ORIGINAL ARTICLE



Characteristics and main clinical outcomes of patients undergoing transtibial amputation

Perfil dos pacientes submetidos à amputação transtibial e os principais desfechos clínicos

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ABSTRACT

Objective: To analyse the epidemiological profile of patients undergoing transtibial amputation (TTA) of the lower limb, including the prosthetic fitting rate, the degree of patient satisfaction, and postoperative complications.

Methods: This retrospective study was designed to analyse the epidemiological profile of patients undergoing TTA from 2012 through 2016. Prosthetic fitting rate, degree of satisfaction, and postoperative complications were analysed.

Results: The sample included 68 patients, of whom 42 were male (62.7%), with a mean age of 50.3 years. Of the participants, 61.2% had finished elementary school only, and 46.2% were white. The most common reason for amputation was chronic osteomyelitis, which was present in 53.7% of participants. A prosthesis was fitted in 89.6% of patients, with most (78.3%) adapting to it well. Of the participants, 40.3% experienced postoperative complications, and mortality was 21.9%. Regarding satisfaction, 76.1% of patients were not satisfied with the surgical outcome. **Conclusion:** Patients who underwent TTA were most commonly white males of approximately 50 years of age; the most prevalent comorbidities were systemic arterial hypertension and diabetes mellitus, and the most frequent reason for amputation was chronic osteomyelitis. Patient dissatisfaction was significantly associated with age (>60 years old) and depression. The prosthetic fitting rate and adaptation to the prosthesis were directly related to patient satisfaction.

Level of Evidence IV; Therapeutic Studies; Case Series.

Keywords: Amputation; Diabetes mellitus; Survival.

RESUMO

Objetivo: Avaliar o perfil epidemiológico dos pacientes que foram submetidos à amputação do membro inferior, no nível transtibial, bem como o índice de protetização, o grau de satisfação e as complicações pós-operatórias.

Métodos: Foi realizado um estudo retrospectivo para avaliar o perfil epidemiológico dos pacientes submetidos à amputação transtibial, de 2012 a 2016. Foram analisados o índice de protetização, grau de satisfação e as complicações pós-operatórias.

Resultados: Do total de 68 pacientes submetidos à amputação transtibial (ATT), 42 eram do sexo masculino (62,7%), com uma média de 50,3 anos. Concluíram somente o ensino fundamental 61,2% e 46,2% dos pacientes eram da raça branca. A causa principal foi a Osteomielite Crônica (OMC), representando 53,7% dos casos. A protetização foi realizada em 89,6% dos pacientes e 78,3% deles se adaptaram bem à prótese. Todavia, 40,3% apresentaram complicações pós-operatórias e a taxa de óbitos foi de 21,9%. Da amostra total, 76,1% dos pacientes declararam-se satisfeitos com a cirurgia.

Conclusão: A amputação transtibial foi mais comum em homens brancos, com média de idade de 50 anos, tendo como comorbidades mais prevalentes HAS e DM, e etiologia mais comum a osteomielite crônica. A insatisfação foi significativamente relacionada com a idade (>60 anos) e depressão, e o índice de protetização e a adaptação à prótese estiveram diretamente associadas à satisfação do paciente. *Nível de Evidência IV; Estudos Terapêuticos; Série de Casos.*

Descritores: Amputação; Diabetes mellitus; Sobrevida.

Trabalho realizado no Instituto Nacional de Traumatologia e Ortopedia, Rio de Janeiro, RJ, Brazil.

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INTRODUCTION

Amputation, i.e., total or partial removal of a limb⁽¹⁾, is unavoidable in advanced stages of diseases such as diabetes mellitus (DM) or peripheral occlusive vascular disease as well as in the setting of malignant tumours, trauma, and infection, and amputation substantially impacts patients' lives⁽²⁾. The incidence of amputation varies from 1.2 to 4.4/100,000 people worldwide, and in more than 90% of cases, it involves the lower limbs. According to estimates, this rate might double by 2050⁽³⁾. Because preserving the knee joint is crucial for the success of amputees' rehabilitation, transtibial amputation has become the most common form of lower limb amputation⁽²⁾.

