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Effect of Modifiable Risk Factors in Diabetic Foot Management

Abstract

Background: Persons with diabetes, the prevalence of foot ulcers ranges from 4 to 10% and its lifetime incidence may be as high as 25%. Modifiable factors including BMI and HbA1c have gained special attention of researchers and have been extensively studied in relation with diabetic foot ulcers, gangrene, and limb amputation.

Methods: A prospective study on 102 patients with diabetic foot in Bowring and Lady Curzon and Victoria hospital between July 2018 to December 2018. We sought to compare the outcome of diabetic foot healing between individuals with normal and high BMI and assess the relative risk of modifiable factors (BMI, HbA1c and smoking) in lower extremity amputation in diabetic foot.

Results: Higher BMI and HbA1c were strongly associated with non salvagability of lower limb, though smoking was found to have a moderate correlation. Normal BMI individuals were found to have a relatively good healing than high BMI cases.

Conclusion: BMI, HbA1c and smoking, these three modifiable risk factors prove to be primary predictors of outcome in diabetic wound healing. From the present comparative study, persons with higher BMI had a more risk of lower extremity amputation hence “Obesity paradox proves to be a fallacy in diabetic foot healing”.

Keywords: Lower Extremity Amputation (LEA); Diabetic foot; Obesity; Basal Metabolic Index (BMI)

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Introduction

A diabetic foot is defined as a foot that exhibits any pathology that results directly from diabetes mellitus or any long-term complications of diabetes. In Diabetic patients, the prevalence of foot ulcers is 4% to 10% and lifetime incidence may be as high as 25%. About 40-60% of non-traumatic lower limb amputations have been reported to be due to diabetic foot [1,2]. Hence there is a need for spot on predictors in diabetic foot patients:

1. For identification of high-risk patients
2. For early intervention
3. For planning a management strategy
4. To decrease the lower extremity amputations.

Some of the predictors of complications in diabetic foot are:

- a) HbA1c

- b) Hypertension
- c) Peripheral arterial diseases
- d) Age
- e) Gender
- f) Grade
- g) Depth
- h) Site
- i) Smoking
- j) Neuropathy
- k) Recurrence
- l) Fibrinogen
- m) Obesity

Manikanta KS and Monisha Gunasekaran*

Department of General Surgery, Bangalore Medical College and Research Institute, Bangalore, India

Corresponding author:

Monisha Gunasekaran

 gmonishachmc@gmail.com

Department of General Surgery, Bangalore Medical College and Research Institute, Bangalore, India.

Tel: +919884398671

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Defining modifiable risk factors is the key step to reduce Lower Extremity Amputation (LEA) rates. Most important modifiable factors are:

- A. Obesity -Body Mass Index (BMI)
- B. Glycaemic Control (HbA1c)
- C. Smoking

The correlation of the three factors with diabetic foot, needs to be evaluated further. In order to counsel the patients for modifying these risk factors, especially in diabetics. However, we would like to introduce the terminology “Obesity Paradox” which is referred as “Reverse Epidemiology”, which is an inverse correlation between BMI and morbidity, which has been observed in few diseases [3] i.e., high BMI individuals have a protective effect due to overweight and obesity in Chronic diseases [4] like stroke, thromboembolism, Chronic Obstructive Pulmonary Disease (COPD), peripheral artery disease [5].

This study aimed to correlate the protective effect of three modifiable risk factors (i) BMI (ii) HbA1c (iii) smoking on outcome of diabetic foot management. Further to establish any protective effect of overweight-obesity in diabetic patient with respect to lower extremity amputation.

Objectives of the Study

1. To determine the significance of modifiable risk factors as predictors of prognosis in diabetic foot ulcers.
2. To compare the management outcome of diabetic foot in individuals with:
 - I. High vs low BMI
 - II. High vs low HbA1c
 - III. Smokers vs non-smokers

Materials and Methods

- A. **Study design:** A prospective study
- B. **Study period:** June 2018-December 2018
- C. **Place of study:** The study was conducted at the General Surgery department in the hospitals attached to Bangalore Medical College and Research Institute, Bengaluru, India.
- D. **Sample size:** 102.

Inclusion criteria

- Admitted diabetic foot ulcers (TRUST NHS guidelines)
- Willing for management including grafting, amputation etc.
- Feasible for follow-up.

Exclusion criteria

- Non-diabetic foot ulcers.
- Peripheral occlusive vascular diseases.

Research Methodology

The study was conducted on 102 inpatient diabetic foot patients as already described; relevant history of smoking, along with general examination which includes BMI and laboratory values including HbA1c was recorded.

