Factors Associated with Return to Ambulation Following Major Lower Limb Amputation at an Urban US Tertiary Healthcare Center

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Statement of Purpose and Literature Review

Despite a good understanding of risk factors for amputation and the development of multidisciplinary diabetic foot amputation prevention teams, literally hundreds of major limb amputations are performed worldwide on the daily basis. One relatively universal goal following major limb amputation is for the patient to return to ambulation with a prosthetic. In fact, however, there is little published evidence on how many patients actually return to ambulation following major limb amputation and what factors are associated with a successful return to ambulation [1-6].

The objectives of this retrospective, observational investigation were to 1) determine what percentage of patients return to ambulation within one year following major limb amputation, and 2) assess which patient factors may be associated with successful return to ambulation within one year following major limb amputation at an urban US tertiary care health system with a multidisplinary limb salvage team.

Methodology

Following approval by our institution's IRB (Protocol #22923), a retrospective chart review was performed over a two-year data collection period allowing for at least 12 months of follow-up for all major lower limb amputations performed at a single tertiary health care system. The primary outcome measure was documented ambulation in a prosthetic within one year following major lower limb amputation. Comparisons were performed between differing end-result amputation groups (unilateral below knee [BKA], unilateral above knee [AKA], bilateral major amputation and "other" major amputation) as well as between ambulators vs. non-ambulators. Extracted patient demographics included age, gender, race/ethnicity, insurance coverage, follow-up, mortality, living situation, body mass index, smoking history and a specific history of diabetes, end-stage renal disease, COPD, dementia, coronary artery disease, and peripheral arterial disease.

Results

We extracted data on one hundred and sixty-seven consecutive patients who met study inclusion/exclusion criteria. Seventy-four patients (42.05%) had a final result of a **unilateral BKA with a 50.0% return to ambulation**, 55 patients (31.25%) had a final result of an **unilateral AKA with 20.0% return to ambulation**, 35 patients (19.89%) had a final result of a **bilateral major limb amputation with a 2.86% return to ambulation**, and 3 patients (1.70%) underwent another type of major amputation with a 33.3% return to ambulation. **Patients whose final result was a BKA as opposed to an AKA were statistically more likely to** be younger (p=0.0036), Hispanic (p=0.0353), ambulatory pre-operatively (p=0.0004), diabetic (p=0.0126), have ESRD (p=0.0095), and have an amputation that primarily healed without requiring additional intervention (p<0.0001**). Patients whose final result was an AKA as opposed to a BKA were more likely to** have a history of dementia (p<0.0001) and at least one attempted revascularization (p=0.0005). **Ambulators were statistically more likely to** be younger (p<0.0001), of male gender (p=0.0255), have follow-up > 6 months (p<0.0001), be ambulatory pre-operatively (p=0.0008), return home following their amputation (p<0.0001), and have an amputation that primarily healed without requiring additional intervention (p=0.0155). **Non-ambulators were statistically more likely to** be deceased at one post-operative year (p=0.0169), have a history of PAD (p=0.0058), and have at least one attempted revascularization (p<0.0001).

Full study results are demonstrated in the following tables. Table 1 (Left) demonstrates descriptive statistics and a comparison between patients undergoing unilateral BKA vs. unilateral AKA. Table 2 (center) demonstrates descriptive statistics and a comparison between ambulators vs. non-ambulators in a pooled BKA/AKA group. Table 3 (right) demonstrates descriptive statistics and a comparison between ambulators vs. non-ambulators in those undergoing unilateral BKA. Descriptive data of continuous variables is reported in terms of the mean ± standard deviation (range) and compared with the unpaired t-test. Descriptive data of categorical variables is reported in terms of the frequency count (%) and compared with the Fisher's exact test. A level of significance was set at $p < 0.05$.

