

Risk factors for impaired wound healing and prolonged hospitalization in patients after amputation of the lower limb above the knee joint

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B – Data Collection
C – Statistical Analysis
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ABSTRACT:

Introduction: Lower limb amputation is a surgery performed as a last resort, when all other therapeutic options have been exhausted. The duration of treatment lasts from a few to several months and depends on the extent of amputation, the patient's overall health and the course of the stump healing process.

Materials and methods: A retrospective analysis was performed using the database of the General and Vascular Surgery Ward of the Nikolay Pirogov Regional Specialist Hospital in Łódź. Patients who underwent lower limb amputation at the transfemoral level in 2017 were analyzed. 92 patients undergoing surgery were qualified for the study. Patients were divided into two groups: those with no healing complications and those with stump healing complications. Medical records of both groups were analyzed for risk factors for impaired healing. The obtained data were subjected to statistical analysis.

Results: Patients with impaired stump healing most often had minimal bleeding and higher ASA scores compared to patients without healing complications. No differences between the two groups were found for the remaining parameters. Patients with complications needed an average of 28 days to heal the wound and spent an average of 40 days in hospital, compared to 14 and 21 days, respectively, for patients without complications. The percentage of deaths in the group of patients with complications was also significantly higher (35%) than in the group of patients without complications (5%).

Conclusions: Statistically significant factors increasing the risk of impaired stump healing include high ASA scale and minimal muscle bleeding during surgery. Patients who experienced this complication are at greater risk of prolonged hospitalization and death in the postoperative period. This study showed statistically significant risk factors for impaired stump healing following amputation and confirmed the negative impact of this complication on the length of hospitalization and risk of death.

KEYWORDS:

amputation, impaired healing, risk factors, stump

INTRODUCTION

Large limb amputations are one of the most extensive and mutilating surgeries performed. This procedure is associated with a huge injury to the patient both in the mental and physical sphere. Often in the initial period, patients respond with negation and do not agree to the procedure. The surgeon should show a great understanding of the patient's fears and explain the possibilities of functioning after the surgery, taking into account the process of rehabilitation and prosthesis. Despite the development of endovascular techniques and the increased availability of specialized procedures, the number of amputations performed in Poland is increasing. Within 4 years, the number of large non-traumatic amputations of lower limbs in patients with diabetes increased from 7703 in 2009 to 8111 in 2012 [1]. This unfavorable trend may be caused by an aging population and an increase in the incidence of diabetes.

Lower limb amputation is a last resort surgery, performed when all other therapeutic options have been exhausted. Most often this procedure is performed in patients with peripheral arterial disease and diabetes. For patients after unsuccessful revascularization, infection or limb tissue defect, and for those in whom there is no possibility of reconstruction procedure, amputation remains the only form of treatment. The duration of treatment depends on the

type and extent of amputation, the general health of the patient and the possible occurrence of complications [2, 3]. It should be kept in mind that patients requiring amputation usually have numerous concurrent diseases and represent a very sick population. In a 5-year follow-up, mortality in the knee amputation group ranges from 40% to 90%. Elderly patients with renal failure, peripheral arterial disease and after proximal amputation are at greatest risk [4].

Currently, the surgeons' approach is based not only on performing efficient amputation, but also planning it for wound healing and creating a stump that will provide the patient with the best possible locomotion capabilities with a limb prosthesis. Amputations above the knee are characterized by a higher percentage of primary healing and a lower risk of reoperation [5]. On the other hand, many authors have shown a negative relationship between the level of amputation and the possibility of rehabilitation. The higher the level of amputation, the lower the mobility. It is extremely important for the further functioning of the patient and affects the quality of life after surgery [6].

The consequence of every amputation is the formation of a stump and postoperative wound, which are subject to healing processes. Factors that negatively affect the healing process can be divided into two groups. The first of these are local factors, which may include tissue oxygenation, inflammation, foreign body in the wound and

venous insufficiency. The second group includes systemic factors. This includes age, sex, sex hormones, ischemia, obesity, concurrent diseases, smoking, alcohol abuse, certain medications [7]. Many of those factors a priori affect the healing process of the stump in patients with critical limb ischemia and/or diabetes. This phenomenon should prompt surgeons to be especially vigilant and to intensify supervision of such wounds.

