Original Article

Treatment Outcome of Diabetic Foot Based on the Control of Random Blood Glucose and HbA1c in BIRDEM General Hospital, Dhaka, Bangladesh

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Abstract

Background: *Diabetic foot is a common and potentially disastrous complication that can rapidly progress to irreversible septic gangrene, necessitating foot amputation.* ***Objectives:*** *To assess the clinical outcome of treatment of diabetic foot in diabetic patients based on random blood glucose (RBG) and HbA1c level.* ***Materials and method:*** *This prospective observational study was conducted in the Department of Surgery, BIRDEM General Hospital, Shahbag, Dhaka, Bangladesh, from July 2018 to December 2018. A total of 350 patients with diabetic foot were enrolled in the study based on inclusion and exclusion criteria. The patients were divided into four groups based on RBS and HbA1c level. A complete history was taken, thorough clinical examination was done and relevant investigation reports were collected. Collected data were classified, edited, coded, and entered into the computer for statistical analysis using SPSS version 23.* ***Results:*** *Mean age was 47.6±13.3 years in group A, 48.2±12.7 years in group B, 46.7±13.1 years in group C, and 49.9±12.5 years in group D. Male to female ratio was 2.3:1 in group A, 3.5:1 in group B, 1.5:1 in group C and 2.9:1 in group D. One hundred eight patients were found to have Wagner ulcer grading I. Among them, 2(20.0%) were in group A, 9(33.3%) were in group B, 12(36.4%) were in group C, and 85(30.4%) were in group D. Twenty-two patients were found to have Wagner ulcer grading IV. Among them, 1(3.0%) of group C and 21(7.5%) of group D. The difference was statistically significant ($p<0.05$) among the four groups. Two hundred eighty-eight patients had wound healing time of 2-6 weeks. Among them were 1(10.0%) in group A, 25(92.6%) in group B, 29(87.9%) in group C, and 233(83.2%) in group D. The mean wound healing time was found to be 1.5±0.7 weeks in group A, 3.1±1.3 weeks in group B, 3.6±1.2 weeks in group C and 4.9±1.8 weeks in group D. The difference was statistically significant ($p<0.05$) among four groups. One hundred six patients underwent amputation at a different level. Among them, 1(10.0%) in group A, 5(18.5%) in group B, 13(39.4%) in group C and 87(31.1%) in group D. The difference were not statistically significant ($p>0.05$) among four groups.* ***Conclusion:*** *Elevated HbA1c was associated with slower and incomplete foot healing in diabetic patients. Random blood glucose and HbA1c parameters can be used as dependable predictors of foot ulcer healing in the diabetic patients.*

Keywords: *Diabetic Foot; Random Blood Glucose; HbA1c.*

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Introduction

Diabetes is a significant cause of morbidity and mortality, costing an estimated $245 billion in 2012 in the United States due to increased use of health resources and lost productivity.[1] Asia and the eastern Pacific region were particularly affected in 2011; China was home to the most significant number of adults with diabetes (i.e., 90.0 million, or 9% of the population), followed by India (61.3 million, or 8% of the population) and Bangladesh (8.4 million, or 10% of the population).[2,3] In Bangladesh, the diabetic population was about 7.1 million in 2015, which is likely to increase to 13.6 million by 2040.[4] Apart from glycemic status, other local and general factors may influence the wound healing process (e.g., anemia, albumin, ischemia). The wound healing process relies heavily on oxygenation. In essence, low oxygen levels caused by anemia can halt or slow the wound healing stages. Almost 25% of people with diabetes will develop a diabetic foot at some time during their life, and 85% of major leg amputations begin with a foot. In the course of management of diabetic foot, blood sugar control and HbA1C have a tremendous impact on the treatment outcome. The healing rate, rate of infection, amputation rate, hospital stay, re-admission rate, diabetic complications, etc. are significantly higher in cases of patients with poor control.[5] The optimal and desirable random blood glucose level should be <8.0 mmol/L in foot cases, reflected in different recent clinical studies. HbA1c is another essential clinical parameter to predict the outcome, which was neglected in the previous years. HbA1c level < 7% is associated with better results in surgical practice. It is estimated that approximately 15–25% of diabetic patients develop diabetic foot during the course of the disease, which is associated with worse out comes, especially when it is related to poor glycaemic control (random blood glucose >10 mmol/L). People with diabetes can progress into chronic ulcers, often leading to amputation if not treated promptly. Advanced age, male gender, and neglected glycaemic control are the prime factors associated with amputation.[6] Most often, the incidence of infection has a positive association with poor blood sugar control, predominantly random blood glucose. Some studies also suggest that glycaemic control is also a major contributing factor to the development of superseded infection on a diabetic foot.[7] Over this less emphasized issue, there is no satisfactory clinical trial yet in our country, nor is there sufficient, authentic, and evidence-based data regarding the management of diabetic foot based on the control of random blood glucose and HbA1c in our clinical context. From that point of view, this research study is designed to find out different dimensions of clinical outcome of diabetic foot in relation to the control of blood sugar.