Variable Mean ± SD (range) or Frequency count (%)	BKA (n=74)	AKA (n=55)	Statistical Comparison
Age (years)	58.78 ± 13.16 (21-92)	66.07 ± 14.65 (18-97)	**P = 0.0036***
Gender	45 (60.81) Male; 29 (39.19) Female	32 (58.18) Male; 23 (41.82) Female	P = 0.8563
Race	32 (43.24) black; 21 (28.38) white; 1 (1.35) Asian; 20 (27.03) other	30 (54.55) black; 18 (32.73) white; 7 (12.73) other	Black (p=0.2176) White (p=0.6988) Other (p=0.0507)
Ethnicity	18 (24.32) Hispanic; 56 (75.68) not	5 (9.09) Hispanic; 50 (90.91) not	**P = 0.0353***
Laterality	35 (47.30) right; 39(52.70) left	29 (52.73) right; 26 (47.27) left	P=0.5954
Insurance	26 (35.14) Medicare; 26 (35.14) Medicaid; 22 (29.73) Private	19 (34.55) Medicare; 20 (36.36) Medicaid; 16 (29.10) Private	Medicare (p=1.00) Medicaid (p=1.00) Private (p=1.00)
6 month F/U with Vascular and/or Rehab?	47 (63.51) yes; 27 (36.49) no	28 (50.91) yes; 27 (49.09) no	P=0.2064
1 year mortality	70 (94.59) alive; 4 (5.41) deceased	46 (83.64) alive; 9 (16.36) deceased	P=0.0726
Ambulatory Pre-op?	70 (94.59) yes; 4 (5.41) no	39 (70.91) yes; 16 (29.09) no	**P=0.0004***
Confirmed ambulatory Post-op?	37 (50.0) yes; 37 (50.0) no or unknown	11 (20.0) yes; 44 (80.0) no or unknown	**P=0.0005***
Pre-Op Living Situation	64 (86.49) home; 5 (6.76) nursing facility; 5 (6.76) unknown	48 (87.27) home; 7 (12.73) nursing facility	P=1.00
% Returned home Post-Op	32 (43.24) home; 42 (56.76) not or unknown	25 (45.45) home; 30 (54.55) not or unknown	P=0.8586
DM?	61 (82.43) yes; 13 (17.57) no	34 (61.82) yes; 21 (38.18) no	**P=0.0146***
HbA1c	8.75 ± 2.67% (5.3-15.6) (n=39)	7.60 ± 1.93% (6.83-8.36) (n=27)	P=0.0598
BMI	28.52 ± 6.69 (19-57) (n=60)	27.08 ± 7.33 (18.4 -53) (n=54)	P=0.2751
ESRD?	19 (25.68) yes; 55 (74.32) no	4 (7.27) yes; 51 (92.73) no	**P=0.0095***
COPD?	9 (12.16) yes; 65 (87.87) no	6 (10.91) yes; 49 (89.09) no	P=1.00
Any tobacco history?	44 (59.46) yes; 30 (40.54) no	40 (72.73) yes; 15 (27.27) no	P=0.1375
Dementia?	0 (0.0) yes; 74 (100.0) no	13 (23.64) yes; 42 (76.36) no	**P<0.0001***
CAD?	32 (43.24) yes; 42 (56.76) no	31 (56.36) yes; 24 (43.64) no	P=0.1574
PAD?	46 (62.16) yes; 28 (37.84) no	43 (78.18) yes; 12 (21.82) no	P=0.0570
History of Revascularization?	26 (35.14) yes; 48 (64.86) no	36 (65.45) yes; 19 (34.55) no	**P=0.0008***
Amputation Healed or Require Secondary Procedure?	65 (87.84) healed primarily; 9 (12.16) required intervention or revision	32 (58.18) healed primarily; 23 (41.82) required intervention or revision	**P=0.0002***

