Research Article

STUDY OF FACTORS AFFECTING WOUND HEALING FOLLOWING SEVERE FOOT INFECTIONS IN PATIENTS WITH DIABETES MELLITUS

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A R T I C L E   I N F O

A B S T R A C T

Aims and Objectives: This prospective study attempted to identify the risk factors governing the healing of infected diabetic foot and segregate individuals who may benefit with an early surgical intervention.

Methods: The study was an observational study on diabetic patients admitted to Safdarjang Hospital with severe foot infections. Patients were assessed for Peripheral arterial disease (PAD), Peripheral neuropathy (PN), wound severity by International consensus of Diabetic Foot (ICDF) classification, Glycosylated Haemoglobin values and malnutrition.
The patients were managed with insulin, IV antibiotics and wound debridement.
Subjects were followed up for 6 weeks and data was recorded in terms of wound healing or not healing.

Results: Our study was conducted over a period of 2 years, 6 months on 58 patients.
26 patients belonged to grade 2 and 3 each and 6 were characterized as ICDF grade 4.
In our study 20 patients had a satisfactory glycaemic control, 42 were malnourished, 39 had peripheral neuropathy and 24 had vasculopathy.
Out of 23 cases that did not heal, 20 were high grade ICDF with a p value of .000., 5(21.7%) had a satisfactory glycaemic control (p value .098.), 22(95.7%) were malnourished (p value 0.001), 20(87%) had peripheral neuropathy (p value 0.01.), Vasculopathy was present in 17(73.9%) (p value .000.)
Out of 35 patients who healed,15 had a satisfactory glycaemic control (p value .098.), 20 were malnourished, 16 had peripheral neuropathy (p value 0.01.), Vasculopathy was present in 7 (p value. 000.)

Conclusion: Vasculopathy, peripheral neuropathy, malnutrition and poor ICDF grade were significant risk factors for non-healing of wound. We did not find a significant correlation between satisfactory glycaemic control and wound outcome.

INTRODUCTION

Of the several clinical conditions complicating diabetes mellitus, foot infection is one of the most dreaded. Unless treated appropriately, a worsening infection can set off a chain of events: a spreading infection which penetrates into the deep soft tissue, excites cellulitis, produces necrosis and gangrene, and eventually, necessitates the amputation of the limb. Of the diabetic foot ulcers which eventuate in an amputation, infection plays a critical role in 60% of the cases [1].

Salvaging the limb in this clinical setting requires an assiduous standard of care. A thorough glycemic control, intravenous antimicrobial therapy to reduce the bacterial bioburden, and surgical interventions in the form of aggressive wound debridements are the cornerstone of treatment.

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Nevertheless, even in developed countries, the incidence of non-healing wounds and persistent infection is considerable, with the result that over 25% severely infected diabetic foot need to be amputated [2].

Several studies have established the determinants in ulcer prevention and chronic ulcer healing in diabetic foot. However, little or no data exists as regards the relative significance of individual risk factors that may impede or inhibit the process of healing in an infected diabetic foot [3, 4, 5].

The putative pathogenic mechanism underlying the phenomenon of non-healing and persistent infection has been attributed to a complex interaction of diverse yet related factors, viz., immunopathy, neuropathy, vasculopathy and the size and depth of the wound [6,7,8,9].

This prospective study attempted to identify the risk factors which govern the healing of infected diabetic foot and

segregate those individuals who may benefit with an early surgical intervention. Such patients who require surgical manoeuvres may benefit with either an early revascularisation or require an early amputation. In essence, the study will propose a risk-guided management approach for electing patients who may benefit with an early vascular intervention or amputation.

Aims and Objectives

1. To assess the wound grade (ICDF), glycosylated haemoglobin level, serum albumin level, Peripheral neuropathy (PN), and vasculopathy (PAD) in patients of infected diabetic foot.
2. To evaluate the significance of the above factors in predicting the wound healing outcome.
3. To propose a risk guided management approach for electing patients requiring an early vascular intervention or early amputation.

MATERIALS AND METHODS

The study conducted was an observational study. Material for the present study was collected from diabetic patients admitted to Surgical Emergency of Safdarjang Hospital with severe foot infections i.e. with superficial necrotizing and all deep foot infections requiring immediate surgical debridement.

Number of cases had been kept at 58 and all the relevant statistical data was collected. Patients with major co-morbidities and those needing immediate amputation were excluded.

