 23, 27, 31-33]

6: *Mobility before amputation.* Patients who are unable to walk independently before surgery, especially those that are wheelchair bound are less likely to walk independently after amputation. This relates to contractures from wheelchair use, compromised balance and muscle strength.[9, 28]

7: *Cognitive impairment.* Impaired cognitive function and dementia can affect rehabilitation outcomes. [9, 16, 34]

8: *Special risks*

a. *Co-existing systemic disease*. Systemic co-morbidities including diabetes mellitus, cardiovascular or severe respiratory disease, arthritis, degenerative spinal disease and renal failure can affect outcome.[4, 9, 11, 26, 35, 36]
b. *Impairment of the contralateral limb.* Patients who cannot fully bear weight on the contralateral limb because of tissue damage, tissue loss, previous surgery or pain are less likely to walk with a prosthesis after amputation because of pain, impaired balance, coordination or muscle strength .[9, 11, 12, 16]

We defined ischaemic heart disease as current angina or previous myocardial infarction (within 6 months). Severe respiratory disease was defined as COPD causing shortness of breath at rest or requiring home oxygen therapy. Cognitive impairment included overt confusion, with 'limited carry over' being the inability of patients to retain and repeat verbal information shortly after it had been discussed. These variables were included in the BLARt (Blatchford Allman Russell tool) score (Table 1).

Insert Table 1 about here.

Validation of the dataset

The study population for the validation dataset comprised all patients referred after lower limb amputation to the rehabilitation service in Leicester during 2010-2013 and the Northern General Hospital, Sheffield during 2012-2013. The level of functional rehabilitation for the validation dataset was recorded 12 months after surgery using the SIGAM scoring system (A – non limb user, B – Therapeutic, wears only for transfers, C – Limited/Restricted, walks up to 50m, D- Impaired, walks 50m or more with walking aid, E- Independent, walks 50m or more without walking aid, F – Normal/Near normal walking).[39] The SIGAM classification was used (instead of the A0L activity code used for the creation dataset) because of a change in the NHS Trust requirements for data recording. For the purposes of analysis, prosthetic mobility outcomes were grouped into 2 categories representing a functional or non-functional disability mobility outcome using the SIGAM scale. Non-functional mobility outcomes were defined as patients who had died or had a SIGAM grade A (non-limb user) or B (wearing prosthesis only for transfer, unable to walk independently). Functional outcomes were classed as SIGAM grade C or above. This division into binary outcomes compares closely to the activity grades (A0L and A1L; or A2L and greater).

Statistical analysis

Univariate binary logistic regression analysis of the creation dataset was used to identify potential variables that were predictive of functional outcome after amputation. All potential predictors that had an odds ratio >1, and a *p*-value<0.1 were analysed using multinomial stepwise forward logistic regression analysis. Variables associated with poor rehabilitation mobility (odds ratio >1 on binary regression analysis of the creation dataset, *p* value <0.1) and those identified from published studies were included in the scoring system, as were variables statistically significant on multinomial analysis. Multinomial regression analysis used outcome after amputation as the dependent variable, and independent predictors as covariates. Since our intention was to develop a system that could predict acceptable outcome at 12 months, outcome was primarily divided into functional (SIGAM grade C or greater) or non-functional (dead, or SIGAM grade A or B). We also compared outcomes according to good walking function (SIGAM grade E or F) and poor function (SIGAM grade D or lower). The performance of the score, calibration and goodness of fit to the validation dataset was determined by calculating the Hosmer-Lemeshow statistic and Nalgekirke R^2 value. Data are presented as Exp (B) Odds ratios with 95% confidence intervals, where Exp (B) represents the ratio-change in the odds of the event of interest for a one-unit change in the predictor. Receiver operating characteristic (ROC) curves were constructed and area-under-the ROC curve (AUROC) with SE and 95% confidence intervals to assess sensitivity and discrimination. Specificity and sensitivity of the BLARt score for predicting functional walking outcomes (defined by SIGAM grade) were calculated for the overall score and at key threshold values. Sensitivity was calculated as the proportion of patients correctly predicted by a high BLARt score as having a non- or poor functional walking outcome) and specificity was calculated as the proportion of patients correctly predicted by a low BLARt score as having a good functional walking outcome.

