

ASSOCIATION BETWEEN HIGH RISK FOOT, RETINOPATHY AND HbA1c IN SAUDI DIABETIC POPULATION

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Background: One of the important complications of diabetes is diabetic-foot-ulcer, also reported in Saudi Arabia, like other countries. Similarly, the complications, like retinopathy and nephropathy are also occurring in diabetic patients of this region. Apart from the care and monitoring of these patients, it is important to find out association between these complications and their relation with common factors, like HbA1c levels. Such relation is not yet reported in literature. **Objective:** Therefore, this study was planned to find out association between neuropathy (leading to high risk foot) and retinopathy by the estimation of HbA1c levels in Saudi population. **Methods:** After exclusion of the cases of gestational diabetes and children with type-1 diabetes, 333 Patients having age 21 to 97 years were examined in the Diabetology Clinic of Diabetes Centre, Aseer Central Hospital, Abha. All patients were screened for neuropathy (High risk of the foot) and retinopathy (by Fundus Photography). HbA1c levels were determined, using standardised procedure. The obtained data was analysed statistically by SPSS-12 for Windows. **Results:** HbA1c levels of ≥ 10 have been found to be associated with neuropathy, high risk foot, and as well as non-proliferative and proliferative retinopathy. Pearson chi square test has demonstrated association between progressive retinopathy and development of high risk foot. **Conclusion:** The observed data indicate poor glycemic or diabetes control on the basis of higher HbA1c levels and strong association between high risk foot and the development of progressive retinopathy.

Keywords: Diabetes, High Risk Foot, HbA1c, Retinopathy

INTRODUCTION

Diabetes is one of the foremost causes of death in many countries and a leading cause of blindness, renal failure, and non traumatic amputation. Global prevalence of diabetes in the year 2003 was estimated to be 194 million.¹

One of the most common complications of diabetes in the lower extremity is the diabetic foot ulcer. An estimated 15% of patients with diabetes develop a lower extremity ulcer during the course of their disease.^{2,3} Diabetes is also associated with numerous complications such as retinopathy, nephropathy, and neuropathy.⁴

Diabetic foot syndrome (DFS) is a complex and heterogeneous disorder that affects 1 out of 5 patients with diabetes at least once in his or her lifetime with relevant consequences both on lower limb survival and general morbidity.⁵

Lower limb complications are major contributors to hospitalisation of patients with diabetes, and they account for the vast majority of in-hospital stay and resource consumption in this patient population.³ According to the international consensus guidelines' protocols⁶, such a complex pathology necessitates the participation of a multidisciplinary team, including the diabetologist, the podiatrist, the vascular surgeon, the radiologist, and the infectious disease specialist, to manage and address all the various aspects and presentations of the pathology.

Only about half of patients actually notice the lesion themselves, with the majority occurring on the digits.⁷ Ill-fitting footwear frequently contributes to foot ulceration.^{8,9} Inadequate shoe fitting cannot be felt in those patients with sensory neuropathy.¹⁰ Ulcers can form because of tight-fitting shoes causing constant pressure. However, loose shoes also cause ulcers, as a result of friction.¹⁰ Neuropathy is a major contributing risk factor for foot ulcers and can involve both somatic and autonomic fibres. The myelinated (A-type) sensory fibres are associated with proprioception, sensation of light touch, pressure, and vibration, and motor innervations of the muscle spindles. Neuropathy of the A-type nerve fibre results in ataxic gait and intrinsic weakness of the foot muscles. Neuropathy of the C-type sensory fibres is the loss of protective sensation; it results in the loss of pain threshold with prolonged and increased shear forces and repeated trauma. In addition, loss of protective sensation due to peripheral neuropathy is the most common cause of ulceration.¹¹

When footwear is fitted properly, it can reduce high pressure areas and hence reduce callus formation and the threats for ulceration. It will also fulfil its function as a barrier to the environment.⁹ Ill-fitting footwear can disrupt the biomechanics of the foot and ankle, and can subsequently give rise to problems, including pain.¹² Footwear should be designed to relieve pressure areas, reduce shock and shear forces and be able to accommodate deformities by supporting and

stabilizing them. It is necessary that shoes fit for both size and shape.¹³⁻¹⁵

Patients with diabetes, especially those with sensory neuropathy need appropriate shoes. The shoe must be wide enough to accommodate the first metatarsophalangeal joint.¹⁴ Shoes should be fitted whilst weight bearing. The location of the widest part of the shoe should be checked allowing extra room at the toe box, adequate room should be left across the ball of the foot and a snug fit should be made around the heel.^{14,15} It is also important to realize that many people have mismatched foot sizes.¹⁶

Footwear should be designed according to findings based on clinical examination. Good shoe fit is essential for prophylactic care of the diabetic foot.¹⁷