A survey performed from 1999 through 2017 identified approximately 500,000 individuals with DM in Brazil, and 57% were female⁽⁴⁾. A study from North America reported that 5-7% of diabetic patients develop foot ulcers⁽⁵⁾. Ulcers, gangrene, infection, peripheral arterial disease, and Charcot neuropathy are risk factors for amputation^(5,6). When associated with other systemic conditions, ulcers with unfavourable progression significantly increase the morbidity and mortality of diabetic patients^(5,7).

Osteomyelitis, i.e., severe and persistent infection of bone tissue, is one of the main challenges of orthopaedic surgery. Definitive treatment is difficult due to the limited penetration of antibiotics into the relatively avascular structures, and the rate of relapse varies from 20-30%⁽⁸⁾. According to some studies, even after three surgical treatments, infection persists in 23% of patients^(8,9). As a result, amputation is the best option in some cases⁽¹⁰⁾.

The five-year mortality of amputees may be as high as 40%. The main associated risk factors are older age, male sex, peripheral vascular disease (PVD), and kidney disease⁽¹¹⁾.

A study conducted in Rio de Janeiro, Brazil, found that major lower limb amputations have considerable socioeconomic impact, cause significant impairment in patient quality of life, and are associated with high morbidity and mortality rates. As a result, they should be considered a public health problem⁽¹²⁾.

The aim of the present study was to analyse the epidemiological profile of patients who undergo transtibial amputation (TTA) of the lower limb, including the prosthetic fitting rate, degree of satisfaction, and postoperative complications.

METHODS

This study was approved by the Research Ethics Committee with registration in the Brazil Platform under CAAE number: 81221017.5.0000.5273.

The present retrospective cross-sectional study evaluated patients who underwent TTA from 2012 through 2016 by the foot and ankle surgery group of a Brazilian referral hospital. The study complied with all principles concerning humans subject research.

All skeletally mature patients who underwent infrapatellar TTA of the lower limb were included in the study regardless of age and sex. Cases with missing data in the medical records and patients who refused participation were excluded.

The following data were collected from the participants' medical records: sex, age, time of surgery, comorbidities, laterality of the involved limb, surgical complications, number of previous surgical procedures, reason for amputation, and prosthetic fitting. Adaptation to prosthesis was evaluated using a protocol designed by the hospital rehabilitation service, which assesses mobility, function, satisfaction, treatment continuation, and use of the prosthesis for more than one year.

Surgical technique

First, the desired stump length is measured, seeking to preserve the longest part of the leg as possible. Then, a fish-mouth incision is drawn on the skin. The incision is made at the level of the intended bone section, followed by superficial and deep soft-tissue dissection and identification and isolation of the neurovascular bundle for later ligation/division. Once the noble structures are protected, the bone is cut, followed by myodesis, control of haemostasis, and plane-by-plane closure.

Statistical analysis

Descriptive statistics were based on plots, variable distributions, and descriptive measures (proportions of all variables; for the variable of age minimum, maximum, mean, median, 25th and 75th percentiles, standard deviation, and coefficient of variation [CV]). The variability of distribution of quantitative variables was categorised as follows: low, CV < 0.20; moderate, $0.20 \le CV < 0.40$; and high, $CV \ge 0.40$. Proportions were compared with the binomial test. Associations between two qualitative variables were investigated using the chi-squared test or Fisher's exact test when the former was inconclusive. When associations were significant, risk was estimated as the odds ratio (OR), i.e., the ratio of the odds of an individual with a given risk factor having a complication to the odds of an individual without the risk factor having a complication.

RESULTS

Of 68 patients who underwent TTA, one was excluded because he underwent transfemoral amputation. Therefore, 67 patients were analysed. Participants' age at the time of surgery ranged from 24 to 76 years, with a mean of 50.3 years. Twenty-five patients were female (37.3%), and 42 were male (62.7%).