Fig. 1: Diabetic foot

Fig. 2: Diabetic foot

Materials and method

This prospective observational study was conducted in the Department of Surgery, BIRDEM General Hospital, Shahbag, Dhaka, Bangladesh, from July 2018 to December 2018. A total of 350 patients with diabetic foot were enrolled in the study based on inclusion and exclusion criteria and were divided into four groups based on HbA1c and RBS. Group A: Controlled both (HbA1c and RBS), Group B: Controlled HbA1c but uncontrolled RBS, Group C: Controlled random blood sugar (RBS). but uncontrolled HbA1c, Group D: Uncontrolled both (HbA1c and RBS). Patients aged between 18 to 80 years, with no congenital disability or disorder or disease of foot, and patients with ASA (American Society of Anesthesiologists) scores of I, II, or III were included in this study. Diabetic foot problems were confirmed by one of the following physician's handwritten diagnoses as: 'diabetic foot,' 'diabetic foot ulcers,' 'diabetic foot infections, or 'diabetic foot gangrene'. Wagner ulcer grading was used for grading the ulcer. Following admission, the initial random blood sugar (RBS) and glycosylated hemoglobin (HbA1c) were recorded. The results of HbA1c were stratified in percentage graded as per our national guidelines. A data collection sheet was filled with relevant information and investigation, and a written informed consent form was added.

Wagner ulcer grading

Grade	Lesion
0	No open lesion; may have deformity or cellulitis
I	Superficial diabetic ulcer (partial or full thickness)
IIA	Ulcer extension to ligament, tendon, joint capsule or deep fascia without abscess or osteomyelitis
IIB	Deep ulcer with abscess, osteomyelitis or joint sepsis
III	Gangrene is localized to a portion of the forefoot or heel.
IV	Extensive gangrene involvement of the entire foot

Statistical analysis was carried out using the Statistical Package for Social Sciences version 23.0 for Windows (SPSS Inc., Chicago, Illinois, USA). The mean values were calculated by frequencies and percentages. ANOVA test was used for continuous variables and chi-square test was used for categorical variables. A probability (p) value of <0.05 ($p<0.05$) was considered statistically significant and $p<0.001$ was considered highly significant but $p>0.05$ was taken as non-significant.

Results

A total of 350 patients were included in the study based on inclusion and exclusion criteria. Based on the control of random blood sugar (RBS) and HbA1c before the initiation of treatment, the total study population was divided into four groups. The mean age was found to be 47.6±13.3 years in group A, 48.2±12.7 years in group B, 46.7±13.1 years in group C, and 49.9±12.5 years in group D. Two hundred fifty-seven patients were male; among them 7(2.7%) in group A, 21(8.2%) in group B, 20(7.8%) in group C and 209(81.3%) in group D. The difference was not statistically significant ($p>0.05$) among four groups (Table I). One hundred fifty-nine patients had wound size <5 cm^2. Among them, 8(80.0%) in group A, 15(55.6%) in group B, 19(57.6%) in group C, and 117(41.8%) in group D. The difference were statistically significant ($p<0.05$) among four groups (Fig. 4). One hundred eight patients were found to have grade I Wagner ulcer. Among them, 2(20.0%) were in group A, 9(33.3%) were in group B, 12(36.4%) were in group C, and 85(30.4%) were in group D. Twenty-two patients were found to have grade IV Wagner ulcer. Among them, 1(3.0%) was from group C, and 21(7.5%) were from group D. The difference was statistically significant ($p<0.05$) among four groups (Fig. 5). Two hundred eighty-eight patients had wound healing time of 2-6 weeks. Among them 1(10.0%) was in group A, 25(92.6%) in group B, 29(87.9%) in group C, and 233(83.2%) in group D. The mean wound healing time was found to be 1.5±0.7 weeks in group A, 3.1±1.3 weeks in group B, 3.6±1.2 weeks in group C and 4.9±1.8 weeks in group D. The difference was statistically significant ($p<0.05$) among four groups (Fig. 6). One hundred six patients underwent amputation at a different level. Among