RESULTS

Creation dataset

Of 350 patients included in the creation dataset, functional outcome data was not recorded for 12 patients so data from 338 patients were analysed (Table 2). The characteristics of the patient groups are indicated in Tables 2 and 3. Mortality at 12 months was 18.6%.

Insert tables 2 & 3 about here.

Factors independently associated with a poor functional outcome (AOL or A1L) on univariate analysis were trans-femoral amputation, age > 70 years, male sex, vascular aetiology, renal failure requiring dialysis, diabetes and prior stroke (Table 4) and these were entered into the multinomial analysis.

Insert table 4 about here.

Ischaemic heart disease, obesity, respiratory disease, contralateral limb problems, cognitive dysfunction were not associated with mobility outcome but absolute numbers of patients with these pathologies were low. On multinomial analysis, age, sex, trans-femoral amputation, vascular aetiology and renal failure were independent predictors of non-functional mobility outcome (Table 5).

Insert table 5 about here.

Validation dataset and BLARt scoring system development

One hundred and ninety nine patients were included in the validation dataset (101 from Leicester, 98 from Sheffield). Patient characteristics in the validation dataset (*n*=199) were similar to the creation dataset (Tables 6 & 7), though the presence of diabetes was not recorded. Body mass index was calculated. The proportion of patients undergoing transfemoral amputations was lower, and 30 patients underwent bilateral amputations or hip disarticulation. Mortality at 12 months in the validation dataset was 10% (*n* = 20) but other clinical outcomes were similar. *Insert tables 6 & 7 about here.*

The BLARt scoring system (Table 1) was devised based on these variables, with additional weight given to those significant on multinomial analysis. In addition, some factors considered important by the research and clinical teams but not recorded in the creations dataset (body mass index, pre-amputation mobility) were included. The validation dataset was then used to assess the performance of the BLARt score. Using the Hosmer and Lemeshow Test, the BLARt score showed good concordance between predicted and observed functional outcome ($\chi 2$ value 8.31, $p = 0.403$). Table 8 summarises the correlation between BLARt score and functional outcome.

Insert table 8 about here.

No patient with a BLARt score ≥13 was able to walk independently with a prosthesis (SIGAM E or F) and only 6 patients with a BLARt score ≥17 were able to walk independently with a prosthesis for any distance (SIGAM C or greater). The overall sensitivity of the BLARt score for predicting poor functional outcome (SIGAM D or below) was 95.5% and the specificity was 77.2%; positive and negative predictive values were 97.2% and 45.5% respectively. Using a threshold of BLARt score ≥13 or less gave 100% sensitivity and 66.7% specificity for poor functional outcome (SIGAM D or below). A threshold of BLARt score ≥17 identified non-functional outcome (SIGAM B or below) with a sensitivity of 93.4% and a specificity of 75.9%.

The ROC curve for non-functional outcome (Figure 1) confirms the predictive ability of the BLARt score. The AUC is 0.914 (SE 0.2), 95% confidence intervals 0.87-0.95. AUROC for poor functional outcome was 0.941 (SE 0.017) (95% CI 0.91-0.97).

Insert Figure 1 about here.

DISCUSSION

In this study we found that patients with a BLARt score of ≥ 13 did not achieve a good functional outcome (SIGAM grade E or F) following lower limb amputation and those with a score of ≥17 did not achieve any walking function (SIGAM grade C or greater). The BLARt assessment was highly sensitive in identifying a patient's subsequent ability to walk.

