

## Original Research Article

# Predictive value of the risk factors for amputation of lower extremity in patients with diabetic foot in Al-Karama teaching hospital

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### ABSTRACT

**Background:** Diabetic foot disease is a foot that exhibits any pathology that results directly from diabetic mellitus or any long-term chronic complication of diabetes mellitus. The aim of the study was to determine the risk factors and indications for amputations among diabetics.

**Methods:** this clinical prospective study includes 120 diabetic foot patients admitted to AL- Karama teaching hospital from 1<sup>st</sup> January 2015 to 1<sup>st</sup> January 2019. All patients assessed for age, gender, duration of diabetes, hyperglycemia at admission and control of diabetes, history of smoking, hypertension, assess dominant foot and examination of diabetic foot lesion and classify it according to Meggit-Wagner grading status, indications for amputation and outcome.

**Results:** The male to female ratio was 2:1. Most frequent age group of patients treated by amputation was between 50-80 years. Among patients treated with amputation (68.33%) of patients had diabetes mellitus for 11-20 years. From patients admitted with diabetic foot (53.33%) were smokers. Regarding hypertension (93.33%) of all patients were hypertensive. It was noted that (65%) of patients lesion occur in dominant foot Regarding Wagner's grading system (36.66%) of patients were grade 4 followed by grade 1 (21.66%). regarding mode of treatment (53.33%) of patients treated by amputation and other treated conservatively. Only 3 patients from 60 died while other discharged well after complete treatment.

**Conclusions:** Increasing in age, long duration of diabetes mellitus, poor control of diabetes, smoking and occurrence of lesion in dominant foot all considered as a significant risk factors for increase liability amputation.

**Keywords:** Amputation, Diabetic foot, Hyperglycemia, Risk factors, Smoking

### INTRODUCTION

Diabetes mellitus is a disorder of carbohydrate metabolism that causes hyperglycemia.<sup>1</sup> It results from deficiency of insulin (insulin dependent diabetes mellitus) or resistance to action of insulin (non-insulin dependent diabetes mellitus).<sup>2</sup> With little discrimination, it affects rich and poor, young and old, and industrialized areas or less economically developed areas in equal measure. In 2011, the prevalence was estimated at 366 million (i.e.,

>8.3% of the adult population worldwide).<sup>3,4</sup> The number is expected to increase to 552 million by 2030 – a consequence of sedentary lifestyles, changes in dietary patterns and longer life expectancy. Diabetic foot remains the most common reason for hospital admission in diabetes.<sup>5</sup> The prevalence being lower in young and high in older patients.<sup>6</sup> Diabetic foot causes substantial morbidity, impairs quality of life, engenders high treatment costs and is the most important risk factor for

lower extremity amputation, which is one of the most disabling complication of diabetes.<sup>7,8</sup>

It has been estimated that about 1 in 100 diabetic patient per year will require amputation, and is responsible for about 40% of non-trauma related amputation in UK and 50% in USA.<sup>9-11</sup>

Survival rates after diabetes-related lower extremity amputation are significantly lower than those in age-matched non diabetic individuals as well as persons with diabetes without history of amputation.<sup>11</sup>

Following one lower extremity amputation, there is a 50% incidence of serious contralateral foot lesion and 50% incidence of contralateral amputation within 2-5 years.<sup>11</sup>

In case the ulcer is established, careful assessment of the patient with thorough history and physical examination which include evaluation of the foot according to Wagner classification of diabetic foot is needed.<sup>12</sup>

- Grade 0: foot at risk, no obvious ulcer but thick callus, Rocker bottom foot or claw foot.
- Grade I: superficial ulcer not clinically infected.
- Grade II: deep ulcer often infected involving tendons, joint capsules but not the bone.
- Grade III: ulcer extending to the bone usually causing osteomyelitis.
- Grade IV: localized gangrene.
- Grade V: gangrene of major part(s) of foot.

