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The frequency and Risk Factors of Re-amputation in Diabetic Foot Disease at a tertiary care hospital.

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Abstract:

Introduction: The prevalence of diabetes in Pakistan is 11.7% and the prevalence of diabetic foot in Pakistan is 13.9% with amputation rate of as high as 48%. Re-amputation carries significant morbidity in form of economic impact. Like most re-operations, it reflects failure of previous surgery and thus translates into wastage of resources.

Objective: To determine the frequency and associated risk factors of re-amputation, in patients who undergo amputation secondary to diabetic foot syndrome in our population.

Methodology: This study was conducted at the Department of Surgery Department of Surgery, and Diabetic Clinic Ruth Pfau Civil Hospital Karachi, from August 2020 to July 2021, after approval of ethical review board. We enrolled a total of 125 patients in our study. Data was entered and analyzed using SPSS version 22.0. Mean \pm SD/ Median (IQR) was computed for age, HbA1C, duration of diabetes, duration of symptoms leading to amputation, ulcer size, ankle-brachial index and duration of re-amputation. Frequency and percentage were computed for all the categorical variables like gender, co-morbid, type of diabetes, diabetic neuropathy, morphology of diabetic foot ulcer, indication of amputation, peripheral arterial disease, level of amputation, indication of re-amputation, and level of re-amputation.

Result: Among enrolled 125 patients, 85 patients (68%) were male and 40 patients (32%) were females. Mean age was 48.75 ± 9.702 years. Mean duration of diabetes was 11.12 ± 6.64 years and mean HbA1C was 8.246 ± 1.1357 . During study period 61 (48.8%) patients required re-amputation. Mean ABPI in patient requiring re amputation is 0.790 ± 0.2501 ($p=0.000$).

Conclusion: Patients at risk of re-amputation may be identify by focusing upon good evaluation that includes assessing additional risk factors and deciding initial level of amputation. It is important to have enhance informed consent in avoiding the morbidity of additional surgery.

Key words: Diabetic foot disease. Amputation, Re amputation.

Introduction:

Diabetes mellitus is a chronic disease that has become public healthcare problem. Longstanding diabetes leads to many micro and macro vascular complica-

tions including coronary artery disease, stroke, diabetic neuropathy, diabetic nephropathy and peripheral arterial disease. Hyperglycemia is a major contributing factor leading to these complications.¹Diabetic

foot syndrome (DFS) is common consequence of longstanding uncontrolled diabetes.²The pathophysiology of DFS is multi factorial occurring as result of peripheral vascular disease³, peripheral neuropathy and infection affecting the foot.⁴The prevalence of diabetic foot syndrome (DFS) in international literature⁵ is reported to be 25%.The prevalence of diabetes mellitus in Pakistan is 11.7%⁶and is expected to rise over the ensuing years. Thus, by logical extension, the incidence of diabetic foot may well be presumed to be alarmingly high. The diabetic foot syndrome affect up to 60% in diabetic males and 55.5% diabetic females with reported amputation rate of 40% and 33% respectively.⁷The prevalence of diabetic foot ulcer in Pakistan ranges from 13.9%⁸with amputation rate of 48%.⁹Diabetic foot syndrome carries a huge economic burden on health care services all over the world.¹⁰Ascar et al from Turkey, in a retrospective study has identified long standing diabetes, male gender, cigarette smoking, diabetic nephropathy, diabetic neuropathy, peripheral arterial disease, hypertension and wound infection as a major risk factor of re-amputation. Patients with diabetic foot disease are at an increased risk for lower extremity amputation (LEA), premature mortality, and reduced health-related quality of life. In the setting of chronic infection, significant tissue loss, and/or an unstable deformity, limb salvage may not be possible, and major amputation may be necessary. Recent studies have questioned the reliability of initial partial ray amputation as it is associated with greater incidence of re-amputation.¹¹The rate of re-amputation was noted up to 26.7% at 1st year as noted in the study done by Izumi et al.¹² A systemic review showed that one third of the trans-metatarsal amputation will eventually need major amputation.¹³Re-amputation carries significant morbidity in the form of economic impact. Like most re-operations, it reflects failure of previous surgery and thus translates into wastage of resources. More importantly it has a profound psychological impact on patient, who may already be severely depressed. As studied by Neeru et al, among 290 patients with Diabetic foot ulcers 64 were diagnosed as having depression.¹⁴As evaluated in a study, poor walking ability at one year is associated with longer time duration between surgery and fitting of a definitive prosthesis.¹⁵

Rationale:

Little or no data is available on incidence of re-amputation and the risk factors leading to it. For developing nation with a constrained resource, the risk of re-amputation carries a significant implication for overall cost of treatment as well as loss of work hours. Furthermore, this causes unnecessary delay in rehabilitation, further compounding the loss.