Variable Mean ± SD (range) or Frequency count (%)	Ambulator (n=48)	Non-Ambulator (n=81)	Statistical Comparison
Age (years)	54.75 ± 14.01 (18-83)	66.12 ± 12.65 (32-97)	**P<0.0001***
Gender	35 (72.92) male; 13 (27.08) female	42 (51.85) male; 39 (48.15) female	**P=0.0255***
Race	25 (52.08) Black; 11 (22.92) White; 12 (25.0) Other	38 (46.91) Black; 28 (34.57) White; 15 (18.52) Other	Black (p=0.5896); White (p=0.2338); Other (p=0.5036)
Ethnicity	12 (25.0) Hispanic; 36 (75.0) not	11 (13.58) Hispanic; 70 (86.42) not	P=0.1521
Laterality	23 (47.92) right; 25 (52.08) left	40 (49.38) right; 41 (50.62) left	P=1.00
Insurance	16 Medicare 16 Medicaid 16 Private	30 Medicare 30 Medicaid 21 Private	Medicare (p=0.7075); Medicaid (p=0.7075); Private (p=0.4226)
6 month F/U with Vascular and/or Rehab?	41 (85.42) yes; 7 (14.58) no	34 (41.98) yes; 47 (58.02) no	**P<0.0001***
1 year mortality	47 (97.92) alive; 1 (2.08) deceased	68 (83.95) alive; 13 (16.05) deceased	**P=0.0169***
Ambulatory Pre-op?	47 (97.92) yes; 1 (2.08) no	62 (76.54) yes; 19 (23.46) no	**P=0.0008***
Pre-Op Living Situation	45 (93.75) living at home; 3 (6.25) not or unknown	68 (83.95) lived at home; 13 (16.05) no	P=0.1656
% Returned home Post-Op	34 (70.83) home; 14 (29.17) not or unknown	23 (28.40) home; 58 (71.60) not or unknown	**P<0.0001***
DM?	35 (72.92) yes; 13 (27.08) no	60 (74.07) yes; 21 (25.93) no	P=1.00
HbA1c	8.57 ± 2.46% (5.8-15.6) (n=27)	8.08 ± 2.45% (5.3-14.0) (n=39)	P=0.4281
BMI	28.25 ± 5.85 (18.5-48) (n=46)	27.41 ± 7.71 (17.3-57) (n=70)	P=0.5305
ESRD?	9 (18.75) yes; 39 (81.25) no	14 (17.28) yes; 67 (82.72) no	P=0.8169
COPD?	3 (6.25) yes; 45 (93.75) no	12 (14.81) yes; 69 (85.19) no	P=0.1671
Any tobacco history?	31 (64.58) yes; 17 (35.42) no	53 (65.43) yes; 28 (34.57) no	P=1.00
Dementia?	0 (0.0) yes; 48 (100.0) no	13 (16.05) yes; 68 (83.95) no	P=0.0019
CAD?	22 (45.83) yes; 26 (54.17) no	44 (54.32) yes; 37 (45.68) no	P=0.3685
PAD?	28 (58.33) yes; 26 (54.17) no	61 (75.31) yes; 20 (24.69) no	**P=0.0058***
History of Revascularization?	14 (29.17) yes; 34 (70.83) no	60 (74.07) yes; 21 (25.93) no	**P<0.0001***
Amputation Healed or Require Secondary Procedure?	43 (89.58) healed; 5 (10.42) required intervention or revision	57 (70.37) healed; 24 (29.63) required intervention or revision	**P=0.0155***