All p values comparing distributions of variables and prevalence of comorbidities between male and female patients were greater than 5%. These results indicate an absence of significant differences in the distribution of age, race, education level and prevalence of comorbidities between the male and female groups. A total of 46.2% of participants were white, and 61.2% had completed elementary school only. A total of 67.2% of patients exhibited comorbidities, among which systemic arterial hypertension (SAH) and DM were the most frequent, with prevalences of 35.8% and 28.4%, respectively. The characteristics of patients undergoing amputation are described in Table 1.

Amputation-related characteristics are described in Table 2. Of the participants, 43.5% were from 46 to 62 years of age (43.5%). A majority (53.8%) had undergone one or two previous treatments, and amputation was most often due to chronic osteomyelitis (COM) (53.7%), followed by trauma sequelae (13.4%) and DM (10.4%). In 15 cases (22.4%), amputation was due to other reasons, including tumours, peripheral vasculopathy and congenital malformations.

The results of the chi-square test to compare the distribution of reasons for amputation between men and women were inconclusive. While the distributions nonetheless differed considerably, COM was a common cause of amputation in both groups, with 36% of women and 64.3% of men having this indication. The reasons for amputation in both groups are depicted in Figure 1. Post-amputation outcomes are described in Table 3. A total of 89.6% of patients were fitted with a prosthesis, and 78.8% adapted well to it. Of the patients, 59.7% had no postoperative complications, while 40.3% experienced complication such as phantom pain, suture dehiscence, wound infection, and larger amputation. Mortality occurred in 21.9% of patients, but the causes could not be established because most deaths did not occur at the study site.

Table 4 describes characteristics of patients with and without complications. There was no relationship between the occurrence of complications and age. While patients with only an elementary school education predominated among those with complications (14 of 26 cases with complications), this finding was not statistically significant (p>0.05).

Depression was the only comorbidity significantly associated with the occurrence of complications (p=0.0029, Fisher's exact test). Complications occurred in 34.4% of patients with depression and in 83.33% of patients without depression. SAH, DM, smoking, peripheral vascular disease and kidney disease were not statistically significantly associated with post-amputation complications. Table 5 describes relationships between the incidence of complications and qualitative factors.

Figure 2 depicts the incidence of complications stratified by reason for amputation. Patients undergoing amputation due to DM were the most likely to experience complications, whereas 44.4% of patients undergoing amputation for trauma sequelae and 40% of patients undergoing amputation for other causes (tumours, complex regional pain syndrome) experienced complications.

A total of 76.1% of participants reported being satisfied with surgery. Dissatisfaction was significantly associated with age at time of surgery (p=0.040). The mean age of satisfied and dissatisfied patients was 51.9 and 60.1 years old, respectively. The incidence of dissatisfaction was 19.7% among patients without depression; this was significantly higher among patients with depression (83.3%, p=0.003, Fisher's exact test).

Satisfaction was directly related with fitting of and adaptation to the prosthesis, with satisfaction rates of 71.4% and 76.9%, respectively, among those who were fit with and adapted well to a prothesis. The incidence of dissatisfaction was 20% in the group that were fitted with a prosthesis and was significantly higher among patients who were not fit with a prothesis (71.4%, p=0.009, Fisher's exact test).