them were 1(10.0%) in group A, 5(18.5%) in group B, 13(39.4%) in group C, and 87(31.1%) in group D. The difference were not statistically significant (p>0.05) among four groups (Table II).

Table I: Demographic characteristics of the study population (N=350)

		Group A (n=10)		Group B (n=27)		Group C (n=33)		Group D (n=280)		*p-value*
	Total	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	
Age (years)										
<30	**80**	1	1.3	2	2.5	3	3.8	74	92.5	
31-50	**174**	6	3.4	13	7.5	22	12.6	133	76.4	
51-70	**69**	3	4.3	9	13.0	5	7.2	52	75.4	
>70	**27**	0	0.0	3	11.1	3	11.1	21	77.8	
Mean±SD		47.6	±13.3	48.2	±12.7	46.7	±13.1	49.9	±12.5	[a]0.493 [ns]
Sex										
Male	**257**	7	2.7	21	8.2	20	7.8	209	81.3	[b]0.346 [ns]
Female	**93**	3	3.2	6	6.5	13	14.0	71	76.3	

ns= not significant
a=p value reached from ANOVA test
b=p value reached from chi-square test

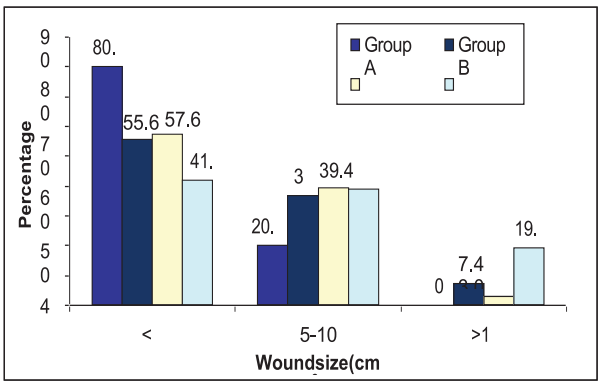

Fig. 4: Wound size of the study subjects

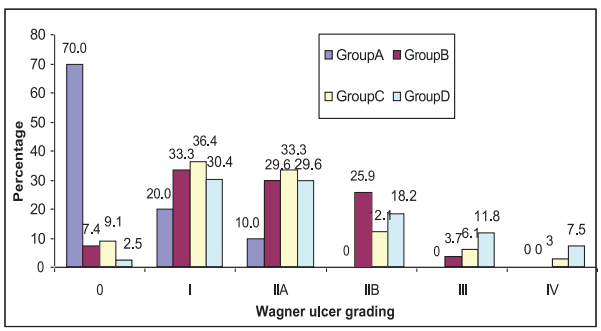

Fig. 5: Wagner ulcer grading of the study subjects

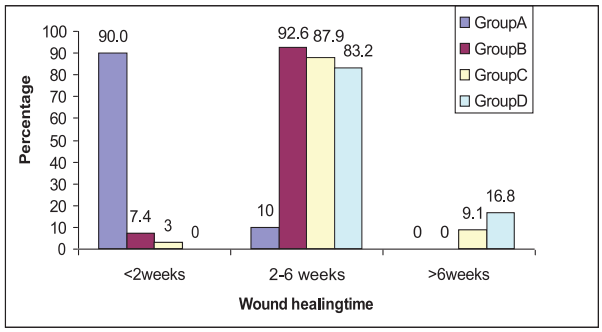

Fig. 6: Wound healing time of the study subjects

Table II: Distribution of the study patients according to the technique of wound healing (N=350)