Variable Mean ± SD (range) or Frequency count (%)	BKA Ambulator (n=37)	BKA Non-ambulator (n=37)	Statistical Comparison
Age (years)	56.0 ± 12.17 (21-83)	61.57 ± 13.68 (32-92)	P = 0.0684
Gender	27 (72.97) male; 10 (27.03) female	18 (48.65) male; 19 (51.35) female	P = 0.0559
Race	19 (51.35) black; 7 (18.92) white; 11 (29.73) other	14 (37.84) black; 14 (37.84) white; 9 (24.32) other	Black (p=0.3497); White (p=0.1208); Other (0.7940)
Ethnicity	11 (29.73) Hispanic; 26 (70.27) not	7 (18.92) Hispanic; 30 (81.08) not	P = 0.4169
Laterality	18 (48.65) right; 19 (51.35) left	17 (45.95) right; 20 (54.05) left	P = 1.00
Insurance	15 Medicare 11 Medicaid 11 Private	12 Medicare 16 Medicaid 9 Private	Medicare (p=0.4734); Medicaid (p=0.3342); Private (p=0.7940)
6 month F/U with Vascular and/or Rehab?	32 (86.49) yes; 5 (13.51) no	15 (40.54) yes; 22 (59.46) no	**P < 0.0001***
1 year mortality	36 (97.30) alive; 1 (2.70) deceased	34 (91.89) alive; 3 (8.11) deceased	P = 0.6145
Ambulatory Pre-op?	37 (100.0) yes; 0 (0.00) no	33 (89.19) yes; 4 (10.81) no	P = 0.1148
Pre-Op Living Situation	35 (94.59) lived at home; 2 (5.41) no	31 (83.78) lived at home; 6 (16.22) no	P = 0.2611
% Returned home Post-Op	23 (62.16) home; 14 (37.84) other	9 (24.32) home; 28 (75.68) other	**P = 0.0021***
DM?	30 (81.08) yes; 7 (18.92) no	31 (83.78) yes; 6 (16.22) no	P = 1.00
HbA1c	8.72 ± 2.63% (5.8-15.6%) (n=23)	8.80 ± 2.81% (5.3-14.0%) (n=16)	P = 0.9258
BMI	28.21 ± 5.57 (21-48) (n=35)	28.48 ± 8.13 (19-57) (n=27)	P = 0.8789
ESRD?	9 (24.32) yes; 28 (75.68) no	10 (27.03) yes; 27 (72.97) no	P = 1.00
COPD?	3 (8.11) yes; 34 (91.89) no	6 (16.22) yes; 31 (83.78) no	P = 0.4790
Dementia?	37 (100.0) no; 0 (0.0) yes	37 (100.0) no; 0 (0.0) yes	P = 1.00
Any tobacco history?	22 (59.46) yes; 15 (40.54) no	22 (59.46) yes; 15 (40.54) no	P = 1.00
CAD?	15 (40.54) yes; 22 (59.46) no	17 (45.95) yes; 20 (54.05) no	P = 0.8147
PAD?	21 (56.76) yes; 16 (43.24) no	25 (67.57) yes; 12 (32.43) no	P = 0.4725
History of Revascularization?	10 (27.03) yes; 27 (72.97) no	16 (43.24) yes; 21 (56.76) no	P = 0.2231
Amputation Healed or Require Secondary Procedure?	35 (94.59) healed; 2 (5.41) required intervention or revision	32 (86.49) healed; 5 (13.51) required intervention or revision	P = 0.4297

Discussion

As with any scientific investigation, critical readers are encouraged to review the study design and results and reach their own conclusions, while the following represents our interpretation of the specific results. As scientists, we also never consider data to be definitive, but do think that these results are worthy of attention and future investigation.

We present findings of rate of ambulation following major lower limb amputation at an urban US tertiary health care center with a multidisplinary limb salvage team:

-We observed a lower than hypothesized documented rate of successful ambulation with a prosthetic. We did not observe an ambulation rate >50% in any major amputation group potentially emphasizing the importance of limb salvage techniques and perhaps demonstrating that major amputation may not be as definitive or functional as is sometimes thought. Although many patients may function well with a major amputation, we found that this occurred in the minority of our urban cohort.

-We also believe these results emphasize the importance of follow-up from a limb salvage team after an amputation. The role of the team should not end with a healed amputation stump, but rather after the patient has achieved their maximal functional outcome.

-Finally, we present patient demographic variables associated with amputation and ambulation groups that has the potential to be useful in surgical decision planning. This information could have benefit in determining which patients may be most likely to have a functional result following a specific level of major amputation. We believe this information should factor into our patient education and consent process.

In conclusion, this investigation provides evidence on the outcome of major amputation at an urban US tertiary healthcare center with a multidisplinary limb salvage team. Major amputation is a realistic outcome that often occurs despite our best efforts, and we hope these findings emphasize that our care of patients should extend beyond what is sometimes viewed as a short-term or immediate treatment "failure".

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