Variable	Fema	e n=25	Male	Male n=42 Tota		l n=67		
	F	%	F	%	F	%	p-value comparing men and women	
Age (years)								
26 - 32	1	4.0%	4	9.5%	5	7.5%	0.501 ^(a)	
32 - 40	2	8.0%	7	16.7%	9	13.4%		
40 - 48	1	4.0%	5	11.9%	6	9.0%		
48 - 56	8	32.0%	8	19.0%	16	23.9%		
56 - 64	8	32.0%	5	11.9%	13	19.4 %		
64 - 72	2	8.0%	7	16.7%	9	13.4%		
72 - 80	3	12.0%	6	14.3%	9	13.4%		
Race								
White	10	40.0%	21	50.0%	31	46.3%	0.728 ^(a)	
Black	7	28.0%	10	23.8%	17	25.4%		
Brown	8	32.0%	11	26.2%	19	28.4%		
Education level								
Elementary school	16	64.0%	25	59.5 %	41	61.2%	0.814 ^(a)	
Secondary school	6	24.0%	13	31.0%	19	28.4%		
Higher education	3	12.0%	4	9.5%	7	10.4%		
Comorbidities								
None	6	24.0%	16	38.1%	22	32.8%	0.235 ^(b)	
SAH	12	48.0%	12	28.6%	24	35.8%	0.109 ^(b)	
Diabetes	10	40.0%	9	21.4%	19	28.4%	0.103 ^(b)	
Other	5	20.0%	8	19.0%	13	19.4%	1.000 ^(c)	
Smoking	3	12.0%	6	14.3%	9	13.4%	1.000 ^(c)	
PVD	3	12.0%	3	7.1%	6	9.0%	0.664 ^(c)	
Depression	4	16.0%	2	4.8%	6	9.0%	0.186 ^(c)	
Kidney disease	4	16.0%	1	2.4%	5	7.5%	0.061 ^(c)	

Source: Prepared by the author based on the results of the study.

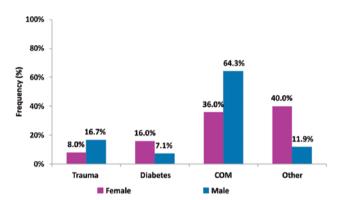
Table 2. Amputation-related characteristics,	overall and stratified by sex
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Variable	Female n=25		Male n=42		Total n=67			
variable	F	%	F	%	F	%	p-value comparing men and women	
Age on day of amputation (years)								
22 - 30	0	0.0%	5	11.9%	5	7.5%	0.243 ^(a)	
30 - 38	2	8.0%	8	19.1%	10	15.0%		
38 - 46	2	8.0%	5	12.0%	7	10.5%		
46 - 54	9	36.0%	8	19.1%	17	25.5%		
54 - 62	7	28.0%	5	11 .9 %	12	18.0%		
62 - 70	4	16.0%	4	9.6%	8	12.0%		
70 - 78	1	4.0%	7	16.8%	8	12.0%		
Laterality								
Right-sided	11	44.0%	25	59.5%	36	53.7%	0.311 ^(b)	
Left-sided	14	56.0%	17	40.5%	31	46.3%		
Previous procedure								
None	5	20.0%	6	14.3%	11	16.4%	0.734 ^(b)	
1	7	28.0%	9	21.4%	16	23.9%		
2	8	32.0%	12	28.6%	20	29.9 %		
3	4	16.0%	8	19.0%	12	17.9%		
4 or more	1	4.0%	7	16.7%	8	11.9%		
Reason for amputation								
Trauma	2	8.0%	7	16.7%	9	13.4%	*	
Diabetes	4	16.0%	3	7.1%	7	10.4%		
СОМ	9	36.0%	27	64.3%	36	53.7%		
Other	10	40.0%	5	11.9%	15	22.4%		

Source: Prepared by the author based on the results of the study.

DISCUSSION

According to the literature, 71-88% of patients undergoing amputation are male^(1,13). In the present study, 62.7% of participants were male, and 46.2% were white. Ahmad et al.⁽¹⁴⁾ reported amputation to be associated with lower socioeconomic status; the highest prevalence was among men (68.5%) from the most deprived areas (28.6%). In the



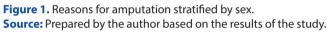


Table 3. Post-amputation outcomes, overall and stratified by sex

present study, 61.2% of the patients had completed elementary school only. We believe this finding speaks to the difficulty this group has accessing high-quality health care and therapeutic resources.

Analysis showed that 67.2% of patients had at least one comorbidity, with SAH (35.8%) and DM (28.4%) being the most frequent. In the study by Cassefo et al.⁽¹⁾, the prevalence of these conditions was 55.5% and 63.9%, respectively. The age of participants in the present study ranged from 24 to 76 years, with a mean of 50.3 years, which is younger than the mean age of 69.3 years reported by Seker et al.⁽¹⁵⁾.