In the creation dataset of 338 patients, those undergoing through-knee or trans-femoral amputation had a 10.5% chance of achieving good functional outcome (A2L, A3L or A4L) compared to 41% in the trans-tibial amputation group. The poorer outcome after trans-femoral amputation is consistent with published data.[23, 38] In the second cohort of 199 patients used as the validation dataset, a good functional outcome was achieved by 36% of the through-knee/transfemoral group and 69% of trans-tibial group. This suggests that rehabilitation outcomes may have improved in the last decade, which probably reflects improvements in rehabilitation services. Other strong predictors of poor functional outcome were renal failure, female sex and amputation for peripheral vascular disease, again consistent with previous data. The effects of renal failure may be because of reduced life expectancy[40-42] and the multiple co-morbidities associated with end-stage renal disease[43.] In our experience, inconsistency in physical wellbeing on a day-to-day basis is a major limitation in the rehabilitation process, and this occurs in patients with renal failure. Our data demonstrated that older female patients with peripheral vascular disease were less likely to walk independently after amputation. This may be related to a number of reasons such as the severity of the underlying vascular disease, frailty, social, demographic and psychological factors associated with adjustment to amputation.[44]

Functional outcomes were better when amputation was performed in younger patients for traumatic or orthopaedic injuries rather than peripheral vascular disease. The BLARt score was less good at predicting a 'good' functional outcome (walking independently). One explanation is that the BLARt score measures pre-amputation factors and does not consider post-amputation factors, which are likely to have an influence on outcome. There are many unpredictable post-operative factors that can affect successful rehabilitation. These include failure of, or poor wound healing, infection requiring revision surgery, contractures, and acute post-operative events such as infectious, respiratory or cardiovascular complications. Patients who undergo amputation have to make many psychological and social adjustments and these influence outcomes. Patients who are discharged home may feel isolated following a prolonged period of hospitalisation. They may withdraw socially and may not perform their physiotherapy exercises as much as patients who go to a community rehabilitation facility where more regular input and help to deal with complications is often available. Motivation is an important determinant of rehabilitation.[11] Factors affecting motivation and compliance include mood changes, anxiety, changes in body image and self-esteem. Social support issues, feelings of helplessness and coping with the physical adaptations required can all influence rehabilitation outcomes.[17, 27] Many of these are difficult to predict before amputation surgery and were not included in the BLARt tool. Hence the utility of the BLARt is to predict those patients who are unlikely to rehabilitate successfully rather than those who will.

Implications for practice

The BLARt score is a relatively simple tool that will allow risk stratification for the purposes of informed consent. It will provide an estimate of prognosis that can guide pre-operative information giving and communication. It may allow better management of the expectations of patients and their carers, during the informed consent process.

It is a simple, reproducible tool that can be easily incorporated into every day clinical practice. The BLARt score can be completed by any member of the clinical team and does not require a specialist practitioner.

Limitations of the current study

The creation dataset comprised routine collected data which did not include variables such as categorised body mass index, pre-amputation mobility levels and classification of cognitive impairment. Hip disarticulation, and bilateral amputations were also not classified separately. However, the study team considered these to be vital factors which affect the success of rehabilitation and therefore, following consensus decision, they were included and weighted in the formulation of the BLARt score. There were very few through-knee amputations in our datasets and so these have been grouped together with the transfemoral group. We feel this is logical as in our experience the absence of a knee joint (as in transfemoral or through knee amputations) is a major limiting factor in rehabilitation The incidence of diabetes was included in the creation dataset analysis and was a significant co morbidity (n=152, 45% of patients undergoing amputation). However, we omitted diabetes from the BLARt assessment because whilst it is an underlying risk factor for peripheral vascular disease and amputation it does not necessarily impact on rehabilitation. In attempting to distinguish between patients with unlimited walking distance before surgery and those able to walk a limited distance unaided, we used ability to walk 3 miles as a surrogate for unlimited walking, which approximates to a SIGAM mobility grade F (normal/near normal walking) and NHS prosthetic activity code A3L. We realise that this definition is to some extent subjective, but our intention was to predict broadly whether a patient would achieve any walking function (SIGAM grade C or greater) or independent mobility (SIGAM grade E or F). To achieve this it is more important to distinguish levels of immobility rather of extended mobility before surgery. It is possible that a different definition of unlimited or normal walking might have improved performance of the BLARt, but we believe this is unlikely, and grouped SIGAM grades E and F together for analysis.