The patients were first grouped into three categories:

- **Based on BMI:**
 1. Normal BMI included patients with BMI<24.9
 2. Pre-obese (25-29)
 3. obese (>30).
- **Based on HbA1c:**
 1. Normal (<7)
 2. High (8-10)
 3. Very high (>10)
- **Based on smoking history:**
 1. Smokers
 2. Non-smokers
 3. Quit smoking >10 years back

Admitted patients underwent Infection control (Microbiological guided). Non-viable tissue excision (debridement/grafting/fasciotomy/amputation) and Glycaemic control. The results were correlated with the management outcomes which include three categories:

1. **Limb saving procedures:**
 - i. Debridement
 - ii. Fasciotomy
 - iii. Graft
 - iv. VAC dressing
2. **Minor amputation:**
 - i. Disarticulation
3. **Major amputation:**
 - i. Above Knee Amputation
 - ii. Amputation Forefoot (FF)
 - iii. Below Knee Amputation

The correlation between the modifiable risk factors (i) BMI (ii) HbA1c (iii) smoking and the management outcome of diabetic foot was assessed. P-value was calculated.

Results

Out of the 102 patients, minimum was of age 30 years and maximum age was 90 years with mean age of 56.71 years. Majority was male patients. 82% was males and 18% was females (**Figure 1**). In these 102 patients, both the limbs were almost

■ MALES (84) ■ FEMALES(18)

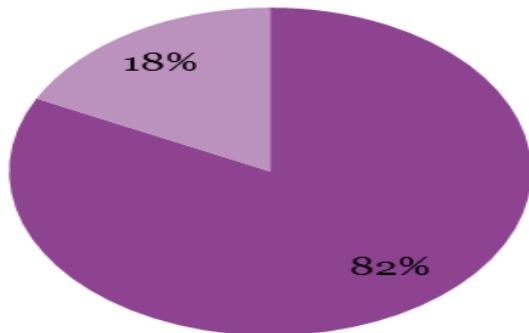


Figure 1 Gender distribution of the study group.

equally involved, with 50% affected on the right, 48% affected on the left and 2% affected bilateral lower limb. The duration of disease was ranging from 2 days to 3 years. When history of smoking was asked 40.20% were non-smokers, 15.9% had quit smoking, 44.12% were smokers (**Figure 2**).

During examination of the BMI of the study group, minimum was 17.5, maximum was 36.9, with mean of 25.1, normal BMI of 45%, probes of 30% and obese patients were 25%. When evaluating the HbA1c levels minimum was 9.18% and maximum was 15.1% with a mean of 9.18% (**Figure 3**).

The duration of stay in hospital ranged from 5 days to a maximum of 60 days with a mean of 18.02 days. the course in the hospital was based on treatment options and response of the patient to regular limb salvaging procedures as already mentioned. Minor amputations were considered if toes were involved distally. When response was not adequate, limb was considered to be not salvageable and major amputations were considered to control the sepsis. About 49.02% of them were treated with simple mechanical debridement. 5.8% of them were grafted (split skin graft) following a raw area. 4.9% were treated with VAC (Vacuum) devise. 0.98% required a fasciotomy which was later closed primarily. 17.65% of the population underwent disarticulation for wet gangrene of the toes. 20.56% of the study group underwent major amputation which included a 11.76% of below knee amputation, 0.98% of forefoot amputation. 8.82% underwent above knee amputation for diabetic foot (**Figure 4**).

The clinical outcome was then correlated with the modifiable risk factors the following results were obtained. Out of 102 patients, 45 were smokers, 16 of them underwent major amputation, 12 underwent minor amputation and 17 were salvaged, 16 who had quit smoking 10 years back, 13 were salvaged. 41 non-smokers almost 35 patient's limbs could be salvaged (**Figure 5**). Hence smokers had a higher risk of amputations.

25 patients had a HbA1c of less than 7, 21 of them could be salvaged and with HbA1c between 8- 10 were 39 out of which 26 could be salvaged while 9 patients underwent a major amputation. 38 patients had HbA1c more than 10 and 23 of

them underwent major and minor amputations. Hence a poor glycaemic control had higher risk of lower extremity amputation.

BMI was evaluated and 46 were found to have a normal BMI, out of which 38 limbs were salvaged. 31 were in the category

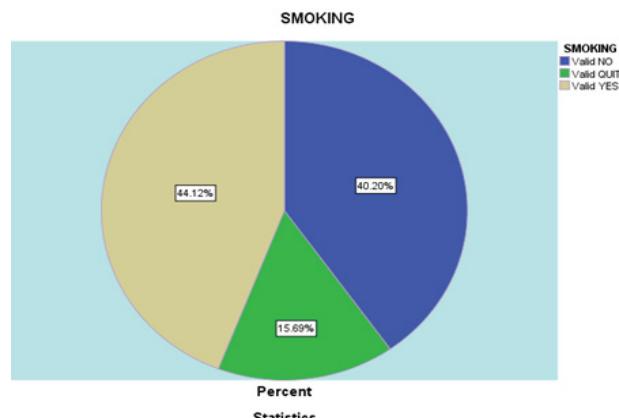


Figure 2 History of smoking in study.

