Investigating the Incidence and Risk Factors of Re-Amputation among Patients Undergoing Amputation, Shahid Beheshti Hospital

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Abstract:

Background and Objective: Diabetes is recognized as a major factor contributing to serious complications that may lead to the need for limb amputation. This study was designed to investigate the incidence and identify risk factors associated with re-amputation in diabetic patients undergoing amputation.

Materials & Methods: This research is a case-control study conducted on diabetic patients undergoing amputation at Shahid Beheshti Medical Center in Qom. Data were collected by reviewing patients' medical records. The collected information included age, gender, duration of diabetes, medical history, postoperative infection, vascular problems, and smoking history, which were recorded and compared between the two groups: those with and without re-amputation. Data were analyzed using SPSS version 26 with statistical tests including t-tests and chi-square tests. A significance level of 0.05 was considered for all tests.

Results: Among the 137 patients who underwent amputation, 36 patients were re-amputated within the following 18 months. Statistical analysis indicated that only the site of amputation showed a statistically significant difference between the two groups with and without re-amputation ($P < 0.05$). Other risk factors such as age, length of hospital stay, gender, smoking status, urgency of surgery, cardiovascular diseases, end-stage renal disease (ESRD), immunosuppressive therapy, and the incidence of postoperative infection did not show statistically significant differences between the two groups ($P > 0.05$).

Conclusion: This study demonstrates that above-knee amputation is primarily associated with the need for re-amputation, while other factors such as age, length of stay, gender, and smoking do not have a significant impact. Future research is recommended to focus on increasing sample size and long-term follow-up of patients to improve treatment quality.

Keywords: Diabetes, Re-amputation, Risk Factors

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Background and Objective

Diabetic foot ulcers present a significant threat to the health and well-being of individuals with diabetes, with studies indicating that between 12% and 25% of patients may develop these complications during their lifetime. These ulcers are associated with elevated morbidity rates and contribute to a diminished quality of life, prolonged hospital stays, considerable treatment costs, and increased rates of lower limb amputations.[1] Indeed, diabetic foot ulcers account for 40% to 60% of non-traumatic lower limb amputations, with incidence rates of major amputations (above the ankle) reported to range from 0.5 to 4 per thousand among diabetic patients.[2] Unlike patients who suffer from trauma or malignancies, individuals with vascular disease or diabetes may necessitate re-amputation due to the progression of the underlying condition.[3] Re-amputation, typically involving the same limb, is defined as a surgical procedure in which a previously amputated limb or a portion thereof is surgically removed again due to clinical complications such as infection, vascular insufficiency, or the need to modify the amputation level. This procedure aims to improve prosthetic functionality, address complications arising from the initial amputation, or enhance the patient's overall quality of life.[4] Consequently, studies frequently exclude cases of debridement, incision, drainage, or secondary closure when defining the scope of re-amputation. For many years, the Wagner-Meggitt classification system has been employed to categorize wounds, particularly in Western contexts, and is closely linked to wound healing.[5] However, while this system considers wound depth and the extent of gangrene, it does not account for neuropathy, rendering it an unsuitable choice for categorizing diabetic wounds.[6] Existing alternatives encompass methods for grading diabetic wound severity, assessing bacterial colonization, defining wound phases, and evaluating related etiological factors, including location, ischemia, neuropathy, bacterial infection, depth, and the University of Texas (UT) diabetic wound classification.[7] Both the Wagner-Meggitt and UT classification systems have been recognized as straightforward and effective predictors of the need for lower limb amputation, according to findings from the Joen study.[5] Numerous studies have identified a range of risk factors associated with re-amputation. Notably, atherosclerosis has emerged as a significant risk factor for both amputation and re-amputation in two separate investigations.[4] Moreover, the re-amputation rate is reported to be higher among men than women.[8] Post-operative infection has also been identified as a contributing risk factor for re-amputation.[9] Other recognized risk factors include advanced age, leukocytosis, an elevated level of amputation, clinical evidence of gangrene, the duration of diabetes, and smoking.[10] Understanding these risk factors is imperative for healthcare providers in order to identify patients at risk for re-amputation and to make informed decisions regarding the procedure and its necessary level. Despite the significance of these insights, limited information is available regarding the risk factors for re-amputation among patients with diabetic foot ulcers in Iran, particularly within the field of dermatology. This study aims to investigate the incidence and associated risk factors of re-amputation among diabetic patients undergoing limb amputation at Shahid Beheshti Hospital in Qom from 2017 to 2020 (1396-1399).