According to the literature, the most common causes of amputation are complications related to vascular disease; Cassefo et al.⁽¹⁾ reported this cause in 59.2% of cases. However, in the present study, the most frequent cause was chronic osteomyelitis, which accounted for 53.7% of cases. Trauma sequela accounted for 13.4% of cases, and complications of DM accounted for 10.4%. Other causes, such as tumours and peripheral vascular disease, were responsible for 22.4% of amputations. While these findings are in contrast to previous reports, this might be because patients in

Verieble	Fema	Female n=25		Male n=42		l n=67		
Variable	F	%	F	%	F	%	p-value comparing men and women	
Fit with prosthesis								
No	4	16.0%	3	7.1%	7	10.4%	0.411 ^(a)	
Yes	21	84.0%	39	92.9%	60	89.6%		
Adapted to prosthesis								
No	6	28.6%	7	17.9%	13	21.7%	0.349 ^(b)	
Yes	15	71.4%	32	82.1%	47	78.3%		
Complications								
None	12	48.0%	28	66.7%	40	59.7%	0.359 ^(b)	
Dehiscence	8	32.0%	3	7.1%	11	16.4%		
Infection	4	16.0%	7	16.7%	11	16.4%		
Other	1	4.0%	4	9.5%	5	7.5%		
Death								
No	24	96.0%	35	83.3%	59	88.1%	0.242 ^(b)	
Yes	1	4.0%	7	16.7%	8	11.9%		
Satisfaction								
Very dissatisfied	3	12.0%	3	7.1%	6	9.0%	*	
Dissatisfied	4	16.0%	6	14.3%	10	14.9%		
Satisfied	11	44.0%	13	31.0%	24	35.8%		
Very satisfied	7	28.0%	20	47.6%	27	40.3%		
Satisfaction								
Dissatisfied	7	28.0%	9	21.4%	176	23.9%	0.542 ^(a)	
Satisfied	18	72.0%	33	78.6%	51	76.1%		

Source: Prepared by the author based on the results of the study.

Patient age at amputation	Without complications	With complications	p-value comparing mean age between groups (Student's t-test)
Minimum	24	26	0.501
Maximum	76	73	
Mean	51.3	48.8	
Median	52	49.5	
25th percentile	42	39	
75th percentile	65	59	
Standard deviation	14.7	13.6	
Coefficient of variation	0.29	0.28	
p-value on KS test	0.200	0.200	
p-value on SW test	0.114	0.379	

Table 4. Characteristics of patients with and without complications

Source: Prepared by the author based on the results of the study.

Risk factor		mplications among e analysed risk factor		plications among alysed risk factor	p-value comparing the incidence
	F %		F	%	Incidence
SAH	18	41.9%	8	33.3%	0.492 ^(a)
Diabetes	18	37.5%	8	42.1%	0.727 ^(a)
Smoking	22	37.9%	4	44.4%	0.727 ^(b)
PVD	25	41.0%	1	16.7%	0.392 ^(b)
Depression	21	34.4%	5	83.3%	0.029 ^(b)
Kidney disease	23	37.1%	3	60.0%	0.369 ^(b)
Left-sided amputation	14	38.9%	12	38.7%	0.988 ^(a)
Previous procedure	2	18.2%	24	42.9%	0.181 ^(b)

Table 5. Associations between complications and risk factors

Source: Prepared by the author based on the results of the study.

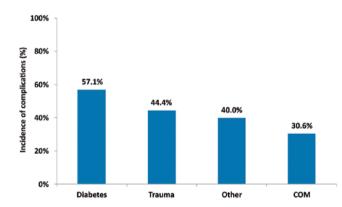


Figure 2. Incidence of complications according to reasons for amputation.

Source: Prepared by the author based on the results of the study.

the present study were recruited from an institution dedicated exclusively to treating orthopaedic patients.