The technique of wound healing		Group A n=10)		Group B (n=27)		Group C (n=33)		Group D (n=280)		p-value
	Total	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	
Secondary intention	**35**	1	10.0	5	18.5	4	12.1	25	8.9	
Secondary closure	**33**	2	20.0	2	7.4	3	9.1	26	9.3	
Skin graft	**40**	2	20.0	4	14.8	5	15.2	29	10.4	0.696[ns]
Flap	**76**	2	20.0	6	22.2	3	9.1	65	23.2	
Combination	**60**	2	20.0	5	18.5	5	15.2	48	17.1	
Amputation	**106**	1	10.0	5	18.5	13	39.4	87	31.1	

ns= not significant
p-value reached from chi-square test

Discussion

Diabetic foot is a devastating complication of diabetes mellitus because it is primarily associated with amputation and the resulting disability of individuals.[8] It is estimated that 70% of nontraumatic amputations performed in First World hospitals are due to diabetic foot.[9] Furthermore, it is estimated that 15% of people with diabetes develop throughout their life a foot lesion,[10] whose prognosis is influenced by vascular disease and infection, which represents an associated complication in more than 50% of

lower limb amputations.[11] Most diabetic foot trials focus more on therapeutic or diagnostic aspects than on prevention. However, the impact of these processes on patients, in terms of their quality of life and disruption of their psychosocial environment, has been studied to a lesser extent.

The present study showed 174 patients belonged to age 31-50 years; among them, 6(3.4%) in group A, 13(7.5%) in group B, 22(12.6%) in group C and 133(76.4%) in group D. The mean age was found 47.6±13.3 years in group A, 48.2±12.7 years in group B, 46.7±13.1 years in group C and 49.9±12.5 years in group D. A similar study was conducted by Porselvi et al.[12] on diabetic foot and incidences based on the age-wise analysis revealed that the age between 51-60 years (39.5% with mean age 55.68) was more vulnerable to develop diabetic foot followed by 61-70 years (31.4%) and 41-50 years (16.3%). Rehman et al.[13] documented their study participants' age ranged from 23-78 years, and the mean age was 53.55 ±11.58 years. Manjunath and Kumar[9] showed that the average age of the patients included in the study was 54 years.

In our study, the male-to-female ratio was 2.3:1 in group A, 3.5:1 in group B, 1.5:1 in group C, and 2.9:1 in group D. The difference was not statistically significant ($p>0.05$) among four groups. Porselvi et al.[12] found that out of 86 patients, men were around 68.6%, and 31.4% were women. Rehman et al.[13] showed that there were more females among the admitted patients as compared to males (72 vs. 40 respectively). The male to female ratio was 1:1.8. Manjunath and Kumar[9] observed in their study where 280 patients (male n = 196, 70%; female n = 84, 30%) were enrolled in the study. Muduli et al.[14] documented that among the 60 diabetic foot ulcer patients studied, 42(70%) were males, and 18(30%) were females. The male-to-female ratio was 2.33:1.

In our study, 108 patients were found to have grade I Wagner ulcer. Among them, 2(20.0%) are in group A, 9(33.3%) are in group B, 12(36.4%) are in group C, and 85(30.4%) are in group D. Twenty-two patients were found to have grade IV Wagner ulcer. Among them, 1(3.0%) are from group C, and 21(7.5%) are from group D. The difference was statistically significant ($p<0.05$) among the four groups. Manjunath and Kumar[9] found that while studying the healing process in relation to HbA1c levels, 70% of patients with normal HbA1c had completely healed diabetic foot, whereas 20% showed partial healing and 5% had uncured foot ulcers. Muduli et al.[14] observed that out of the 60 cases, 5% (n=3) were Wagner grade 0, 10% (n=6) were grade 1, 17% (n=10) were grade 2, 30% (n=18) were grade 3, 25% (n=15) were grade 4, and 13% (n=8) were grade 5. Most of the patients (30%, n=18) presented with Wagner grade 3 diabetic foot ulcer. Only three patients (5%) presented with grade 0 diabetic foot ulcer. Pemayun and Naibaho[15] found that 154 (71.5%) patients were in high-grade Wagner, i.e., Wagner grade ≥ 3. Fifty percent of grade 4 lesions needed amputation, while all grade 1 lesions healed with conservative management.