Materials and Methods

This research was structured as a case-control study, encompassing all patients who underwent non-traumatic amputation surgery at Shahid Beheshti Hospital in Qom during the period from 2017 to 2020 (1396 to 1399). A convenience sampling method was employed to select the study population. Utilizing a sample size formula that accounted for a type I error rate of 5%, a statistical power of 0.9, and an odds ratio of 2.27[9] associated with a history of coronary artery disease, the minimum required sample size was calculated to be 132 individuals. Ultimately, 137 patients were included in this study; among them, 101 had undergone amputation, while 36 were identified as having required re-amputation to facilitate the investigation of potential risk factors. The inclusion criteria for the study encompassed all

patients who underwent amputation due to non-traumatic causes, including conditions such as tumors as well as amputations resulting from diabetes, which led to deformities, wounds, and infections associated with neuropathy. Patients were excluded from the study if they had incomplete medical records, had undergone traumatic amputations, or if their initial amputation was performed at another facility with inaccessible records. The study protocol received approval from the Research Council of the Faculty of Medicine, and ethical clearance was granted by the Ethics Committee of Qom University of Medical Sciences (IR.MUQ.REC.1400.188). Subsequently, the researcher obtained permission from the director of Shahid Beheshti Hospital and accessed the medical records department, where a comprehensive review of all medical files pertaining to non-traumatic amputations was conducted. Data extraction focused on various variables, including age, gender, urgency of surgery, location of amputation, smoking status, duration of hospital stay, history of End-Stage Renal Disease (ESRD), history of coronary artery disease, use of immunosuppressive agents, the interval to re-amputation, and the occurrence of infections post-initial surgery. A tailored checklist was employed for systematic data collection. Information was gathered at the time of both the initial amputation and any subsequent re-amputation. All collected data were entered into SPSS software, version 22, for statistical analysis, utilizing t-tests and chi-square tests. A significance level of 0.05 was adopted for all statistical tests.

Findings

A total of 137 patients participated in the study, comprising 87 males (63.5%) and 50 females (36.6%). The mean age of participants was 63.34 years (± 11.7 years), with ages ranging from 25 to 91 years. The examination of amputation locations revealed that six patients (4.4%) underwent above-knee amputations, 44 patients (32.1%) had below-knee amputations, and 87 patients (63.5%) received amputations at the metatarsal level.

During an 18-month follow-up period, 36 patients (26.3%) required re-amputation. Regarding smoking history, 18 patients (13.1%) reported a history of smoking, whereas 119 patients (86.9%) did not smoke. Only one patient (0.7%) underwent an emergency procedure, while the remaining 136 patients (99.3%) had elective surgeries. Cardiovascular issues were noted in 64 patients (46.7%), while 73 patients (53.3%) had no reported history of such conditions. The prevalence of ESRD among participants was observed in 21 patients (15.3%), while 116 patients (84.7%) had no such history. None of the patients reported prior use of immunosuppressive medications. Post-operative infections were documented in 34 patients (24.8%), while 103 patients (75.2%) did not experience any infections. The average length of hospital stay for the study participants was 12.03 days (± 14.1 days).

