Difficult to predict early failure after major lower-extremity amputations

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ABSTRACT

INTRODUCTION: The successful outcome of a major amputation depends on several factors, including stump wound healing. The purpose of this study was to examine the criteria upon which the index amputation was based and to identify factors associated with early amputation failure after major non-traumatic lower-extremity amputation.

METHODS: We studied a consecutive one-year series of 36 men and 34 women with a median (25-75% quartiles) age of 72 (63-83) years who were treated in an acute orthopaedic ward; 44 below-knee and 26 above-knee amputees of whom 47 had an American Society of Anesthesiologists rating above two. Patient characteristics and other factors potentially influencing early amputation failure within 30 days were evaluated.

RESULTS: Eleven patients died (16%) and 11 (16%) had a re-amputation at a higher level, whereas four (6%) had a major revision at the same level within 30 days. Amputations were performed by a house officer (n = 29), a specialist registrar (n = 27) or a consultant (n = 14). A total of 28 surgeons performed the included operations. Neither a preoperative skin perfusion test (only measured for 25 patients), nor any of the many other factors evaluated predicted early amputation failure. Patients with one or more failures stayed in the ward for a median of 45 (33-57) days versus 20 (14-25) days for those without failures.

CONCLUSIONS: The rate of short-term amputation failures was high, and no clear explanation for this was established. A pre-amputation algorithm to support the right choice of amputation level is needed.

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ORIGINAL ARTICLE

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A successful outcome of a major lower-extremity amputation (LEA) has been defined by Taylor et al [1] as: "1) Wound healing of the below-knee amputation without need for revision to a higher level; 2) maintenance of ambulation with a prosthesis for at least one year or until death; and 3) survival for at least six months." Nonetheless, mortality is high (> 50% within one year) [2, 3], and early amputation failure within 30 days [4] and in the year following a major LEA [1, 5-7] is common. The surgeon's experience seems to influence re-amputation rates [8], but there is a lack of consensus regarding which criteria should be used to determine the amputation level [9, 10]. For instance, recommendations for choosing the right index amputation level using, e.g. the skin perfusion pressure (SPP) test, vary from greater than 20 to greater than 40 mmHg [11-15].

Wound healing is a prerequisite for maintaining the level of amputation and for providing a prosthesis, but observations from the study hospital [16] indicated a high number of early failures. Risk factors for early failure after a LEA are sparsely described in the literature [4].Therefore, the aims of this study were: 1) to examine which criteria were used by the orthopaedic surgeon for the index LEA level and 2) to study risk factors for early failure following a major non-traumatic LEA.

METHODS

We studied a consecutive one-year series of 70 patients who underwent LEA at the study hospital (**Figure 1**). Before amputation, a department of vascular surgery was consulted where relevant to establish if the patient could benefit from vascular surgery instead of amputation.

Early failure

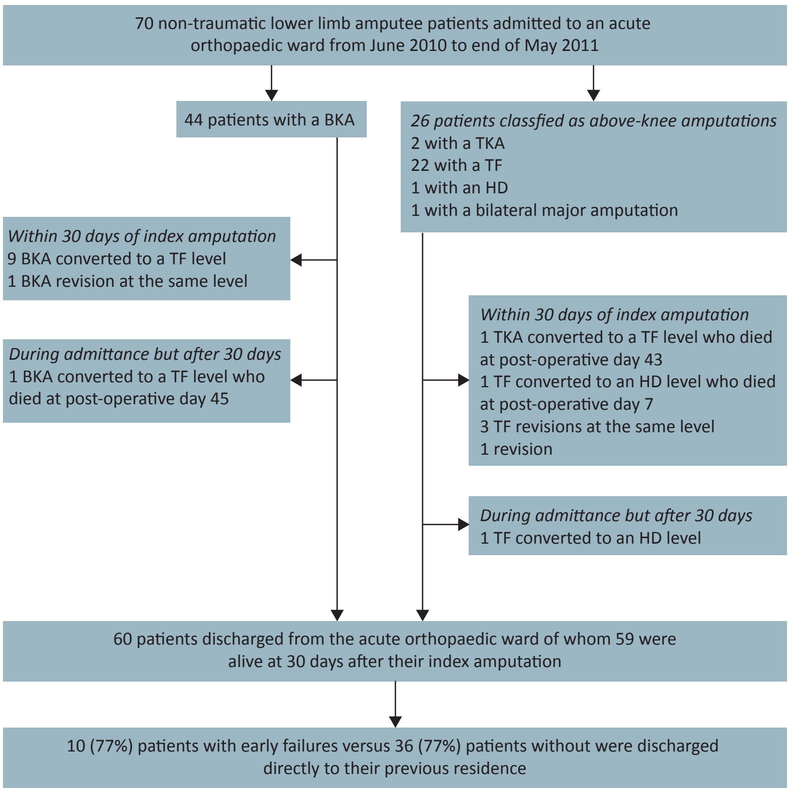
Early failure was defined as a revision at the same level or conversion to a higher level amputation within 30 days of the index LEA in accordance with previous studies including a substantial number of patients [4, 8].