In literature to date, the causes of early failure following amputation are rarely the topic of research. The most frequently mentioned are emergency surgery, sepsis, end-stage renal disease, BMI >30, performing surgery by a resident, smoking. The purpose of this research is to identify risk factors for impaired stump healing in the postoperative period and the length of hospitalization of the patient.

METHODS AND CLINICAL MATERIAL

A retrospective analysis was performed using a database and medical documentation (disease histories) of the General and Vascular Surgery Department of the Nikolay Pirogov Regional Specialist Hospital in Lodz. Patients who underwent lower limb amputation at the transfemoral level in 2017 were analyzed. All amputations were performed due to lower limb ischemia in the course of peripheral arterial disease. The obtained data was subsequently analyzed. 92 patients who underwent surgery were qualified for the study. Patients were divided into two groups: those with no healing complications and those with stump healing complications. Impaired stump healing was defined as postoperative wound infection or other pathology requiring surgical treatment (hematoma, tissue necrosis, wound dehiscence). With the help of a self-constructed questionnaire, the medical documentation of both groups was analyzed in terms of risk factors for impaired stump healing dependent on the patient and related to the perioperative period. Next, the relationship between the occurrence of this complication and the time of hospitalization as well as mortality in the postoperative period in the examined groups was investigated.

STATISTICAL ANALYSIS

Statistical analysis was performed with the R package, version 3.4.4 (<http://cran.r-project.org>). Nominal data was described as n (%), while quantitative data was coded as the arithmetic mean (\pm SD) for variables with normal distribution or as median (Q1-Q3) for variables with non-normal distribution. The normality of the distribution in subgroups was checked using the Shapiro-Wilk test. The comparison of groups for nominal variables was performed using the chi-square test or Fisher's exact test when the number of groups did not permit the use of the chi-square test. Quantitative variables were compared between the two groups with the independent-samples t-test for variables with normal distribution or a non-parametric Mann-Whitney U test in the remaining cases. All tests were two-tailed, with a significance level of 0.05.

The second part of the analysis involved building a multivariate logistic regression model to identify variables that significantly affect the occurrence of amputation complications. The model uses variables for which comparative analysis of groups indicated statistically significant differences. When building the model, the

variables with the number of categories greater than two were transformed into binary variables, adopting the value of the variable with the highest frequency in the group with complications as success, and the remaining values of the given variable as failure. The fit of the logistic regression model was evaluated using the likelihood-ratio chi-square test, the Hosmer-Lemeshow test, and the Nagelkerke's R^2 coefficient of determination.

RESULTS

The study included 92 patients with an average age of 70 years (SD = 9.3), 38 women (41%) and 54 men (59%). Complications following amputation occurred in 29 patients (32%). Patients without complications were 63 people (68%). Demographic variables (age and gender) did not differ significantly between groups with and without complications. Analyzing data related to pre-operative history and tests (Tab. I.), showed a statistically significant difference between the two groups only for the frequency of occurrence of different external iliac artery flow test results ($p = 0.047$). Patients with subsequent postoperative complications were characterized by biphasic flow less frequently than patients without complications – $n = 14$ (50.0%) for patients with complications and $n = 44$ (74.6%) for the group without complications, respectively. No significant differences were found between the groups for the other types of arterial flow test, as well as for such factors such as diabetes, obesity, smoking, receiving NSAIDs, IHD, previous interventions, stroke and amputation of the lower limb on the opposite side.

Data is presented as n (%), arithmetic mean (\pm SD) or median (Q1-Q3). The groups were compared using the chi-square test or Fisher's exact test for nominal variables and the t-test or Mann-Whitney U test for quantitative variables [15].