Peripheral neuropathy, ulceration, infection, and peripheral vascular disease are the principal factors for ulcer complications and loss of a lower limb in diabetic patients.<sup>12,13</sup> Nonetheless, ambiguity remains as to which factors are most conducive to amputation outcomes and how strongly they affect these events.<sup>14</sup> Structured healthcare is one of the most effective approaches to reducing the indicators for diabetic foot amputation, and studies have shown that these can be reduced by as much as 75%.<sup>13</sup>

Factors such as low socioeconomic status, smoking, gender, renal impairment, ischemia, diabetic neuropathy, and high levels of glucose and triglycerides have been reported as importantly associated with the risk of foot amputation.<sup>15-19</sup>

## METHODS

This clinical prospective study in which one hundred and twenty patients with diabetic foot admitted to AL-Karama teaching hospital from 1<sup>st</sup> January 2015 to 1<sup>st</sup> January 2019. All patients assessed for age, gender, duration of diabetes, hyperglycemia at admission and control of diabetes, history of smoking, hypertension, assess dominant foot and examination of diabetic foot lesion and classify it according to Meggit-Wagner

grading status, indications for amputation and outcome. Then we assessed our results statistically to assess the significant risk factors for lower extremity amputation. Patients included if the meet inclusion criteria which are, aged 18 and above, consented to participate in the study, and has not been diagnosed with malignancies or blood disorder that affect the study outcome. Exclusion criteria included, patients who are suffering from other malignant diseases or having serious heart disease that affect outcome of surgery. All data were entered and analyzed using Statistical Package for Social Sciences (SPSS) version 22.

## RESULTS

The most vulnerable age group affected by diabetic foot was between 50– 80 years comprising 92 patients (76.66%). Next group 20-49 years, 28 patients (23.33%). The mean of age was 61.45 years. From 64 patients treated by amputation 56 patients (60.86%) were between 50-80 years of age while 8 patients (28.57%) between 20-49 years. The mean of age 62.52 years. From 56 patients treated by conservative measure, 36 patients (39.13%) age between 50-80 years, patients aged 20-49 years constitute 20 patients (71.42%). Among 120 patients admitted with diabetic foot, male were 74 patients (61.66%), while female 46 patients (38.33%).

Among 64 patients treated with amputation male comprised 50 patients (67.56%) while female 14 patients (30.43%). Among 56 patients treated with no amputation, male comprised 24 (32.43%), female 32 (69.56%) (Table 1).

**Table 1: Relation between age, sex and amputation in diabetic foot patients.**

	No. of patients N (%)	Amputation N (%)	Non amputated N (%)	P value
<b>Age (in years)</b>				
20-49	28 (23.33)	8 (28.57)	20 (71.42)	0.007
50-80	92 (76.66)	56 (60.86)	36 (39.13)	
<b>Gender</b>				
Male	74 (61.66)	50 (67.56)	24 (32.43)	0.107
Female	46 (38.33)	14 (30.43)	32 (69.56)	

### *Duration of diabetes mellitus*

Among 120 patients studied, the majority of patients complaining of diabetic foot had diabetes for 11-20 years, 82 patients (68.33%), followed by patients had diabetes mellitus, while only 38 patients (31.60%) with diabetic foot were newly diagnosed as having diabetes mellitus. The mean of period 13.45 years. While among 48 patients treated by amputation also the majority having diabetes mellitus for last 11-20 years, while only 16 patients (42.10%) with diabetic foot were newly diagnosed as having diabetes mellitus. The mean of period 14.89 years. Among 56 patients treated

conservatively majority of patients having diabetic foot had diabetes mellitus for period between 11-20 years 34 patients (41.46%), while only 22 patients (57.89%) with

diabetic foot were newly diagnosed as having diabetes mellitus. The mean of period 11.84 years (Table 2).