We recognise that there are several other post-operative factors that can impact on the success of prosthetic ambulation and good functional outcome. Wound healing, stump characteristics (affecting prosthetic fitting), phantom limb pain, amputation stump pain and psychosocial issues [37, 46, 47] can all prolong the rehabilitation process. However these cannot be predicted before surgery and therefore are not accounted for in the BLARt assessment.

Further studies

Further studies are required and planned to use the BLARt assessment in a larger population across several centres nationwide, in order to validate the tool in a larger patient group. It is anticipated that this assessment could ultimately be incorporated into routine clinical practice to guide and inform patients about their potential mobility outcomes after lower limb amputation.

CONCLUSIONS

We have developed a novel scoring system to predict the likelihood of walking after lower limb amputation. The BLARt score offers a consistent pre-operative assessment based on objective evaluation of underlying clinical variables and their influence on rehabilitation after lower limb amputation. It could provide patients and clinicians with a more realistic prediction of the chances of walking after surgery, and assist in setting realistic objectives and expectations.

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Declaration of Interest

The authors report no conflicts of interest.

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Table 1: BLARt Assessment Tool

Sex	**Score**		**Special Risks**	**Score**
Male	**0**		Severe respiratory disease[2]	**5**
Female	**1**		Renal failure requiring dialysis	**4**
			Stroke[3]	**3**
Age in years			Recent MI / Angina[4]	**2**
14-49	**0**		Contralateral Limb Problem[1]	**2 -4**
50-64	**1**			
65-74	**2**		**Indication for Amputation**	
75-80	**5**		Trauma	**0**
80+	**6**		Congenital	**0**
			Cancer	**1**
BMI			Orthopaedic	**2**
18.5 - 24.9 (Average)	**0**		Vascular	**3**
25 - 29.9 (Above Average)	**1**			
30+ (Obese)	**3**		**Level of Amputation**	
18.5 or less (Below Average)	**2**		Transfemoral /Through Knee	**3**
			Transtibial	**1**
Mobility Before Amputation			Hip Disarticulation	**5**
Wheelchair bound ≥12 months	**5**		Bilateral[5]	**4-6**
Wheelchair bound <12 months	**4**			
Indoor mobility with aids	**3**		**Cognitive Impairment[6]**	
Outdoor mobility with aids	**2**		Confused	**5**
Unaided outdoor mobility	**1**		Limited Carry Over	**3**
Able to walk ≥3 miles	**0**		Alert / Aware	**0**
			Total Score:	

[1] **Contralateral Limb Problems** - score varies depending on the degree of disability, for example:
Score 2 – Underlying claudication (can weight bear), leg ulcers or knee replacement.
Score 3 – Toe / partial foot amputation (difficulty weight bearing due to neuropathy or balance issues).
Score 4 – Previous amputation or severe disease to limb (not able to weight bear or stand).

[2] **Severe Respiratory Disease –** defined as a history of COPD, home oxygen therapy or shortness of breath at rest.

[3] **Stroke –** defined as a history of stroke with residual motor deficit. Patients who had contralateral lower limb weakness also score on the contralateral limb problems scale.

[4] **Recent MI / Angina –** MI within the last 6 months or ongoing angina.

[5] Level of amputation- through-knee and transfemoral amputations are grouped together
Score 4 - bilateral transtibial amputation
Score 5 - transtibial and contralateral through-knee or transfemoral amputation
Score 6 - bilateral transfemoral or through-knee amputation

[6] **Cognitive Impairment** is defined as the inability of patients to retain information shortly after it had been discussed, such as physiotherapy exercises and basic instructions. It was categorised as:
Score 5 - Confused (unable to understand and retain information).
Score 3 - Limited Carry Over (able to understand but not retain information).
Score 0 - Alert/ Aware (able to understand and retain information).