Comparing the various variables associated with the surgery (Tab. II.), a significant difference was found between the two groups for the size of bleeding during the operation ($p = 0.001$). Patients with complications most often had minimal bleeding; $n = 12$ (41%), compared to patients without complications where the minimal bleeding appeared the least; $n = 4$ (6%). Furthermore, ASA levels significantly differed between groups with and without complications. For the remaining perioperative parameters, no differences were found between the two groups.

Analysis of postoperative variables showed that both the time from amputation to complete wound healing, hospitalization time and the incidence of death after surgery significantly differed between the groups ($p < 0.001$ for each of the above-mentioned variables). Patients with complications needed an average of 28 days for the wound to heal and spent an average of 40 days in hospital, compared to 14 and 21 days for patients without complications, respectively. The percentage of deaths in the group of patients with complications was also significantly higher (35%) than in the group of patients without complications (5%).

The next step in the analysis was to build a multivariate logistic regression model of variables affecting the occurrence of amputation complications. The model uses statistically significant variables from the comparative analysis between groups with a significance level <0.05: flow in the external iliac artery, bleeding amount, and ASA. In order not to ensure that all variables that may have a significant

Tab. I. Comparative characteristics of groups before surgery.

VARIABLE	N	OVERALL	N	GROUP WITH COMPLICATIONS	N	GROUP WITHOUT COMPLICATIONS	LEVEL P
Age	92	70.0 (±9.3)	29	71.1 (±10.1)	63	69.5 (±8.5)	0.468
Gender							
Female, n (%)	92	38 (41.3%)	29	11 (37.9%)	63	27 (42.9%)	0.656
Male, n (%)		54 (58.7%)		18 (62.1%)		36 (57.1%)	
Obesity, n (%)	59	17 (28.8%)	17	5 (29.4%)	42	12 (28.6%)	>0.999
Diabetes, n (%)	92	38 (41.3%)	29	10 (34.5%)	63	28 (44.4%)	0.367
NSAIDs (non-steroidal anti-inflammatory drugs), n (%)	91	33 (36.3%)	29	8 (27.6%)	62	25 (40.3%)	0.239
Smoking, n (%)	89	39 (43.8%)	29	10 (34.5%)	60	29 (48.3%)	0.217
IHD (Ischemic heart disease), n (%)	89	50 (56.2%)	29	18 (62.1%)	60	32 (53.3%)	0.436
External iliac artery flow							
Biphasic, n (%)		58 (66.7%)		14 (50.0%)		44 (74.6%)	
Monophasic, n (%)	87	14 (16.1%)	28	8 (28.6%)	59	6 (10.2%)	0.047
No flow, n (%)		15 (17.2%)		6 (21.4%)		9 (15.3%)	
Femoral artery flow							
Biphasic, n (%)		33 (37.9%)		10 (35.7%)		23 (39.0%)	
Monophasic, n (%)	87	35 (40.2%)	28	11 (39.3%)	59	24 (40.7%)	0.882
No flow, n (%)		19 (21.8%)		7 (25.0%)		12 (20.3%)	
Deep artery of thigh flow							
Biphasic, n (%)		26 (29.9%)		8 (28.6%)		18 (30.5%)	
Monophasic, n (%)	87	36 (41.4%)	28	10 (35.7%)	59	26 (44.1%)	0.593
No flow, n (%)		25 (28.7%)		10 (35.7%)		15 (25.4%)	
SFA (superficial femoral artery) flow							
Biphasic, n (%)		2 (2.3%)		1 (3.6%)		1 (1.7%)	
Monophasic, n (%)	87	5 (5.7%)	28	3 (10.7%)	59	2 (3.4%)	0.319
No flow, n (%)		80 (92.0%)		24 (85.7%)		56 (94.9%)	
Interventions							
Venous bridge, n (%)		11 (12.0%)		2 (6.9%)		9 (14.3%)	
PTA with stent placement, n (%)		5 (5.4%)		1 (3.4%)		4 (6.3%)	
Thrombolysis, n (%)		5 (5.4%)		0 (0.0%)		5 (7.9%)	
Bypass, n (%)		10 (10.9%)		4 (13.8%)		6 (9.5%)	
Embolectomy, n (%)	92	7 (7.6%)	29	2 (6.9%)	63	5 (7.9%)	0.246
TEA, n (%)		11 (12.0%)		7 (24.1%)		4 (6.3%)	
None, n (%)		42 (45.7%)		13 (44.8%)		29 (46.0%)	
PTA, n (%)		1 (1.1%)		(0.0%)		1 (1.6%)	
Opposite side amputations, n (%)	92	15 (16.3%)	29	3 (10.3%)	63	12 (19.0%)	0.374
Stroke, n (%)	91	18 (19.8%)	29	4 (13.8%)	62	14 (22.6%)	0.406