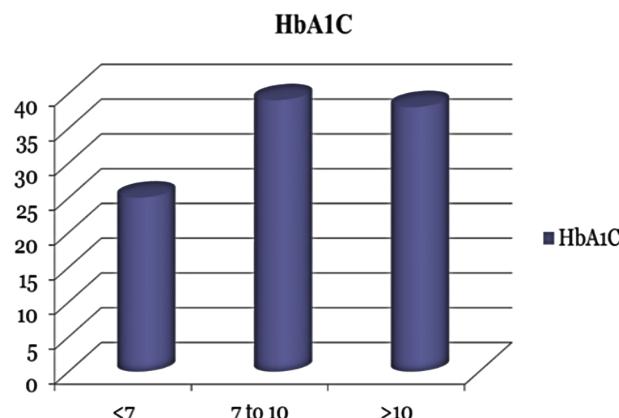


Figure 3 HbA1c levels in study population.

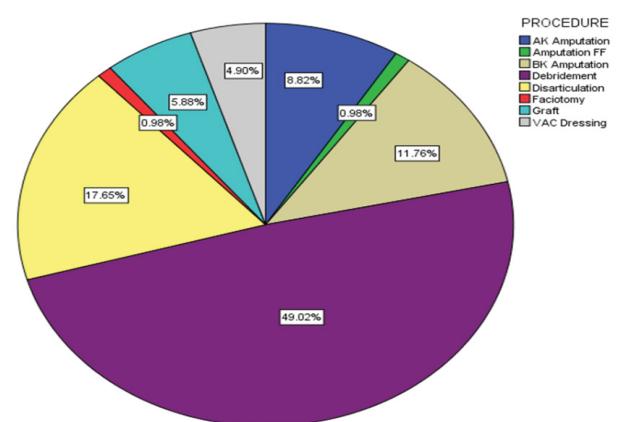


Figure 4 Various procedures done for treatment.

of preobese, of which 17 patients could be salvaged and 6 underwent major amputations. 21 of them were obese and 12 of them underwent major amputation. About 57.21% of the obese patients underwent major amputation and minor amputation in 28.6%. hence obesity is found to have an inverse correlation in salvageability of the limb (**Figure 6**). Higher the BMI, higher the risk of amputation (**Table 1**).

Statistics were applied and p-value was calculated using Fischer test was applied and p-value was found to be significant. BMI as an independent predictor of lower extremity amputation was found to be significant (p-value<0.001) (**Table 2**). Higher HbA1c was also found to have a significant p-value in major and minor amputations (**Table 3**). Smoking though proved to have a strong correlation with peripheral arterial disease in non-salvageability of lower limb, has been proved in our study on diabetic foot (excluding peripheral arterial disease) to have a p-value of 0.001 (**Table 4**). Higher BMI and HbA1c were strongly associated with non-salvageability of lower limb, though smoking was found to

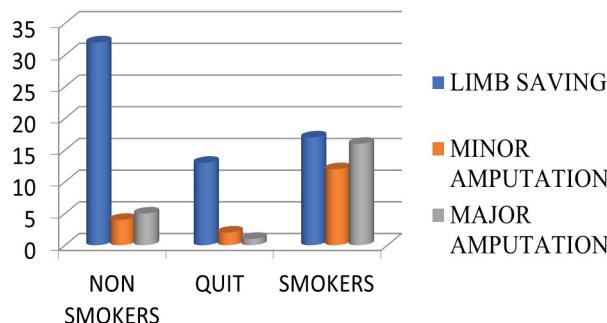


Figure 5 Smoking and outcome.

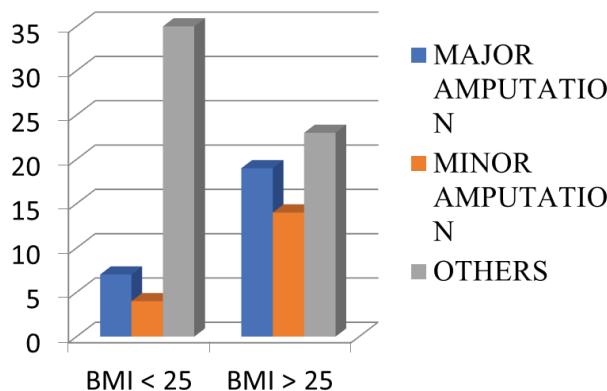


Figure 6 Correlation of BMI with outcome.

Table 1 Correlation of BMI and outcome.

BMI	Major amputation	Minor amputation	Limb saving procedures
Normal	8.60%	8.60%	82.60%
25-29.9	19.35%	25.80%	54.83%
30-34.9	30.40%	26.08%	43.47%
>35	100%	-	-

Table 2 BMI P-value.