Procedure

Data were collected prospectively concerning patient characteristics, indication for amputation (vascular disease with or without diabetes or other reasons), the American Society of Anesthesiologist (ASA, 0–4) rating, the index amputation level (below-knee (BKA), through-knee or above-knee (AKA), the weekday of amputation, days to an early failure, in-hospital and 30-days mortality, length of stay, and discharge location. Data on the charge of the surgeon, the preoperative status of the SPP and distal blood pressure tests were collected retrospectively from medical records along with information concerning the amputated extremity (e.g. infection, gangrene, oedema, wounds, termal level, capillar response, contracture, temperature, and pedal and inginual pulse). We accessed the hospital's surgical database to obtain

FIGURE 1

Flow of patients through the study.



BKA = trans-tibial amputation; HD = hip disarticulation; TF = trans-femoral amputation; TKA = through-knee disarticulation.

data on the time of the day for the amputation, the operative time in minutes and if tourniquet was used during the amputation. The cause of early failure for those with an index BKA was classified independently by three specialists, and consensus was reached at a meeting with the corresponding author.

Classification of preoperative tests

A distal blood pressure at the toe level above 30 mmHg, at the ankle level above 50 mmHg, or an SPP test above 40 mmHg have been proposed to indicate an adequate perfusion for healing of a BKA stump [17]. If none of these measurements were present at the time of amputation, the level of amputation was chosen by the surgeon on the basis of other criteria reported in medical charts.

Statistics

Descriptive statistics were used to describe the sample according to the index LEA level and early failure status. The Mann Whitney, chi-square or Fisher's exact tests were used for univariate analyses as appropriate to evaluate if early failures were associated with patient characteristics and/or other variables. Furthermore, a multiple logistic regression analysis (enter method) was used to examine how early failure was affected by age, sex, residence (nursing home versus own home), diagnosis (diabetes versus arteriosclerosis), health status (ASA 1-2 versus 3-4), amputation level, day of surgery (weekday versus weekend), charge of the surgeon and the operation time in minutes (< 80 min. versus ≥ 80 min.). Data are presented as the median (25-75% quartiles) or as the number of patients (percentage). All statistical analyses were conducted using SPSS version 19.0 (SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606). The level of significance was set at $p < 0.05$.

Trial registration: This trial was registered with the Danish Data Protection Agency (R. no. 01975 HVH-2012-053).

RESULTS

Index amputations were performed by 28 different surgeons, 13 of whom performed one. Eleven patients (16%) had a reamputation to a higher level and four (6%) a revision at the same level within 30 days, in addition to two more during admittance (Figure 1). More men than women ($p = 0.030$) had an index BKA. Otherwise, no significant differences were seen in the patient characteristics for the two amputation levels (**Table 1**). The high number of BKA re-amputations resulted in a 30-day change in the BKA/AKA ratio from 1.7 to 1.0 (Figure 1).