The initial evaluation included a thorough history and clinical examination to determine the patient's overall medical condition.

Haematological and other investigations were done to assess the metabolic state of the patient.

The presence of limb ischemia was closely evaluated to categorize the risk posed on limb survival. PAD was assessed during the history by the features of claudication pain and clinically by checking for the peripheral pulses. Doppler waveform analysis (triphasic or biphasic/monophasic) was done for objective assessment of vascularity of the limb [10].

PN was assessed during the history by features of pain or loss of sensations in the limb and clinically by examination of sensations by Semmes-Weinstein 10g monofilament.

Wound severity was assessed by defining the extent of tissue involvement, i.e. grading the wound by International consensus of Diabetic Foot (ICDF) classification [1]

In accordance with the American Diabetes Association recommendations glycosylated haemoglobin values below 7.0% was taken to be the cut-off levels for good glycemic control. Level of serum albumin less than 3.5g/dl was taken as hypoalbuminemia indicating malnutrition.

The patients were managed with Insulin, IV antibiotics, hydration and regular wound debridement.

Subjects were followed up for 6 weeks at the end of which data was recorded in terms of wound healing or not healing.

Data was recorded in the form of excel sheet and later analyzed.

Chi-square test and Mann Whitney test were used with a P value of 0.05 being considered significant.

RESULTS AND DISCUSSION

Our study was conducted over a period of 2years and 6 months on 58 patients with infected diabetic foot.

Our study group consisted of 12(20.7%) female patients and 46 (79.3%) male patients. The greater percentage of males in our study may be due to males selectively presenting to the health services or due to males being more exposed to foot trauma in the outdoors.

12 of our patients were aged less than 40 years(20.7%), 11 patients aged between 41 to 50 years(19.0%), 17 patients aged between 51 to 60 years(29.3%), 14 patients aged between 61 to 70 years(24.1%) and 4 Patients aged between 71 to 80 years(6.9%).

In our study, at the end of 6 weeks, 35 patients (60.35%) belonged to healing group while 23 patients (39.65%) belonged to non healing group.

The mean age in the healing group was 52.43 years while that in the non-healing group was 55.84.

Mean duration of diabetes of patients was 5.2 years, taking 5.2 years as cut off; duration of diabetes was classified as short or long duration.

The patients were graded into ICDF grades 2, 3 and 4 according to the ICDF classification. Grade 1 ICDF were excluded out of the study. 26 of our patients belonged to grade 2 and 3 each, which was 44.8 percent each. 6 patients were characterized as ICDF grade 4(10.3%).

Fig 1 Healing Wound

Fig 2 Non Healing wound

Patients with ICDF Grade 2 were classified as low grade, i.e. 26 cases (44.8%) while rest of the patients in Grade 3 and 4 were classified as high grade, 32 cases (55.2%).

In our study 20 patients had a satisfactory glycaemic control (34.5%) while 38 patients had a poor glycaemic control (65.5%).

In our study, 42 patients were malnourished (72.4%) and 16 patients were adequately nourished (27.6%). The high prevalence of malnutrition in our study was a reflection of the underprivileged section presenting to a centre like ours.

39 patients had peripheral neuropathy (67.2%). 19 patients did not have peripheral neuropathy (32.8%).

24 patients had vasculopathy (41.4%) while 34 patients did not have vasculopathy (58.6%). Lesser prevalence of vasculopathy compared to neuropathy in our study may be due to more objective criteria (colour Doppler) being used to asses vasculopathy.

On assessing the patients with respect to duration of diabetes, 7 out of the 23 non healing cases had short duration while 16 had long duration. On the other hand out of 35 patients who healed, 26 had short while 9 had long duration of diabetes. On applying chi square test p value was 0.001, which meant a significant correlation between the duration of diabetes and wound healing.

While analyzing the wound outcome and ICDF grade, out of the 35 patients that healed, 23 were grade 2(65.7%), 11 were grade 3(31.4%) and 1 case was grade 4(2.9%). Out of the 23 patients that did not heal, 3 were grade 2(13%), 15 were grade 3(65.2%) and 5 cases were grade 4(21.7%).On assessing the significance by Chi square test, the p value came to be.000, which was significant.