BMI	Procedures			P-value
	Limb saving	Major amputation	Minor amputation	
Normal	38	4	4	<0.001 (23.738) df-4
	82.60%	8.70%	8.70%	
Pre-obese	17	6	8	
	54.80%	19.40%	25.80%	
obese	7	12	6	
	28.00%	48.00%	24.00%	
Total	62	22	18	
%	60.80%	21.60%	17.60%	

Table 3 HbA1C P-value.

hba1ccat	Procedures			P-value
	Limb saving	Major amputation	Minor amputation	
<7	Count	21	2	2
	%	84.00%	8.00%	8.00%
07-Oct	Count	26	4	9
	%	66.70%	10.30%	23.10%
Oct-15	Count	15	16	7
	%	39.50%	42.10%	18.40%
Total	Count	62	22	18
	%	60.80%	21.60%	17.60%

Table 4 Smoking P-value.

Smoking	Procedures			P-value
	Limb saving	Major amputation	Minor amputation	
No	Count	32	5	4
	% within smoking	78.00%	12.20%	9.80%
Quit	Count	13	1	2
	% within smoking	81.30%	6.30%	12.50%
Yes	Count	17	16	12
	% within smoking	37.80%	35.60%	26.70%
Total	Count	62	22	18
	% within smoking	60.80%	21.60%	17.60%

have a moderate correlation. Normal BMI individuals were found to have a relatively good healing than high BMI cases.

Discussion

- In Michell et al. study, high BMI is found to have a lower risk of lower extremity amputation [6].
- A J-shaped association between high BMI and diabetic foot healing has been described [7].
- No pathological or been physiological basis have been explained.
- In Abdul et al. study, high BMI has been proved to be associated with poor prognosis in diabetic ulcer healing [8].
- Lower fat-free mass has been linked to reduced antioxidant

capacity and poor outcomes— possible explanation of obesity paradox [9].

- Possible explanation could be the following chart which explains that obesity could lead to reduced mobility, poor tissue perfusion and increased subcutaneous fat which in turn could lead to venous stasis, pressure ulcers and decreased wound healing and wound dehiscence. which in turn lead to chronic ulcers (**Figure 7**).
- BMI irrespective of:
 - i. Neuropathy
 - ii. Retinopathy
 - iii. Nephropathy
 - iv. Hyperlipidaemia
 - v. Previous foot ulcer
- vi. Grade of ulcer Can be an independent predictor of diabetic foot outcome.

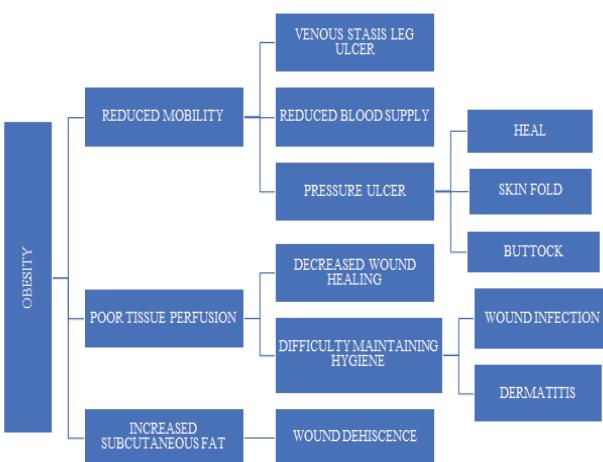


Figure 7 Effect of obesity in ulcer healing.

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- Significant and established modifiable risk factor- HbA1c: poor glycaemic control leads to glycated immune particles which make more prone to infections.
- Cigarette smoking has been reported to be associated with diabetes and its macrovascular complications [10]. Nicotine- induced vasoconstriction. Hydrogen cyanide- induced oxidative stress inside the cells. Carbon monoxide- decreased oxygen transport.
- In a study by Andrea et al. Specifically, for each 1.0%-point increase in HbA1c, the daily wound-area healing rate decreased by 0.028 cm²/day (95% CI: 0.003, 0.0054, p=0.027). The results suggest that glycemia, as assessed by HbA1c, may be an important biomarker in predicting wound healing rate in diabetic patients [11].

Limitations of our Study

1. BMI is a crude and flawed anthropometric biomarkers
2. It does not consider
 - i. Nutritional status
 - ii. Fat mass/fat-free mass ratio
 - iii. Cardio respiratory fitness
 - iv. Body fat distribution
 - v. Other factors affecting health
3. Off-loading devices were not used in our study.

Conclusion

The 3 modifiable risk factors prove to be primary predictors of outcome in diabetic wound healing and management. From the present comparative study, persons with higher BMI had a more risk of lower extremity amputation hence “Obesity paradox proves to be a fallacy in diabetic foot healing”.

Conflict of Interest

There is no conflict of interest.