The analysis conducted did not reveal statistically significant differences concerning age, length of hospital stay, gender, smoking status, urgency of surgery, history of cardiovascular diseases, End-Stage Renal Disease (ESRD), use of immunosuppressive agents, or the incidence of post-surgical infections between patients who underwent re-amputation and those who did not ($P > 0.05$).

However, noteworthy statistical differences were observed regarding the site of amputations between the two cohorts. Specifically, among patients requiring re-amputation, 11% (4 patients) had undergone above-knee amputations, in stark contrast to only 2% (2 patients) in the non-re-amputation group ($P < 0.01$). Additionally, within the re-amputation group, 52.8% (19 patients) had below-knee amputations, while 36.1% (13 patients) underwent amputation at the metatarsal level. In comparison, the non-re-amputation cohort consisted of 24.8% (25 patients) with below-knee amputations and a significant proportion of 73.3% (74 patients) with metatarsal amputations. These findings indicate that patients requiring re-amputation may face a heightened risk for above-knee amputations, potentially attributable to the clinical complexities associated with this level of surgical intervention and the need for additional procedures.

Table 1- Review and comparison of risk factors between two groups of patients with and without re-amputation

Variables		Reamputation		Probability value
		Yes	No	
Age		64.3±12.6	62.9±11.4	0.556
Duration of hospitalization		17.11±14.9	12.91±10.6	0.072
Gender	Male	(61.1)22	(64.4)65	0.841
	Female	(38.9)14	(35.6)36	
Site of amputation	Above knee	(11.1)4	(2)2	
	Below knee	(52.8)19	(24.8)25	0.001
	Metatarsus	(36.1)13	(73.3)74	
Smoking	Yes	(19.4)7	(10.9)11	0.249
	No	(80.6)29	(89.1)90	
Urgency of operation	Yes	(0)0	(1)1	1
	No	(100)36	(99)100	
Cardiovascular disease	Yes	(50)18	(45.5)46	0.711
	No	(50)18	(54.5)55	
ESRD	Yes	(16.7)6	(14.9)15	1
	No	(83.3)30	(85.1)86	
Immunosuppression	Yes	(0)0	(0)0	1
	No	(100)36	(100)101	
Postoperative infection	Yes	(13.3)12	(21.8)22	0.183
	No	(66.7)24	(78.2)79	

Discussion

It is important to note that diabetic foot wounds account for 40% to 60% of non-traumatic amputations in the lower extremities, with major amputations (those above the foot) occurring at an incidence of 0.5 to 4 per 1,000 diabetic patients. Unlike amputations resulting from trauma or cancer, re-amputation in patients with diabetes or vascular disease often represents a response to disease progression within the same limb. Re-amputation is defined as the excision of additional bone to achieve a higher amputation level, thus explicitly excluding procedures such as debridement, incision, drainage, or secondary closure. The Wagner-Meggit classification system has long served as a standard for categorizing wounds. Prior investigations have elucidated various risk factors associated with re-amputation, including older age, leukocytosis, elevated amputation levels, the presence of gangrene identified during clinical assessments, the duration of diabetes, and smoking habits. A comprehensive understanding of these risk factors is vital for healthcare providers in identifying patients at increased risk for re-amputation, thereby informing clinical decision-making regarding the appropriate amputation levels. In a study conducted by Tukenmez, significant predictors of re-amputation included hypertension, coronary artery disease, and leukocytosis, in conjunction with diabetes, with an observed higher prevalence among male patients. Tukenmez's evaluation of 66 patients who underwent amputation encompassed demographic data, smoking history, types of amputations, infection presence, microbial culture results, and leukocyte counts.[11] Izumi, in a separate study, assessed 121 diabetic foot patients and found that 26 (21.5%) required re-amputation during an 18-month follow-up period. Over a five-year duration, a re-amputation rate of 60% was documented, predominantly occurring within the initial six months following the surgery. Notably, re-amputation was more prevalent among patients with involvement limited to one or two toes; age over 70 years and heel lesions were significantly linked to increased re-amputation rates.[12] Miyajima investigated a cohort of 210 diabetic foot patients over a nine-year period with an average follow-up of 492 days. This study revealed that 113 participants were male and 97 were female; 9% underwent bypass surgery, 6% received skin grafts, and 52% necessitated amputations by the conclusion of the follow-up period. Among the amputation cohort, two patients experienced vision loss due to retinopathy, while 30 required hemodialysis due to nephropathy. This cohort exhibited a notably elevated prevalence of vascular stenosis and atherosclerosis obliterans. While numerous studies have underscored postoperative infection as a critical factor influencing outcomes,[13] Kono's research involving 116 amputee patients over three years indicated that 57 patients experienced re-amputation in the same limb within the initial six months, of whom 16 developed postoperative infections. Interestingly, although higher levels of amputation, prolonged hospital stays, insulin-dependent diabetes, and clinical gangrene were identified as risk factors for re-amputation, postoperative infections did not appear to exacerbate this risk.[9] A systematic review conducted by Thorud, which evaluated 24 studies on re-amputation rates following metatarsal amputations, uncovered a re-amputation rate of 29.7% at any level following transmetatarsal surgery and 33.2% for major amputations.[24] These findings suggest that while various patient characteristics contribute to the risk of re-amputation, the intricate interplay of clinical factors necessitates further investigation to establish effective preventive strategies.[14]