ICDF grade was further classified as Low grade (grade 2) and high grade (grade 3 and 4). Out of the 23 non-healing group patients, 3 were low grade while 20 were high grade. Out of the 35 healing group patients 23 were low grade while 12 were high grade. A p value of .000 meant a significant correlation. On calculating the risk estimation, odds ratio came out to be 12.778, i.e. patients with high ICDF grade have a 12.778 times greater risk of non-healing of wound. This was in accordance with D.G. Armstrong who graded diabetic wounds according to the University of Texas classification system and found a worsening outcome with increasing grade. [9]

Out of the 35 patients who healed, 15 had a satisfactory glycaemic control (42.9%) while 20 did not (57.1%). Out of the 23 non healing patients, 5 had satisfactory glycaemic control (21.7%) while 18 did not (78.3%). Chi square test on the above data found out the p value to be .098, i.e., satisfactory glycaemic control was statistically not significant for wound outcomes. On estimating the odds ratio, it came out to be 0.817. A value of less than 1 here signifies, satisfactory glycaemic control not being a significant factor for the wound outcome. This is in contrast to Sharon A Watts et el [7] and Nather A. et al al [6] who found glycosylated haemoglobin levels to have a significant bearing on the wound outcome, which may be attributable to our smaller sample size.

Out of the 35 healing group patients, 20 were malnourished (57.1%) while 15 were not (42.9%). Out of the 23 non-healing group patients, 22 were malnourished (95.7%) while 1 case was not (4.3%). P value was calculated to be .001 and malnutrition was found to be a significant prognostic factor for wound outcome. An odds ratio of 16.50 here implies a 16.5 times more chances of wound not healing in the presence of malnutrition.

Peripheral neuropathy was present in 16 out of the 35 healing group cases(45.7%) while neuropathy was absent in 19 such cases. Out of the 23 non healing groups, 20 had peripheral neuropathy (87%) while 3 did not (13%). A p value of .01 here establishes peripheral neuropathy to be significant factor for wound outcome. An odds ratio of 5.614 implies a 5.614 times chances of wound not to heal. This was in accordance to Nather et al[6] prospective study of 202 patients where sensory neuropathy based on Semmes Weinston monofilament was found to be a significant predictor of outcome. Similar relationship had earlier been established by Andrew J M Boulton[3], Dellon and Caroline A Abbott et al[5].

Vasculopathy was present in 7 out of 35 healing group cases (20%) and was absent in 28 cases (80.0). Out of the 23 non healing group cases, 17 had vasculopathy (73.9%) while 6 did not (26. %). A p value of .000 implies significance of vasculopathy for wound outcome. An odds ratio of 11.33 implies 11.3 times risk of the wound not to heal in the presence of vasculopathy. This was in accordance with Jennifer A Mayfield et al [8], Goldenberg et al [11], Chauhan et al [12], Dulle et al [13] and Ballard [14] et al who affirmed the role of peripheral vascular disease as a predictor of wound outcome in infected diabetic wounds.

On multi variate analysis, satisfactory glycaemic control was excluded out of the analysis as it was statistically not significant, and the significant factors in the order of importance were peripheral neuropathy, malnutrition, ICDF grade and then vasculopathy.

Our patients were stratified as mild risk(19 cases), moderate risk(25 cases) and severe risk(14 cases) on the basis of presence of 1 or 2 risk factors, 3 or 4 risk factors and 5 or 6 risk factors respectively. Wound of all patients in the mild risk category healed. 10 out of 25 moderate risk patients (40.00%) had a non healing wound while 13 out of 14 high risk patients (92.90%) had a non healing wound. On the basis of above observation, we proposed that all severe risk cases, i.e. cases having 5 or 6 adverse risk factors, can be offered early amputation to spare them and their families, the agony of prolonged unyielding expectant management. However all the mild risk cases should be managed on expectant lines while moderate risk cases can be given a trial of expectant management.

CONCLUSION

Our study revealed age and sex distribution to be non contributory for wound outcome.

Longer duration of diabetes and poor ICDF grade were found to be adverse factors for wound outcome. Patients who were malnourished were less likely to have their infected wound to heal. Vasculopathy and peripheral neuropathy were reaffirmed to be significant risk factors for wound not healing.

However contrary to other studies, in our study we did not find a statistically significant correlation between satisfactory glycaemic control and wound outcome.

Based on the number of significant adverse risk factors present, the outcome of the wound can be predicted, and

patients who are unlikely to have their infected wound to heal, can be offered early amputation, which saves the hospital resources. Also the patients and their attendants are spared of going through the trauma and morbidity of expectant management in a wound unlikely to heal.

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