Data is presented as arithmetic mean (±SD) or n (%). The groups were compared with a t-test for age and the chi-square test or Fisher's exact test for the other variables. NSAIDs – nonsteroidal anti-inflammatory drugs, IHD – ischemic heart disease, SFA – superficial femoral artery, PTA – percutaneous endovascular angioplasty, TEA – tromendarterectomy.

impact on the modeled risk of complications are included in multivariate analysis, univariate logistic regressions were performed for all variables. On that basis, it was decided to take into account when creating the multivariate model also those variables for which the significance level in the Wald test was <0.25, as recommended by Hosmer and Lemeshow [15]. These variables were: receiving NSAIDs ($\beta = -0.57$; $p = 0.242$), smoking ($\beta = -0.58$; $p = 0.219$), SFA flow - no flow ($\beta = -1.14$; $p = 0.157$) and transfusion during the procedure ($\beta = -0.77$; $p = 0.106$). For the aforementioned variables, a multivariate logistic regression model was built using the progressive stepwise method (Tab. III.). Four variables were loaded

into the model: two-phase external iliac artery flow, SFA flow – no flow, minimal bleeding, and ASA, with only minimal bleeding and ASA appearing to be statistically significant at $p < 0.05$, increasing the risk of amputation complications. NSAIDs, smoking and transfusion did not appear to improve the fit of the model, and as such did not appear in it.

Minimal bleeding during surgery resulted in an over 8-fold increase in the risk of complications after surgery, $\exp \beta = 8.776$, CI95 [2.077, 48357]. Increasing the level of ASA by one increases the risk of complications 3 times $\exp \beta = 3.172$, CI95 [1,109, 10,679].

Tab. II. Comparative characteristics of groups during and after surgery.

VARIABLE	N	OVERALL	N	GROUP WITH COMPLICATIONS	N	GROUP WITHOUT COMPLICATIONS	POZIOM P
Operator							
Specialist. n (%)	92	37 (40.2%)	29	10 (34.5%)	63	27 (42.9%)	0.447
Resident. n (%)		55 (59.8%)		19 (65.5%)		36 (57.1%)	
Time (min)	92	45.0 (35.0–60.0)	29	45.0 (35.0–60.0)	63	45.0 (36.5–60.0)	0.519
Bleeding							
Very good. n (%)		36 (39.1%)		9 (31.0%)		27 (42.9%)	
Good. n (%)	92	22 (23.9%)	29	5 (17.2%)	63	17 (27.0%)	0.001
Medium. n (%)		18 (19.6%)		3 (10.3%)		15 (23.8%)	
Minimal. n (%)		16 (17.4%)		12 (41.4%)		4 (6.3%)	
Anaesthesia							
Conduction n (%)	92	8 (8.7%)	29	1 (3.4%)	63	7 (11.1%)	0.428
General. n (%)		84 (91.3%)		28 (96.6%)		56 (88.9%)	
ASA	92	3.0 (3.0–3.0)	29	3.0 (3.0–3.0)	63	3.0 (2.0–3.0)	0.003
HCT (%)	92	31.8 (±3.9)	29	31.9 (±3.6)	63	31.8 (±3.9)	0.885
HGB (mg/dl)	92	10.2 (9.4–11.7)	29	10.5 (9.4–11.5)	63	10.2 (9.4–11.9)	0.863
Transfusion. n (%)	92	40 (43.5%)	29	9 (31.0%)	63	31 (49.2%)	0.159
Necrosis. n (%)	92	65 (70.7%)	29	21 (72.4%)	63	44 (69.8%)	0.996
Time from amputation to healing. days	92	15.0 (14.0–20.8)	29	28.0 (23.0–35.0)	63	14.0 (14.0–15.5)	<0.001
Time of hospitalization (days)	92	24.5 (16.0–34.3)	29	40.0 (30.0–53.0)	63	21.0 (15.0–26.5)	<0.001
Death. n (%)	92	13 (14.1%)	29	10 (34.5%)	63	3 (4.8%)	<0.001