Patient rehabilitation requires a multidisciplinary staff duly trained to deal with the clinical, physical, functional, emotional, and social limitations derived from physical disability. The rate of prosthesis utilisation was 89.6% at the end of the rehabilitation program, which is similar to the average rates reported in the literature of 75-95%^(16,17). All amputees are referred to the institutional rehabilitation service. The criteria used to assess adaptation to the prosthesis are mobility, function, patient satisfaction, continuation, and use of prosthesis for more than one year. Using these criteria, 78.3% of participants were considered to have adapted well to the prosthesis, which is similar to what was reported by Pohjolainen et al.⁽¹⁸⁾, who found that 8% of patients had stopped using the prosthesis at their one-year follow-up visit⁽¹⁸⁾. Considering that many patients have difficulty travelling far distances to the study hospital, this finding was a pleasant surprise.

Short-term mortality is more closely related to surgical characteristics (amputation level, intraoperative complications, extent of surgery), whereas late mortality is more closely related to comorbidities⁽¹²⁾. In the present study, five-year mortality was 21.9%. In the study by Lim et al.⁽¹⁹⁾,

it increased from 10% within the first 30 days to 43% one year after surgery. We believe this discrepancy might be partially due to the fact that our population was at lower risk of complications because participants underwent TTA.

Depression was the only comorbidity significantly associated with postoperative complications (p=0.0029). Other comorbidities, such as SAH, DM, smoking, peripheral vascular disease, and kidney disease were not significantly associated with post-amputation complications. Fortington et al.⁽²⁰⁾ found that age, kidney disease, and cerebrovascular disease were directly related to higher mortality among amputees. In their study⁽²⁰⁾, patients older than 85 years of age survived an average of 8.8 months, while younger patients survived an average of more than 20 months (p=0.028). The odds of dying within one year were 2.5 times higher among patients with cerebrovascular disease (95% confidence interval [CI]: 1.21; 5.34; p=0.013) and 3.53 times higher among patients with kidney disease (95% CI: 1.79; 6.96; p<0.001). At five years, the odds among patients with kidney disease were 5.35 higher (95% CI: 1.79; 16.0; p=0.03)⁽²⁰⁾. The low prevalence of comorbidities in the present study accounts for the difference in mortality reported by these studies.

In the present study, 76.1% of patients reported satisfaction with surgery. Dissatisfaction was significantly associated with age (>60 years old) and depression (p=0.04 and p=0.003, respectively). These findings might be due to the emotional reactions developed by amputees, which could trigger depression. Sabino et al.⁽²¹⁾ performed a study of patients undergoing nontraumatic amputations and stratified them into four groups according to their risk for depression; 51.61% were at minimal risk, 22.58% were at low risk, 16.13% were at moderate risk, and 9.68% were at high risk.

Older patients are more dependent due to factors such as ageing and comorbidities. After TTA, they might undergo maladjustment derived from forced dependence and reduced self-esteem⁽²²⁾. Corroborating this assumption, prosthetic fitting dramatically reduced the rate of dissatisfaction, whereas the odds of dissatisfaction among patients not fitted with a prosthesis might be 10 times higher, even among older patients.

Our study has several limitations, including a small sample size and retrospective design. Patients undergoing amputation due to DM experienced more complications. However, due to the small size of each group, we could not establish whether the difference was statistically significant (inconclusive chi-square test results). We chose to include only patients undergoing TTA because it is a procedure often dismissed by surgeons and one that brings a lot of shame to the patient. We did not apply functional scores, as our aims were to perform an epidemiological study and analyse satisfaction and patient quality of life.

CONCLUSION

Patients undergoing TTA performed by the foot and ankle surgery group of a Brazilian referral hospital were most commonly male and white and had a mean age of 50 years. The most common comorbidities were SAH and DM, and the most common reason for amputation was COM.

Patient dissatisfaction was significantly associated with older age (> 60 years old) and depression. Use of and adaptation to prosthesis were directly related with patient satisfaction.

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