Table 2: Characteristics of Patients in creation dataset (n=338) who underwent major amputation between 2000-2008 presented as mean (range) or number (%)

	Transfemoral/through-knee amputations *(n=152)*	**Transtibial amputations *(n=186)***
Age (years)	69.5 (15-95)	65 (15-92)
Male/Female	109 (72%)/43 (28%)	144 (77%)/42 (23%)
Indication for Amputation		
Vascular *(n=282)*	127 (84%)	155 (83%)
Orthopaedic/Trauma/Congenital *(n=45)*	19 (12%)	26 (14%)
Cancer *(n=11)*	6 (4%)	5 (3%)
Coexisting Morbidity [1]		
Diabetes *(n=152)*	52 (34%)	100 (54%)
Ischaemic heart disease *(n=81)*	32 (21%)	49 (26%)
Stroke *(n=44)*	16 (11%)	28 (15%)
Renal Failure *(n=33)*	13 (9%)	20 (11%)
Severe respiratory Disease *(n=32)*	12 (8%)	20 (11%)
Contralateral limb problem *(n=33)*	0	33 (18%)
Cognitive impairment *(n=10)*	0	10 (5%)
Obesity *(n=7)*	0	7 (4%)
Congestive heart failure *(n=6)*	0	6 (3%)
Activity Level Achieved at 12 months[2]		
AOL *(n=110)*	80 (52%)	30 (16%)
A1L *(n=73)*	24 (16%)	49 (26.5%)
A2L *(n=62)*	9 (6%)	53 (28.5%)
A3L *(n=26)*	7 (5%)	19 (10%)
A4L *(n=4)*	0	4 (2%)
Died *(n=63)*	32 (21%)	31 (17%)

[1]Many patients had more than 1 coexisting morbidity hence column totals = >100%. Contralateral limb problem was defined as in Table 1. Obesity was defined as BMI>30 kg m^{-2}.

[2]NHS activity coding classification – see Figure 1

Table 3: Comparison of Patient Characteristics according to Level of Functional Rehabilitation at 12 months – Creation dataset (*n=338*)

Level of Functional Rehabilitation	Functional A2L, A3L + A4L *(n=92)*	Non-Functional A0L + A1L *(n=183)*	Died *(n=63)*
Age (years)			
14-49	34 (37%)	6 (3%)	2 (3.1 %)
50-64	24 (26%)	57 (31%)	9 (14.3 %)
65-74	16 (17%)	52 (29%)	16 (25.5 %)
75-80	12 (13%)	35 (19%)	19 (30.1 %)
81+	6 (7%)	33 (18%)	17 (27%)
Male: Female	84:8	124:59	45:18
Indication for Amputation			
Vascular	58 (63%)	166 (91%)	58 (92%)
Orthopaedic/Trauma/Congenital	31 (34%)	11 (6%)	3 (5%)
Cancer	3 (3%)	6 (3%)	2 (3%)
Coexisting Morbidity			
Diabetes	37 (40%)	80 (44%)	35 (56%)
Ischaemic heart disease	18 (19%)	43 (23%)	20 (32%)
Stroke	7 (8%)	28 (15%)	9 (14%)
Renal failure	3 (3%)	17 (9%)	13 (21%)
Severe respiratory disease	8 (9%)	19 (10%)	5 (8%)
Obesity			
Obese	3 (3%)	4 (2%)	0 (0%)
Not obese	89 (97%)	179 (98%)	63 (100%)
Contralateral Limb Problem	10 (11%)	16 (9%)	7 (11 %)
Cognitive Impairment			
Confused	2 (2%)	3 (2%)	5 (8%)
Alert/aware	90 (98%)	180 (98%)	58 (92%)
Level of Amputation			
Transfemoral /through knee	16 (17%)	104 (57%)	32 (51%)
Transtibial	76 (83%)	79 (43%)	31 (49%)

Percentages refer to column totals. Many patients had more than 1 coexisting morbidity hence some column totals = > 100%.