Amputee-related assessments

The review of medical records revealed that 42 of the 70 patients had a blood pressure test, and 25 had an SPP test before their index amputation (**Table 2**). We found no significant differences in the rate of early failures in relation to the patients' characteristics (Table 1) or pressure levels considered adequate for healing, nor did any of the other variables evaluated seem to influence early failure (Table 2 and **Table 3**). Correspondingly, early failures were not significantly ($p > 0.1$) associated with any of the variables evaluated in the multiple logistic regression analysis.

Nevertheless, the odds for an early failure were higher for patients who had an index BKA (odds ratio (OR) = 1.6; 95% confidence interval (CI): 0.4-6.4), nursing home status (OR = 2.1; 95% CI: 0.3-13.5) and for those amputated during weekends (OR = 3.2; 95% CI: 0.8-13.1).

Evaluation of the 44 patients with an index BKA showed that 24 out of the 33 patients with assessments had adequate perfusion levels (one or more of the three cut-off-points), that nine patients had values below the predefined criteria, and that 11 patients had none of these pre-amputation assessments. Early failure was seen for six out of the 24 BKA (25%) with adequate perfusion levels as compared with three out of nine (33%) with values considered inadequate (p = 0.6). Furthermore, five out of 11 patients with an index BKA and reports of knee contracture had an early failure (Table 2).

The ten (23%) patients (seven men) with an index BKA who had an early failure (nine converted to the femoral level) were divided equally between patients with diabetes and arteriosclerosis, and the early failures were caused by necrosis (n = 7) and infection (n = 3).

Cause of death

Eleven patients (16%) died within 30 days, one of whom suffered an early failure. Another patient, who was re-amputated at post-operative day 27 died at day 43 post-index amputation, while a third patient who was re-amputated after 30 days died during admittance at day 45 post-index amputation (Figure 1). The cause of death showed no direct association with early failure, nor did any of the deaths that occurred after 30 days in patients who were still hospitalised.

Length of stay and discharge location

Patients with an early failure stayed a median of 25 days longer in the ward post-amputation compared with patients who experienced no failure (p < 0.001, Table 1). The greater length of stay was not related to a different discharge location. Three out of 13 (23%) with an early failure compared with 11 out of 47 (23%) without early failure were not discharged directly to their previous residence. Four of the 13 patients experienced re-surgery more than once, and two of these were discharged to a nursing home after three and four re-visits, respectively, to the operating theatre, and discharged 57 and 97 days, respectively, post-index amputation, but within two weeks of their last surgery.

DISCUSSION

We found that 21.4% of the patients in our one-year

TABLE 1

Patient characteristics and association with early failure (30 days) of index amputation.

	Index amputee level			Early failure		
	BKA (N = 44 (63%))	AKA (N = 26 (37%))	p-value	yes (N = 15 (21%))	no (N = 55 (79%))	p-value
Age, yrs, median (25-75% quartiles)	72 (63-83)	73 (62-84)	0.620	67 (60-78)	74 (63-84)	0.311
Gender, n (%)			0.030			0.868
Women	17 (50)	17 (50)		7 (21)	27 (79)	
Men	27 (75)	9 (25)		8 (22)	28 (78)	
Residence, n (%)			0.193			0.691
Own home	39 (66)	20 (34)		12 (20)	47 (80)	
Nursing home	5 (46)	6 (54)		3 (27)	8 (73)	
Health status, n (%)			0.775			0.691
High, ASA 2	15 (65)	8 (35)		5 (22)	18 (78)	
Low, ASA 3-4	29 (62)	18 (38)		10 (21)	37 (79)	
Days from admittance to amputation, median (25-75% quartiles)	2 (1-6)	2 (1-3)	0.159	1 (1-4)	2 (1-5)	0.341
Index amputee level, n (%)						0.730
BKA	–	–		10 (23)	34 (77)	
AKA	–	–		5 (19)	19 (81)	
Referred from, n (%)			0.210			0.411
Department of Vascular Surgery	13 (50)	13 (50)		5 (19)	21 (81)	
Specialized Wound Healing Centre	6 (55)	5 (45)		2 (18)	9 (82)	
General Practitioner	15 (75)	5 (25)		3 (15)	17 (85)	
Medical wards	10 (77)	3 (23)		5 (39)	8 (62)	
Primary diagnosis, n (%)			0.209			0.792
Diabetes	22 (73)	8 (27)		6 (20)	24 (80)	
Arteriosclerosis	21 (58)	15 (42)		9 (24)	27 (76)	
Other	1 (25)	3 (75)		None	4 (100)	
30-day mortality, n (%)			0.086			0.439
Died within 30-days	4 (36)	7 (64)		1 (9)	10 (91)	
Alive after 30-days	40 (68)	19 (32)		14 (24)	45 (76)	
Length of stay, postindex amputation, days, median (25-75% quartiles)	21 (16-32)	24 (15-33)	0.95	45 (33-57)	20 (14-25)	< 0.001