Objective:

To determine the frequency and associated risk factors of re-amputation, in patients who undergo amputation secondary to diabetic foot syndrome in our population.

Operative Definitions:

Diabetic foot Syndrome:

Diabetic foot syndrome comprises complications associated with DM including infection with neurological deficits and peripheral vascular disease of lower limb.⁸

Minor Amputation: Minor amputation includes all amputation at or below the level of ankle like ray amputation and trans metatarsal amputation.

Major Amputation: Major amputation includes amputation above the ankle joints like below or above knee amputation.

Re-amputation: When amputation at a higher level is needed within six months of initial amputation.

Methodology:

This prospective Case control study, after approval from Institutional review board was conducted at the Department of Surgery, and Diabetic Clinic Ruth Pfau Civil hospital Karachi from August 2020 to July 2021.

Sample size was calculated using Open EPI software with the following assumptions. Anticipated % prevalence of re-amputation (p)= 19.8% Confidence limits: 7% Attrition rate: 10% and it turn out 120. To account for any dropout, we taken sample size as 125. The Sample technique was non-probability consecutive. 125 diabetic patients who underwent first amputation or re-amputation were included after taking written and informed consents. Pregnant female and patient with vascular disease were excluded from study. Patients were divided into two groups, A with first amputation and second group B with re-amputation.

Data Collection Procedure:

As per selection criteria diabetic patients who underwent amputation were selected from the general surgery clinics, emergency department of surgery and

diabetic foot care clinic. Selected cohort followed for 6 months after taking informed consent. Clinical history and clinical examination done. Data collected includes history of addiction, co-morbid conditions, type and duration of diabetics, time period from onset of foot lesion to amputation, level and extent of amputation. The peripheral vascular disease was assessed by palpating the dorsalis pedis and posterior tibial artery identified by assessing the sensation of pain (nociception) and joint neuropathy (proprioception) in the affected limbs. Wound assessment and evidence of osteomyelitis were recorded. A Performa was used to fill the above mentioned finding.

Data Analysis Procedure:

Data was entered and analyzed using SPSS version 22.0. Mean \pm SD/Median (IQR) was computed for age, HbA1C, duration of diabetes, duration of symptoms leading to amputation, ulcer size, ankle-brachial index and duration of re-amputation. Frequency and percentage were computed for all the categorical variables like gender, co-morbid, type of diabetes, diabetic neuropathy, morphology of diabetic foot ulcer, indication of amputation, peripheral arterial disease, level of amputation, indication of re-amputation, and level of re-amputation. Independent sample-test/Mann-Whitney U test were applied as appropriate to assess significant difference in age, duration of diabetes, duration of symptoms leading to amputation, ulcer size, and ankle-brachial index between re-amputation statuses. Chi-square test/Fisher-exact test were applied to assess significant association of gender, co-morbid, type of diabetes, diabetic neuropathy, morphology of diabetic foot ulcer, indication of amputation, peripheral arterial disease and level of amputation with re-amputation statuses. P-value <0.05 was considered as statistically significant.

Result:

Among 125 patients studied, 85 patients (68%) were male and 40 patients (32%) were females. During period of study 64(52.2%) patients do not have re-amputation and 61(48.8%) patients required re-amputation. Mean age was found as 48.75 ± 9.702 years ($p=0.421$). Mean duration of diabetes is 11.12 ± 6.64 years ($p=0.001$) and mean HbA1C is 8.246 ± 1.1357 % (see table 1). Mean ABPI in patient requiring re amputation is 0.790 ± 0.2501 ($p=0.000$). Out of

125 patients 101 patients require minor amputation and 24 patients requires major amputation (Table 1). 23 patients requiring re-amputation have co existing chronic renal disease ($p=0.004$) and 35 patients requiring re-amputation have hypertension ($p=0.001$). Out of 61 patients that requires re-amputation, 18 (14%) underwent minor amputation and 42(33.6%) underwent major amputation. Mean duration between index amputation and re-amputation was found as 4.42 ± 2.676 months. Indications for re-amputation includes gangrene in 33patients (26.4%), infection in 20(16%) patient and both gangrene and infection in 7 (5.6%) patients.(Table2) Major factors that lead to re-amputation were; not consenting for index amputation 16 patients(12.8%), residual infection 17 patients (13.6%) and not adequately evaluating the disease at the time of index amputation found in 27 patients(21.6%). (Table 3)