Table 4: Results of univariate binary logistic regression of the creation dataset according to mobility grade A0L or A1L (*n = 338*)

Variable	Odds ratio (95% confidence interval)	Significance (*p value*)
Level (transfemoral or through-knee amputation)	6.01 (3.36-11.1)	<0.001
Age > 70 years	5.70 (2.80-11.63)	<0.001
Male Sex	4.88 (1.51-27.2)	<0.001
Vascular indication for amputation	1.84 (1.36-2.47)	0.004
Renal failure	4.19 (1.25-14.11)	0.02
Diabetes	1.96 (0.93-4.14)	0.07
Stroke	1.95 (0.85-4.66)	0.10
Ischaemic heart disease	1.39 (0.77-2.50)	0.28
Obesity	2.00 (0.11-2.27)	0.37
Arthritis	1.46 (0.24-1.9)	0.47
Cognitive impairment	1.54 (0.32-7.38)	0.59
Severe respiratory disease	1.10 (0.48-2.56)	0.82
Contralateral limb problem	1.16 (0.39-1.89)	0.86

See main text and Legend to Table 1 for definitions

Table 5: Multinomial stepwise forward logistic regression analysis of creation dataset (*n = 338*).

Variable	**Odds ratio**	**95% confidence interval**	**Significance *(p value)***
Age >75 years	2.15	1.49-3.13	<0.001
Sex	4.60	2.79-17.95	<0.001
Vascular disease	4.79	2.08-11.0	<0.001
Level (trans-femoral/through-knee amputation)	9.46	4.49-19.9	<0.001
Renal failure	5.7	1.53-21.43	0.009
Stroke	1.67	0.62-4.45	0.31
Diabetes	1.54	0.79 -3.02	0.21

Table 6: Characteristics of Patients in Validation dataset (*n=199*) who underwent major amputation. Data presented as mean (range) or number (%).

	Transfemoral/through-knee amputations *(n=101)*	**Transtibial Amputations *(n=68)***	**Bilateral or Hip Disarticulation *(n=30)***
Age (years)	71 (38-97)	63 (14-92)	66 (32-88)
Male/Female	60 (59%)/41 (41%)	49 (72%)/19 (28%)	21 (70%)/9 (30%)
Indication for Amputation			
Vascular	85 (84%)	52 (76%)	27 (90%)
Orthopaedic/Trauma/Congenital	14 (14%)	14 (21%)	2 (6.6%)
Cancer	2 (2%)	2 (3%)	1 (3.3%)
Coexisting Morbidity			
IHD	8 (8%)	8 (12%)	1 (3.3%)
Stroke	8 (8%)	7 (10%)	3 (10%)
Renal Failure	2 (2%)	6 (9%)	3 (10%)
Severe respiratory disease	16.5 (17%)	7 (10%)	4 (13%)
Diabetes	NR	NR	NR
Body Mass Index (BMI)			
< 18.5 (Below Average)	17 (16.5%)	5 (7%)	5 (17%)
18.5 - 24.9 (Average)	46 (46%)	37 (54%)	13 (43%)
25 - 29.9 (Above Average)	21 (21%)	16 (24%)	9 (30%)
>30 (Obese)	17 (16.5%)	10 (15%)	3 (10%)
Contralateral Limb Problem	27 (27%)	9 (13%)	7 (23%)
Cognitive Impairment			
Confused	10 (10%)	3 (5%)	2 (7%)
Alert / Aware	75 (74%)	54 (79%)	20 (66%)
Limited Carry Over	16 (16%)	11 (16%)	8 (27%)
Activity Level Achieved at 12 months			
SIGAM A	46 (45%)	8 (12%)	20 (66%)
SIGAM B	7 (7%)	6 (9%)	2 (6%)
SIGAM C	18 (17%)	19 (26%)	5 (17%)
SIGAM D	13 (13%)	11 (16%)	2 (7%)
SIGAM E	4 (4%)	4 (6%)	0
SIGAM F	1 (1%)	13 (20%)	0
Died	12 (12%)	7 (11%)	1 (4%)
Mobility Before Amputation			
Wheelchair bound ≥12 months	14 (14%)	4 (6%)	10 (33%)
Wheelchair bound <12 months	10 (10%)	2 (3%)	1 (3.5%)
Indoor mobility with aids	34 (34%)	14 (20%)	8 (27%)
Outdoor mobility with aids	15 (15%)	15 (22%)	6 (20%)
Unaided outdoor mobility	16 (16%)	17 (25%)	1 (3.5%)
Able to walk ≥3 miles	12 (11%)	16 (24%)	4 (13%)