In a study conducted by Acar, a total of 132 patients who underwent lower limb amputation (110 patients) or re-amputation (22 patients) due to complications associated with diabetic foot were systematically analyzed. The investigation meticulously recorded a variety of factors, including patient demographics (age and gender), smoking history, duration of diabetes, diabetes-related comorbidities (such as

nephropathy and neuropathy), general comorbidities (including peripheral vascular disease, hypertension, hyperlipidemia, and malignancy), leukocytosis, the status of wound infections, and the results of microbial cultures along with antibiotic susceptibility testing. The majority of the amputations were performed on male patients. The study identified multiple risk factors correlated with amputation, including prolonged duration of diabetes, the presence of wound infections, diabetic neuropathy, and a history of smoking. Similarly, male patients, those with a lengthy history of diabetes, and individuals with wound infections, diabetic neuropathy, or a smoking background exhibited higher rates of re-amputation.[15]

In a parallel study conducted by Trier and colleagues,[16] re-amputation rates were reported as 29% for above-knee amputation (TKR) and 30% for knee disarticulation (KD), with a comparatively lower rate of 11% for below-knee amputation (BK). In contrast, our study discovered an overall re-amputation rate of 26.3%, which is lower than the global averages documented in the existing literature. Moreover, Trier's research indicated that a significant proportion (58%) of re-amputations occurred within the first 30 days following surgery, with risk factors such as dyslipidemia, renal failure, and a history of vascular surgery linked to these outcomes. Conversely, our analysis did not uncover any significant risk factors influencing the occurrence of re-amputation, thereby highlighting the necessity for enhanced identification and comprehension of the demographic and clinical characteristics specific to our patient population. Correa and colleagues[17] reported that certain factors, including a history of tobacco use, male gender, vascular obstruction identified through Doppler ultrasound, and stenosis greater than 50%, were associated with an increased risk of re-amputation. Nevertheless, our findings suggest that above-knee amputation is more strongly correlated with the need for re-amputation, while age, length of hospital stay, smoking status, and prior medical history did not significantly influence this outcome.

Conclusion

In conclusion, our findings indicate a significant association between above-knee amputation and the necessity for subsequent re-amputation. Conversely, factors such as age, length of hospital stay, gender, smoking history, and pre-existing medical conditions do not appear to exert a notable impact on this outcome. It is essential for future studies to encompass larger sample sizes, integrate long-term follow-ups, and exercise meticulous control over risk factors. This approach will enhance our understanding of the relationship between these factors and clinical outcomes, ultimately contributing to improved quality of patient care.

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