AKA = above-knee amputation; ASA = American Society of Anesthesiologists rating; BKA = below-knee amputation.

TABLE 2

Early failures according to pre-amputation assessments and observations[a]. The values are n (%).

	Early failure			
	yes (N = 15 (21%))	no (N = 55 (79%))	subtotal	p-value
Toe pressure test				1.0
> 30 mmHg	2 (29)	5 (71)	7	
≤ 30 mmHg	4 (36)	7 (64)	11	
Ankle pressure test				1.0
> 50 mmHg	2 (17)	10 (83)	12	
≤ 50 mmHg	2 (17)	10 (83)	12	
Skin perfusion test	1.0			
> 40 mmHg	4 (19)	17 (81)	21	
≤ 40 mmHg	1 (25)	3 (75)	4	
Toe pressure > 30 mmHg or ankle pressure > 50 mmHg or skin perfusion > 40 mmHg?				0.440
Yes	6 (20)	24 (80)	30	
No	4 (33)	8 (67)	12	
Infection?				0.380
Yes	5 (17)	24 (83)	29	
No	9 (26)	25 (74)	34	
Gangrene?				1.0
Yes	12 (21)	44 (79)	56	
No	1 (14)	6 (86)	7	
Oedema?				0.252
Yes	3 (15)	17 (85)	20	
No	2 (40)	3 (60)	5	
Pedal pulse?				0.254
Yes	2 (40)	3 (60)	5	
No	4 (16)	21 (84)	25	
Knee contracture?				0.056
Yes	5 (45)	6 (55)	11	
No	1 (7)	13 (93)	14	

a) Data not complete for any of the variables evaluated.

TABLE 3

Early failures according to surgery. The values are n (%).

	Early failure		
	yes (N = 15 (21%))	no (N = 55 (79%))	p-value
Amputation performed			0.497
8 a.m.-4 p.m.	13 (24)	42 (76)	
4 p.m.-midnight	2 (13)	13 (87)	
Operative time			0.616
< 80 min.	9 (24)	29 (76)	
≥ 80 min.	6 (19)	26 (81)	
Tourniquet during amputation			0.927
Yes	5 (23)	17 (77)	
No	10 (22)	36 (78)	
Amputation performed by			0.731
House officer	5 (17)	24 (83)	
Specialist registrar	7 (26)	20 (74)	
Consultant	3 (21)	11 (79)	
Index amputation			0.097
Weekday	10 (18)	47 (82)	
Weekend	5 (39)	8 (61)	

consecutive series of major LEA had an early failure within 30-days of their index amputation. However, the present study provides no clear picture of the factors that caused these failures. Patients who had an early failure stayed in hospital for a median of 25 days longer than those without an early failure, despite no difference in the percentage of patients discharged to their own home. An early failure did not influence mortality rates; nor was there any indication that any deaths had been caused directly by a failure.