Percentages refer to column totals. NR = not recorded

Table 7: Comparison of Patient Characteristics according to Level of Functional Rehabilitation at 12 months in validation dataset using the SIGAM scale[39] (n=*199*). SIGAM grades C, D & E were used to define a good functional outcome; non-functional rehabilitation outcome equated to SIGAM grades A & B.

Level of Functional Rehabilitation	**Functional SIGAM C, D, E + F (*n=90*)**	**Non-functional SIGAM A + B (*n=89*)**	**Died (*n=20*)**
Age (years)			
14-49	20 (22%)	7 (8%)	0
50-64	26 (29%)	16 (18%)	4 (20%)
65-74	23 (26%)	24 (27%)	6 (30%)
75-80	13 (14%)	16 (18%)	4 (20%)
80+	8 (9%)	26 (29%)	6 (30%)
Male: Female	69: 21	46: 43	15: 5
Indication for Amputation			
Vascular	66 (74%)	90 (90%)	18 (90%)
Orthopaedic /Trauma/Congenital	19 (21%)	10 (10%)	2 (10%)
Cancer	5 (5%)	0 (0%)	0
Coexisting Morbidity			
IHD	6 (7%)	10 (11%)	2 (10%)
Stroke	5 (5%)	11 (12%)	2 (10%)
Renal Failure	1 (1%)	7 (8%)	4 (20%)
Severe respiratory Disease	3 (3%)	20 (22%)	3 (15%)
Diabetes	NR	NR	NR
Body Mass Index (BMI)			
18.5 - 24.9 (Average)	54 (60%)	29 (33%)	13 (65%)
25 - 29.9 (Above Average)	19 (21%)	24 (27%)	3 (15%)
30+ (Obese)	8 (9%)	20 (22%)	2 (10%)
18.5 or less (Below Average)	9 (10%)	16 (18%)	2 (10%)
Contralateral limb Problem	13 (14%)	33 (37%)	1 (5%)
Cognitive Impairment			
Confused	1 (1%)	10 (11%)	4 (20%)
Limited Carry Over	8 (9%)	21 (24%)	6 (30%)
Alert/ Aware	81 (90%)	58 (65%)	10 (50%)
Level of Amputation			
Transfemoral /Through Knee	36 (40%)	53 (60%)	12 (60%)
Transtibial	47 (52%)	14 (16%)	7 (35%)
Hip Disarticulation	3 (3.5%)	10 (11%)	0
Bilateral	4 (4.5%)	12 (13%)	1 (5%)
Mobility Before Amputation			
Wheelchair bound ≥12 months	0 (0%)	27 (30%)	1 (5%)
Wheelchair bound <12 months	1 (1%)	10 (11%)	2 (10%)
Indoor mobility with aids	17 (19%)	30 (34%)	9 (45%)
Outdoor mobility with aids	22 (24.5%)	11 (12%)	3 (15%)
Unaided outdoor mobility	28 (31%)	5 (6%)	1 (5%)
Able to walk 3 miles or more	22 (24.5%)	6 (7%)	4 (20%)

Table 8: BLART score and walking ability at 12 months after amputation

Patients were classified in 2 ways: good/poor function (left columns) or functional/non-functional (right columns), according to SIGAM mobility grade. No patient with a BLARt score ≥13 was able to walk independently (good functional outcome: SIGAM E or F). No patient with a BLARt score ≥22 and only 6 patients with a BLARt score ≥17 were able to walk to any degree (functional outcome: SIGAM C or greater). However there was no clear relationship between low BLARt scores and poor walking ability (SIGAM A-D).