ASA – American Society of Anesthesiologists scale, HCT – hematocrit, HGB – hemoglobin.

In order to verify the correctness of the model, the likelihood ratio test χ^2 was conducted, which indicated that all variables in the model were significant, $\chi^2(4) = 24.78$, $p < 0.0001$. Model fit assessed by the Nagelkerke's R² coefficient of determination indicates that the explanatory variables in the model explain 36.4% of patients' belonging to one of the two groups (with and without complications following amputation). Model verification using the Hosmer-Lemeshow test also indicates a good fit of the model, $\chi^2(8) = 1.616$, $p = 0.991$.

DISCUSSION

Large lower limb amputations remain a significant issue in Poland. According to the available literature in our country, we are constantly seeing an upward trend in the number of surgeries performed. It should be noted, however, that the increased number of amputations is observed only in patients with diabetes. In patients not burdened with this disease, there is a slight decrease in the frequency of performed amputations [1]. This is, of course, data from several years ago, which does not depict the current situation. However, studies conducted over a similar period of time in the United States showed quite different results. Over the period of 10 years (1996–2011), the number of large amputations has decreased by 45%. This is mainly related to the development and increase in the number of endovascular procedures performed to save ischemic limbs. In both cases, the authors pointed out the underestimated role of patient education regarding amputation risk factors. Without lifestyle modification and elimination of harmful behaviors: smoking or poor diet, in a country such as Poland with limited outlays devoted to healthcare, amputation will remain a common procedure performed by surgeons. An ag-

ing population and an increase in diabetes will further exacerbate this phenomenon.

The occurrence of a complication in the form of impaired stump healing is associated with a significant worsening of prognosis for the patient. The present study showed a negative impact of impaired healing on length and mortality during hospitalization. Patients with this complication were characterized by mortality rate of 35% as well as prolonged hospitalization, an average of 40 days. O'Brien PJ et al. came to partially different conclusions. While they showed a correlation between prolonged hospitalization and the occurrence of early amputation failure, they did not find a statistically significant relationship with increased mortality in the postoperative period [9]. However, it should be noted that there are significant differences between both studies. Their work was based on amputations at the transfemoral, transtibial, and foot level. The second significant difference was the study endpoint. Early amputation failure was defined as the need for reoperation within 30 days of the original surgery. Differences between the studies can significantly affect the results obtained. In the available literature, many authors have shown increased mortality and prolonged hospitalization in patients after large amputations. According to Cruz CP et al., the most common cause of death in the postoperative period was cardiopulmonary failure [12]. Many authors point to the importance of amputation levels as a factor for increased mortality after large amputations. Ablation above the knee is associated with increased mortality in the postoperative period and in the longer follow-up period [10, 11]. Thorold JC et al., in their meta-analysis based on 31 studies, found that in 5-year observation patients after amputation above the knee are characterized by mortality from 40% to 90%, and below the knee joint from 40% to 82% [4]. Therefore, synergistic effects of ampu-

Tab. III. Estimating the value of the parameters of the logistic regression model.