**Table 2: Relation between clinical features and amputation in diabetic foot patients.**

Variable	No. of patients N (%)	Treated by amputation N (%)	Non amputation N (%)	P value
<b>Duration of DM</b>				
1-10 years	38 (31.66)	16 (42.10)	22 (57.89)	0.037
11-20 years	82(68.33)	48 (58.53)	34 (41.46)	
<b>Hyperglycemic at admission</b>				
Yes	112 (93.33)	62(96.87)	50 (89.28)	0.002
No	8 (6.66)	2 (3.12)	6 (10.71)	
<b>Smoking</b>				
Yes	64 (53.33)	42 (65.62)	22(34.37)	0.003
No	56 (46.66)	22 (39.28)	34 (60.71)	
<b>Hypertension</b>				
Yes	66 (55.00)	42 (63.63)	24 (36.36)	0.192
No	54(45.00)	22 (40.73)	32 (59.25)	
<b>Lesion in dominant foot</b>				
Yes	78 (65.00)	48(61.53)	30 (38.46)	0.045
No	42 (35.00)	16 (38.09)	26 (61.90)	
<b>Family history</b>				
Yes	74 (61.66)	44 (68.75)	30 (53.57)	0.034
No	64 (38.33)	20 (31.25)	27(46.42)	

#### **Hyperglycemia at admission and control of diabetes**

It was observed that among 120 patients studied 112 patients (93.33%) hyperglycemic at admission, fasting blood sugar more than 10 mmol/l. While only 8 patients (6.66%) non hyperglycemic at admission fasting blood sugar was within normal. Among 64 patients treated with amputation 62 patients (96.87%) hyperglycemic at admission only 2 patient non hyperglycemic at admission.

In 56 patients treated with non-amputation 50 patients (89.28%) hyperglycemic at admission while 6 patients (10.71%) non hyperglycemic at admission (Table 2).

#### **History of smoking**

Among 120 patients studied 64 (53.33%) patients were smokers and 56 (46.66%) patient's nonsmokers. In smokers the mean of years of smoking is 8 years and the mean of number of cigarette is 20 cigars. While among 64 patients treated with amputation 42 patients (65.62%) were smoker and 22 nonsmokers (39.28%). And among 56 patients treated with non-amputation 22 patients (34.37%) smokers and 34 (60.71%) were nonsmokers (Table 2).

#### **History of hypertension**

It was seen among 120 patients studied 66 patients (55%) were hypertensive and on regular treatment of hypertension, while 54 (45%) non hypertensive.

In 64 patients treated with amputation 42 patients (63.63%) on regular treatment of hypertension and 22 (40.74%) non hypertensive. While in 56 patients treated with non-amputation 24 (36.36%) patients hypertensive and 32 (59.25%) non hypertensive (Table 2).

#### **Relation between diabetic foot and dominant foot**

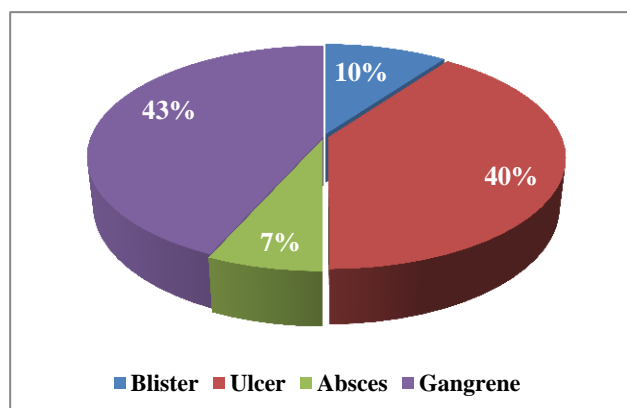
It was noted among 120 patients studied 78 patients (65%) developed lesion in dominant foot and 42 (35%) had lesion in non-dominant foot. In 64 patients treated with amputation 48 (61.53%) develop lesion in dominant foot and amputation was done in dominant foot while 16 (38.09%) developed lesion and amputation done in non-dominant foot. While in 56 patients (treated with non-amputation 30 (38.46%) had lesion in dominant foot and 26 (61.90%) patients had lesion in non-dominant foot (Table 2).