	Activity Level at 12 months after amputation			
BLARt score	Good function (SIGAM E- F) (n=22)	Poor function (SIGAM A-D or died) (n=179)	Functional (SIGAM C-F) (n=91)	Non-functional (SIGAM A-B or died) (n=108)
1	3	0	3	0
2	1	0	1	0
5	4	3	7	0
6	4	2	6	0
7	3	2	5	0
8	1	10	9	2
9	1	9	8	2
10	2	7	6	3
11	1	5	6	0
12	2	8	9	1
13	0	13	10	3
14	0	16	9	7
15	0	8	2	6
16	0	6	4	2
17	0	9	1	8
18	0	14	2	12
19	0	9	0	9
20	0	8	1	7
21	0	7	2	5
22	0	8	0	8
23	0	5	0	5
24	0	7	0	7
25	0	6	0	6
26	0	5	0	5
27	0	5	0	5
28	0	1	0	1
29	0	1	0	1
31	0	2	0	2
32	0	1	0	1

SIGAM mobility grades:

A – non limb user, B – Therapeutic, wears only for transfers, C – Limited/Restricted, walks up to 50m, D- Impaired, walks 50m or more with walking aid, E- Independent, walks 50m or more without walking aid, F – Normal/Near normal walking).[39]

Figure 1:

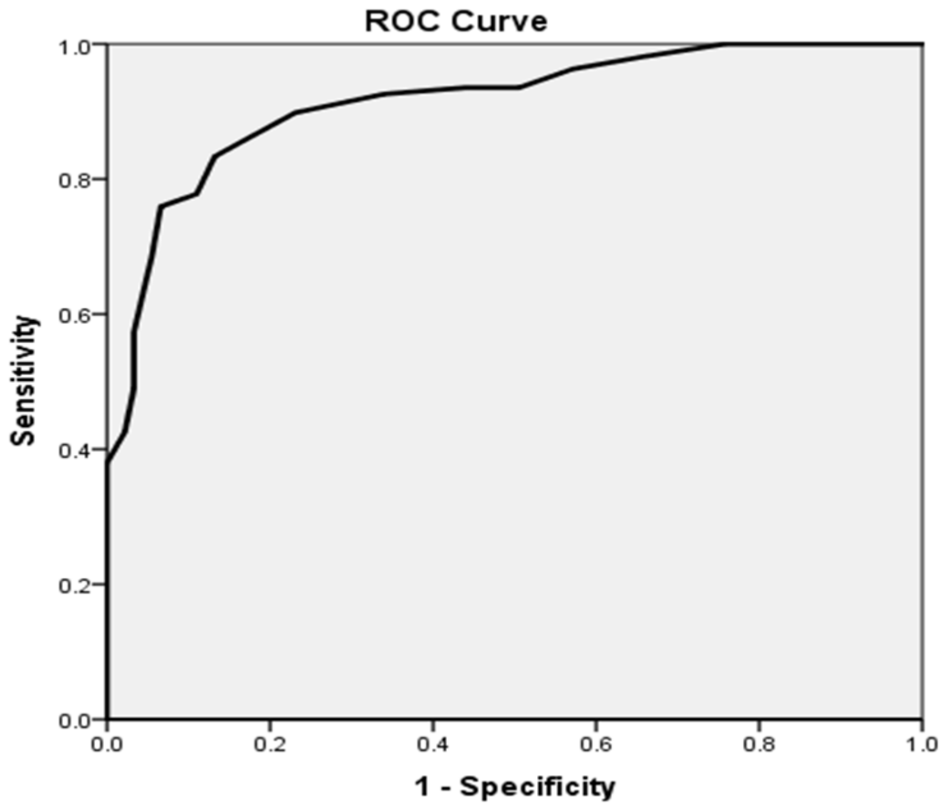

Figure 1: ROC Curve of BLARt score against likelihood of a non-functional outcome, defined as a SIGAM grade B or below at 12 months after amputation. The area-under-the-curve is 0.914 (SE 0.2, 95% confidence intervals 0.87-0.95)