Sufficient perfusion of the tissue at the site of the amputation is a prerequisite for tissue survival and stump healing. In 1985, Holstein [18] determined that a preoperative SPP test > 30 mmHg was associated with successful healing of BKA. Subsequently, this method and pressure level have been the standard choice in Denmark. However, as Sarin et al [17] point out: "Many tests (Doppler indices, segmental pressures, skin blood flow, skin perfusion pressure, TcpO2, thermography) have been described to predict the likelihood of successful healing of an amputation stump, but none appears to have gained widespread acceptance". Although a distal blood pressure and/or a skin perfusion test are considered standard in our department, and a conservative SPP treshold of 40 mmHg is considered adequate for healing, many of our patients were amputated without these tests. Thus, it seems as if surgeons tended to rely on the clinical appearance or, e.g., skin temperature or present pulses for the decision on index amputation level although no clear evidence exists in support of such evaluations. However, even in patients who presumably had adequate perfusion, we observed a 20% early failure rate, while the rate reached 33% for patients who did not fulfil any of the predefined blood pressure levels.

Nonetheless, due to the incomplete dataset in the present study, we can make no conclusion as to which test, examination or observation is superior. The reason fo early failure in our BKA group was related mainly to necrosis. However, this is an assumption based on the retrospective review of medical records which should be interpreted with caution as it is difficult to distinguish between infection and necrosis without further laboratory examinations. Although a large number of surgeons were involved in the present study and the charge of the surgeons varied, this did not seem to influence the early failure rate, as was indicated in a previous study [8]. Still, only 12% of BKA in the latter study were converted to an AKA within 30 days, which corresponds to the 12.6% reported in a large American database series [4]. This should be compared with an overall early failure rate of 6% in a previous Danish series from the same hospital unit [2] as the present study.

The higher index BKA/AKA ratio of 1.7 found in the present study as compared with the 1.2 ratio reported in the American series [4] and the 1.0 ratio recorded in the previous Danish series [2] may explain the higher failure rates recorded in the present study. Still, these ratios are way below the 3.0 level reported in a Swedish series with an overall re-amputation rate of 17% [19], and with only 8% of dysvascular BKAs re-amputated within the following year [20]. In comparison, another Danish hospital that studied 69 patients who underwent an index through-knee amputation and 85 patients with an AKA in a retrospective 2009-2013 series reported a reamputation rate of 34.8% within 90 days for through-knee amputations as compared with 9.4% for AKA [7]. Only two patients in the present study had an index through-knee amputation, one of whom was reamputated. Thus, comparing failure rates between different hospitals and even within the same unit should generally be done with caution as the index amputation level might differ.

Specifically, the high 30-day mortality rate of 32% for major LEA in the 2009 series from the same hospital unit [2] as the present study was positively reduced to 16% in the present one-year series, but with the above-mentioned differences in the BKA/AKA ratio. The latter mortality rate is below that observed in a Finnish series [3].

Concequently, the next obvious step towards further improvement of the treatment of LEA must be to reduce the high number of early failures. Still, the goal should not simply be to avoid early failures, but to define the optimal cut point with a view to avoiding an excessive number of AKA. This needs to be further explored, and it emphasises the need for monitoring not only mortality but also the early failure rates, a measure which, as a first step, presupposes standardised pre-amputation assessments in all patients.

The weaknesses of the present study are that our analyses are based on a small number of patients treated at the same hospital with incomplete and retrospectively collected data for most of the pre-amputation variables evaluated in relation to early failures. Our findings should therfore be interpreted with caution as the non-significant findings may potentially be due to the limited power of analyses.

CONCLUSIONS

A high number of early amputation failures were seen within the first month of the index amputation, but we identified no specific risk factors for early failures in this consecutive one-year series. Although a retrospective medical chart review revealed a large number of pre-amputation assessments related to the choice of the index amputation level, none of these assessments were present in all patients. Therefore, there is an urgent need for further prospective studies in a multidisciplinary setting including the same standardised pre-amputation assessments and an associated index amputee-level algorithm for all patients. Such studies will hopefully provide more valid knowledge and thereby up-to-date guidelines for surgeons in choosing the correct index amputation level.

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