#### **Family history of diabetes**

In 120 patients studied 74 patients (61.66%) had positive family history first and second degree relative of diabetes while 64 (38.33%) have negative family history. Among 64 patients treated with amputation 44 patients (68.75%) had family history just 20 patients (31.25%) negative for family history. In 56 patients kept on non-amputation treated 30 patients (53.57%) had positive family history, 26 patients (46.42%) had negative family history (Table 2).

### Types of lesions

Among 120 patients studied. 12 of them (10%) had blister, 48 patients (40%) had ulcer, and 8 patients (6.66%) had abscess while 52 patients (43.33%) had gangrene, when observe Figure 1, we found that gangrene and ulcer were the main presenting feature.



**Figure 1: Type of lesion in diabetic foot patients.**

### Wagner's grading and mode of treatment

Diabetic foot grading (according to Wagner's) is shown below, the highest number in grade four 36.66%, while the least number in grade zero 3.33%. Among 120 patients, 64 (53.33%) patients treated with non-amputation, among them 44 (78.57%) treated conservatively and 12 patients (21.42%) treated by debridement or drainage of pus, 64 (53.33%) treated by amputation. The types of amputation were as follow, Ray's amputation 22 (34.37%) patients, trans-metatarsal amputation in 2 (3.125%) patients, below knee amputation in 16 (25%) patients and above knee in 24 (37.5%) patients (Table 3).

**Table 3: Wagner's grading.**

Wagner's grade	Number	Treated by amputation	Treated conservatively
Grade zero	4	None	4
Grade one	26	None	26
Grade two	16	4	12
Grade three	16	10	6
Grade four	44	42	2
Grade five	14	14	None

### Outcome of patients

Among 120 patients admitted with diabetic foot, 64 (53.33%) patients treated with amputation, 60 (93.75%) of them discharged well and 4 (6.25%) patients died of systemic complications (two patients with renal failure, and two patients of ischemic heart disease), of those treated conservatively, 56 patients (46.66%) 2 (3.57%)

patients died because of ischemic heart disease while 54 (96.42%) patients discharged well.

### DISCUSSION

The highest proportion of patients was in the (50-80 years) age group, with a male to female ratio that began with 1:1.5 then it was reversed and increased gradually to reach a final male preponderance of 2:1. This is in accordance with:

By comparing these results with the results of other studies done in our country: Al-Khazraji also found most of the diabetic lesions in the (51-60 years) age group with a male to female ratio of 1.5:1, and studies done in other countries like 23.<sup>22</sup> Wolrond and Ramesh who found female to male ratio of 1.2:1.<sup>23</sup> It was observed in present study that the incidence of lower extremities amputation increases with age, were (60.86%) of patients treated with amputation age above 50 years, this mean age significant risk factor for amputation,  $p < 0.05$ , this is in agreement with many studies like Frykberg et al, Tseng et al, Gina et al, Ching et al, Kapelrud H.<sup>11,24-27</sup> This result also obtained by Diabetes surveillance (1993) were found increase in rate of lower extremity amputation in advance age, the estimated amputation rate was 2.4 times higher for individual age more than 65 years compared with those age less than 64 years.<sup>27</sup>

This may be due to increase peripheral vascular disease with age or increase in impairment of visual acuity.<sup>11,25</sup>

### Gender

In our study among 120 patients admitted with diabetic foot (61.66%) of them were men. This in agreement with Ahmed El-Tahawy.<sup>28</sup> In present study although incidence of diabetic foot increase in male gender, but male gender is considered as a non-significant risk factor for increasing lower extremity amputation. This in agreement with Gurlec et al were consider gender non-significant factor in determining the risk of lower extremities amputation, and Humphery et al were consider male sex independent risk factor for amputation using the Cox proportion hazards model.<sup>29,30</sup> This observation contradicts with Lee et al who found the incidence rate was two times higher in man than in women, considering the male sex significant factor for increase lower extremity amputation is diabetic foot.<sup>31</sup> While Chen HF et al were consider female patient especially vulnerable to experience increase risk of non-traumatic lower extremities amputation.<sup>25</sup>