VARIABLE	ESTIMATING β PARAMETER	STANDARD ERROR SE	LEVEL P	OR	95% CONFIDENCE INTERVAL FOR OR
Flow in the external iliac artery – two-phase flow	-1.133	0.588	0.054	0.322	0.097–1.004
SFA flow – no flow	-1.685	0.993	0.090	0.185	0.024–1.324
Bleeding – minimal	2.172	0.783	0.006	8.776	2.077–48.357
ASA	1.154	0.566	0.041	3.172	1.109–10.679
Constant	-2.203	1.864	0.237		

tation levels and impaired stump healing are possible. This would explain the high percentage of deaths in the perioperative period in the group of patients with complications.

At present, there is a lack of agreement among authors as to the risk factors for impaired stump healing after large amputations. This is due to a small amount of research dealing with this issue and the division of large amputations into two separate groups: above and below the knee joint. The very difference in the anatomical location of the procedure may be an important variable modulating risk factors for impaired healing. Only two statistically significant risk factors for impaired stump healing after transfemoral amputation were identified in this study. Minimal bleeding during surgery resulted in an over 8-fold increase in the risk of complications after surgery, $\exp \beta = 8.776$, CI95 [2.077, 48357]. Increasing the level of ASA by one increases the risk of complications 3 times $\exp \beta = 3.172$, CI95 [1,109, 10,679]. There are no similar studies with which those results could be compared. Most authors combine amputations above and below the knee into one research group. For example, in the aforementioned study, O'Brien PJ et al. indicated the following variables as risk factors for early amputation failure: emergency surgery, sepsis, end-stage renal disease, BMI >30, surgery performed by a resident, smoking [9]. In turn, Stone PJ et al. identified the level of amputation above the knee, hematocrit >30% in the preoperative period, permanent stay of the patient in the care facility, and conduction anesthesia as factors increasing the risk of this complication [11]. Other factors mentioned in the literature include rest pain of the stump in the postoperative period, diabetes, advanced age of the patient >80 years old and the use of Redon type drainage and metal staples to close the wound during surgery.

Retrospective design has several limitations. Collecting data based on medical records is associated with possible gaps and the inability to verify data. As a result, the findings are subject to error. Another weakness of the study is the sample size. Statistical relationships and the ability to identify risk factors for impaired healing are characterized by low potency. It should be emphasized, however, that this is one of the few papers dealing with impaired healing in patients after large amputations. Reducing the study

group to patients with amputations above the knee increased the homogeneity of the study group, which simplified the performance of statistical calculations. It seems appropriate to adopt a different approach to groups of patients based on the level of amputation. Holistic comparison of different levels of amputation can lead to misinterpretation of the data. Indications for amputation, differences in blood supply and the anatomical structure of the limb as well as the technique of the procedure support this view.

Little information has been published regarding the risk factors for early amputation failure in the form of impaired stump healing. Knowledge of this topic will allow surgeons to improve early amputation results. This will be possible by identifying and eliminating perioperative procedures that increase the risk of impaired healing, and by identifying a group of patients whose ablation will be related to an increased risk of complications. It should be remembered that the population of patients undergoing ablative procedures for non-traumatic causes is burdened with many chronic diseases. Appropriate preparation of patients and possible diagnostics and treatment of accompanying diseases can significantly improve the results of these treatments.

Patients qualified for amputation above the knee with a high ASA score should pay attention to the operator who, showing particular care and accuracy during the procedure, can minimize the increased risk of impaired stump healing. Postoperative course in these patients should be characterized by increased alertness and care for local treatment of the postoperative wound. During amputation, slight intraoperative bleeding from tissues should prompt the operator to consider extending the scope of amputation to increase the chances of healing the stump. The assessment of Doppler flow does not have predictive properties regarding the risk of postoperative impaired wound healing in patients after amputations above the knee. However, taking into account the results of one-way analysis, attention should be paid to the flow in the external iliac artery. Deterioration of this parameter may adversely affect the healing process. The occurrence of stump healing complications in the postoperative period leads to an increase in hospitalization and an increase in mortality during hospitalization.

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