Discussion:

Diabetes is one of the most common non communicable disease affecting large number of population globally. Pakistan ranks 7th in world for diabetes prevalence, taking an epidemic status for our country.¹⁶ As we are a developing country the high prevalence of diabetes and its associated morbidities impose a substantial social and a economical burden.¹⁷ The purpose of our study is to see the frequency of re-amputation in diabetic foot disease and identify the risk factors culmination in re-amputation. 48.8% patients among enrolled required re-amputation. The duration of disease, uncontrolled glycemic index, HbA1c and peripheral vascular disease are the commonest risk factors for diabetic foot syndrome. These Risk factors of micro-vascular and macro-vascular complications in relation to raised HBA1c levels ($>6.5\%$) with poor glycemic control have also been identified in other studies as well.¹⁸ Studies It has been documented that uncontrolled glycemic index is associated with increase foot ulcers and diabetic foot deformities resulting in amputation.¹⁹ In our study mean duration of diabetes was 11.12 ± 6.64 years (p value 0.001) and mean HbA1C was 8.246 ± 1.1357 %. Among 61 re-amputation performed, 42 were major re-amputations and 18 were minor re-amputations. Mean duration between index amputation and re-amputation in our study was 4.42 ± 2.676 months. These findings are in agreement with published litera-

Table No 1: Factors assessed in Diabetic foot Patients

	N	Minimum	Maximum	Mean	±SD
Age	125	27	72	48.75	9.702
HbA1C	125	6.0	10.2	8.246	1.1357
duration of diabetes	125	1	33	11.12	6.644
ABPI	125	.0	1.3	.890	.2630
Duration between amputation and re-amputation in months	60	1	13	4.42	2.676

Table No 2: Variables assessed for patient undergoing Re-amputation.

	Frequency	p value
Gender		
Male	43	0.572
Female	18	
Type of Diabetes		
Type I	3	0.113
Type II	58	
Co-morbidities		
Hypertension	35	0.001
Chronic Kidney Disease	23	0.004
Diabetic Neuropathy	51	0.009
Peripheral Arterial Disease	39	0.012
Indication for amputation		
Gangrene	37	0.420
Infection	18	
Both	6	
Level of Amputation		
Minor	61	0.000
Major	0	

Table No 3: Factors resulting in re-amputation

	Frequency	Percent	Valid Percent	Cumulative Percent
Not consenting for index amputation	16	12.8	26.7	26.7
Residual infection	17	13.6	28.3	55.0
Not adequately evaluating the disease at the time of index amputation	27	21.6	45.0	100.0
Total	60	48.0	100.0	

ture that reported risk of re-amputation up to 40% within one year of index amputation²⁰; while another study reported as high as 25% within 30 days of index amputation.²¹ Major factors leading to re-amputation included residual infection and gangrene and associated peripheral vascular disease.²² In our study Mean ABPI in patient requiring re-amputation is 0.790 ±0.2501 (p=0.001). Studies have proven that majority of diabetic foot disease patients associated with peripheral vascular and eventually may require re-amputation after index amputation.²³ Insulin dependent diabetic patients presenting with gangrene were on high risk for amputation.²⁴ We also found gangrene as commonest risk factor (26.4%) for re-amputation in our study. The level of first amputation was also identified as a risk factor for re-amputation.²⁵ Another study demonstrated that patients who underwent initial minor amputation with coexistent morbidity, were at high risk of subsequent re-amputation.²⁶ Co morbid condition noted in the study includes chronic kidney disease and hypertension. 23 patients needing re-amputation have co existing chronic renal disease (p value=0.004) and 35 patient requiring re-amputation had hypertension (p value= 0.001). Majority of re-amputations were because of inadequate evaluation in initial assessment, patients not giving consent and residual infection. During current study, major factors that lead to re-amputation includes not consenting for index amputation 16 patients (12.8%), residual infection 17 patients (13.6%) and not adequately evaluating the disease at the time of index amputation found in 27 patients (21.6%). Published study suggest that once amputation becomes inevitable it is always best to manage patient in specialized clinic with good preoperative assessment improving surgical outcomes.²⁷ Although during this study we followed patient for short duration, it is important to note that rate of re-amputation is significantly high even in long-term affecting quality of life.²⁸

Conclusion:

If morbidity of re-amputation is to be avoided than careful assessment of risk factors and decision regarding level of initial amputation are of paramount importance.

Conflict of interest: None

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