### Duration of diabetes mellitus

Depending on the result in this study, among 120 patients studied, 82 patients (68.33%) had diabetes for last 11-20 years. This in agreement with Nicholas et al who consider long duration of having diabetes increase risk of

ulceration and amputation by 2-4 fold.<sup>6</sup> While among 64 patients treated with amputations 48 patients (58.53%) had diabetes for last 11-20 years. From 56 patients treated conservatively 34 patients (41.46%) had diabetes for last 11-20 years. It was found that with increasing duration of diabetes mellitus there is increased risk of lower extremity amputation and it consider significant risk factor for amputation. Similar findings have also been reported by Lee et al were find duration of diabetes significant risk factors for increase lower –extremity amputation  $p < 0.05$ .<sup>31</sup> Similar result were obtained by Letho et al find the duration of diabetes were associated with a twofold risk for amputation.<sup>32</sup>

### ***Hyperglycemia at admission and poor control of diabetes***

It was observed that most of our cases (93.33%) admitted with high blood sugar and history of poor control of diabetes mellitus, similar findings have been reported by Nalini et al.<sup>33</sup> This observation could be due to poor glucose control leading to impaired wound healing.<sup>10</sup> In this retrospective study, analysis of the results obtained showed that, among 64 patients treated with amputation 62 patients (96.87%) hyperglycemic at admission and had poor control of diabetes. This mean hyperglycemic at admission and poor control of diabetes significant factor in increasing risk of amputation in diabetic foot patients. These finding were also reported in other studies conducted by Jbour et al who consider poor glycemic control correlates with prevalence of amputation.<sup>34</sup> Also Lehto et al reported that glycemic control measured at base line by HbA1 was an important predictor of amputation, there was a dose-response relationship between plasma glucose or HbA1 and the risk for amputation, the effect of hyperglycemia on the risk of amputation was seen clearly even after the adjustment for other risk factors.<sup>32</sup> These results were also documented by Lee et al, Tseng, Humphrey et al.<sup>23,30,32</sup>

### ***Smoking***

On detailed findings of our studied cases 64 (53.33%) of admitted patients with diabetic foot were smoker, the mean of years of smoking is 8 years and the mean of number of cigarette is 20 cigarettes per day. Smokers patients were more liable for lower extremity amputation, so smoking consider a significant risk factor in increasing lower extremity amputation. Also these result have been reported in studies conducted by Jbour et al were across-sectional study of 1142 patients with type 2 diabetes in Jordan found smoking to be a strong predictor of amputation.<sup>32</sup> Similarly, Boyko et al found a direct causal association between tobacco use and foot ulceration or amputation.<sup>35</sup>

Also this result in agreement with Humphrey et al, Nalini et al, Tseng, this because smoking commonly contribute to the increase prevalence of peripheral arterial occlusive disease in diabetes.<sup>23,30,33</sup>

### ***Hypertension***

For the relation of occurrence of diabetic foot disease and hypertension, it was seen 66 patients (55%) of all admitted patients were hypertensive and on regular treatment of hypertension.

Hypertension defined by a self-report history and by a reported systolic blood pressure of 140 mmHg or greater, a diastolic pressure of 90 mmHg or greater, or both.<sup>23</sup> Regarding the significance of hypertension in increase rate of lower extremity amputation in diabetic foot patients, hypertension was non-significant factor in increased risk of amputation. This result in agreement with Gürlek et al who state that hypertension were insignificant factors in determining the risk of amputation.<sup>29</sup>

Similar conclusion has been reported by Selby et al who state that blood pressure were independent predictors of amputation.<sup>33</sup> This observation contradicts with Flores et al results were they report that high blood pressure in patients with diabetes mellitus statistically significant risk factors for amputation.<sup>36</sup>