It was observed that 288 patients had 2-6 weeks of wound healing time. Among them, 1(10.0%) in group A, 25(92.6%) in group B, 29(87.9%) in group C and 233(83.2%) in group D. The mean wound healing time was found to be 1.5±0.7 weeks in group A, 3.1±1.3 weeks in group B, 3.6±1.2 weeks in group C and 4.9±1.8 weeks in group D. The difference was statistically significant ($p<0.05$) among four groups. Al Goblan et al.[16] showed similar observations with HbA1c as a predictor of the foot ulcer healing process. Forty-eight percent of diabetic patients with controlled HbA1c (<7 mmol/L) had foot ulcer healing within 3 months, 44% had healed in 3–6 months, and 8% took >7 months for complete healing of the foot ulcers. On the other hand, in patients with uncontrolled diabetes indicated by highly elevated HbA1c (>7 mmol/L), a significant delay in foot ulcers was observed in the majority of the patients. Comparing patients with controlled high HbA1c, only 23% of patients had healed foot ulcers within 3 months, 28% between 3 and 6 months, and 48% at 7 months ($P=0.024$). Given that glycated hemoglobin HbA1c is a reliable marker of glycemic control spanning over the previous 2–3 months,[17] it is now being recommended by the American Diabetes Association and World Health Organization as a reliable marker for diagnosis of diabetes.

Manjunath and Kumar[9] observed that 50% of diabetic patients with controlled HbA1c (7 mmol/L) had foot ulcer healing within 3 months, 40% had healed in 3–6 months, and 10% took 7 months for complete healing of the foot ulcers. On the other hand, in patients with uncontrolled diabetes indicated by elevated HbA1c (>7 mmol/L), a significant delay in foot ulcers was observed in the majority of the patients. Comparing patients with controlled, highly elevated HbA1c, only 20% of patients had healed foot ulcers within 3 months, 30% between 3 and 6 months, and 50% 7months.

In our study, 106 patients underwent amputation at different levels. Among them, 1(10.0%) in group A, 5(18.5%) in group B, 13(39.4%) in group C and 89(76.7%) in group D. The difference were not statistically significant (p>0.05) among four groups. Mahmood et al.[18] found that foot ulcers of 89(76.7%) patients healed without amputation.

It was observed that 46 patients underwent toe amputation. Among them, 1(100.0%) of group A, 2(40.0%) of group B, 5(38.5%) of group C and 38(32.2%) of group D. Twenty-five patients underwent major (below knee or above knee) amputation. Among them, 1(20.0%) in group B, 3(23.1%) in group C and 21(24.1%) in group D. The difference were not statistically significant (p>0.05) among the four groups. Mahmood et al.[18] observed in their study that 17 patients had minor or major amputations, and the rate of amputation was 14.7%, while it was 21% and 48% in studies by Rooh-ul-Muqeem[19] and Llanes[20], respectively. Shojaiefard et al.[21] performed amputation only when there was a gangrenous toe (minor amputation) or foot (major amputation). Major amputation (below knee or above knee) was performed in 5.5% (n = 8) and minor amputation (toe or transmetatarsal) in 22.6% (n = 33). Parisi et al.[22] showed in their study that minor amputation was performed in 82.7% and major amputation in 17.3%.

Several limitations exist in the present study: short time, small sample size, and randomization were not done. Therefore, selection bias in this study cannot be eliminated.

Conclusion

Diabetes foot disease (DFD) causes deterioration in the quality of life and affects the quality of care for diabetic patients. Elevated HbA1c was associated with slower and incomplete foot healing in diabetic patients. Given their reliability as tools to diagnose and monitor diabetes and its related complications, random blood glucose and HbA1c parameter can be used as dependable predictors of foot ulcer healing in the diabetic. Effective glycemic control, optimal wound care, aggressive medical management, and timely surgical intervention may decrease disabling morbidity with a better outcome. This all needs to develop in a multidisciplinary team in all medical institutions for better care of the diabetic foot. Patients with diabetes should be screened for foot complications regularly. Early referral of diabetic patients from primary health care centers to the tertiary health care / diabetic center is of paramount importance to be screened early for the diabetic complications by the multidisciplinary specialist team. Further studies can be undertaken by including a large number of patients.

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