### ***Relation between diabetic foot and dominant foot***

In this research among 120 patients studied 78 (64.28%) patients develop diabetic foot in dominant foot, among 64 patients treated with amputation 48 (61.53%) patients develop lesion in dominant foot increase rate of diabetic foot in dominant foot and the rate of amputation increase when diabetic foot occurs in dominant foot.  $P = 0.045$ , these finding were also reported in other study conducted by Coxon et al were did a retrospective study of amputation in people with diabetes noted a striking laterality, with nearly all occurring on the right side.<sup>37</sup>

This in agreement with Coxon et al and our study because most people had right dominance. This may be due to dominant foot might be subjected to greater shearing or mechanical stress or might be more susceptible to injury by accident.

### ***Family history***

In our research (61.66%) of patients admitted with diabetes had positive family history of diabetes mellitus in first or second degree. This percent increase to (68.75%) in patients treated with amputation.

### ***Types of lesion***

In our research, We observed that the most common type of lesions in admitted patients with diabetic foot were gangrene (43.33%) of part of the foot or extremities gangrene, while result obtained by Morris et al that (29%) of patients admitted complaining of gangrene.<sup>38</sup> The second most common presentation in our research were foot ulceration (40%) comparing with (31%) Morris et



al.<sup>38</sup> With variable extent and site, were most common site of ulcer observe in our study is heel ulcer (32. 40%). This in agreement with Younes et al were consider heel ulcer common and serious type of ulcer which often lead to lower extremity amputation, followed by ulcer in other planter surface of foot (30.15%), then in the dorsum of the foot (20.74%), the remaining invariable site of foot (toes, ankle and lateral or medial surface of foot).<sup>39</sup> Other form of presentation, blister (10%) and abscess (6.66%).

### **Wagner's grading**

Regarding Wagner's grading system, it was observed that most common grade in admitted patients complaining of diabetic foot was grade 4 (36.66%) followed by grade 1 (21.66%). In our study the rate of amputation increased with the increase in Wagner's grade this result also obtain by Kaya et al were found that amputation associated significantly with Wagner's grade  $P < 0.0001$ .<sup>40</sup> Solmon et al proved that the first three grade are risk factor for foot ulceration and the second three are risk factor for amputation.<sup>10</sup>

### **Mode of treatment**

In our study (53.33%) of patients treated with various type of amputation. Level of amputation determination depend on clinical and doppler assessment, while in study present by other researchers' duplex ultrasonography followed by contrast angiography to evaluate macrocirculation and tissue viability assessed by direct methods as fluorescence angiography, thermograph and radionuclide clearance technique, indirect method such as transcutaneous measurements of tissue oxygen and direct measurement of oxygen saturation. Other patient treated by non-amputation (46.66%) of patient treated by control of diabetes antibiotics and some of them need local wound debridement or abscess drainage

### **Outcome of patients**

In the present study, the majority of patients 114 (95%) discharging home well after complete treatment in the hospital only 6 patients (5%) died, four of them (3.33%) died from ischemic heart disease and other two (1.66%) died from renal impairment. Among patients treated with amputation, four patients died two of them died from ischemic heart disease and other two (1.69%) died from renal impairment,

This results also proved by Lee et al were (5.55%) of patients treated with amputation died and most common cause of death are cardiovascular and renal diseases.<sup>31</sup> While those who treated conservatively only two patients (1.88%) died from ischemic heart disease, comparing with (3.35%) of patients treated conservatively died in research presented by Lee et al.<sup>31</sup>

## **CONCLUSION**

Diabetic foot is a common problem and it is an important cause of lower extremity amputation. Increasing in age, long duration of diabetes mellitus, poor control of diabetes, smoking and occurrence of lesion in dominant foot all considered as a significant risk factors for increase liability of lower extremity amputation in diabetic foot patients while hypertension and male gender consider as non significant factor.

Debridement was the main used surgical procedure; however, the incidence of amputative procedures was escalating as the age of the patient increased.

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