The recent recommendation in 2010 for diagnosis of Diabetes Mellitus, as has been stated by American Diabetes Association in position statement, HbA1c (Haemoglobin A1c) is now included in the diagnosis of diabetes. The HbA1c value of ≥ 6.5 is sufficient to make diagnosis. The test should be performed in a laboratory using a method (NGSP; National Glycohaemoglobin Standardization Program), certified and standardized to the DCCT (Diabetes Control and Complication Trial) assay.^{18,19}

Epidemiologic datasets show a relationship between HbA1c and the risk of retinopathy similar to that which has been shown for corresponding FPG (fasting plasma glucose) and 2-hPG (2 hour post glucose) thresholds. The HbA1c has several advantages to the FPG, including greater convenience, since fasting is not required; evidence to suggest greater pre-analytical stability; and less day-to-day perturbations during periods of stress and illness.^{20,21}

Chronic hyperglycaemia as measured by mean blood glucose (MBG) or HbA1c has been linked to the development and progression of micro-vascular diabetes complications.^{22,23}

Blood glucose levels are clearly a major determinant of HbA1c levels, which ultimately shows the diabetes control for the past 2 months. It has been mentioned in the past clinical trials that uncontrolled diabetes or elevated HbA1c levels are associated with the development of retinopathy and as well as other complications.²⁴ Now because HbA1c has been well validated on the basis of standardization, so this tool can be used for the diagnosis and monitoring the diabetes control and treatment as well.¹⁸⁻²⁰

On the basis of research literature mentioned above, the current study was designed to find out association between these complications, i.e., neuropathy leading to high risk foot & diabetic foot and its relation with retinopathy. Also to relate the common factor of serum glucose and HbA1c levels between these complications. Although, various research studies have been reported in recent past regarding these

complications in diabetes alone, especially with diabetic foot, but no study has been done to show relationship between diabetic foot complication and retinopathy.

MATERIAL AND METHODS

This is a cross sectional analytical study of patients who were followed in Diabetology Clinic of Aseer Diabetes Centre & were referred from different peripheral health care centres (PHCCs) of Aseer Region of Saudi Arabia. Aseer Diabetes Centre is located in Aseer Central Hospital, which is the largest tertiary care referral hospital for Ministry of Health in Aseer region.

Three hundred and thirty-three (333) patients of 21 to 97 years of age, who were followed up in diabetology clinic were selected for the study, from January 2008 till September 2009.

In this study, only those patients were included, who were known diabetic. New cases of type-2 diabetes were also included because they might have complications at the time of diagnosis because of the nature of disease. For type-1 diabetics, only those patients were selected who have duration of diabetes of more than five years, because in type-1 diabetics complications usually starts after five years of duration, in accordance to the criteria of American Diabetes Association.²⁵

No upper age limit was set because patients with diabetes can present with complications in their upper extremes of age. However, in this study the age of the selected patients was ranging from 21 to 97 years.

Children with type-1 diabetes (less than 13 years of age) were excluded from this study along with those patients having Gestational diabetes.

Detailed history was taken for full assessment of diabetic condition and complications. Detailed Physical Examination was done especially addressing for neurological examination for the assessment of foot pulses, vibration sense (by tuning fork of 128 Hz), and protective sensations (by 10-gram monofilament). Patients were also assessed for retinopathy by using computerized digital fundus photography camera (NIDEK Corporation, USA; approved by FDA for fundus photography) & full biochemistry especially HbA1c, (by Bayer DCA 2000 Plus Analyser; by Bayer Diagnostics Europe Ltd.), were also done by standardized methodology and laboratory procedures.

Patients having high risk foot were also assessed by Arterial Doppler (atys Medical Doppler System INC USA; approved by FDA, Food and Drug Administration) for the decreased or impalpable pulses, or having diabetic foot. Ankle Brachial Index (ABI) assessment was also done for screening and assessment of the diabetic foot with low or impalpable pulses or Peripheral Arterial Disease (PAD) detection accordingly.

Retinopathy was graded as: Within Normal Limits (WNL), Non-Proliferative Diabetic Retinopathy (NPDR), or Proliferative Diabetic Retinopathy (PDR), according to International Clinical Diabetic Retinopathy (DR) Disease Severity Scale.²⁶

Neuropathy assessment was done using Michigan Neuropathy Scoring Instrument (MNSI) and methodology, which has specificity of 95% and sensitivity of 85%.^{27,28}

High risk foot was labelled if the foot has any condition which may lead to risk for ulceration, on the basis of the following procedure.

Tuning fork 128 Hz was used as one of the tools for screening and detection of neuropathy.^{27,28} Protective sensations were assessed by 10 gram monofilament (5.07 Semmes-Weinstein monofilament)²⁹⁻³² and if the patient was not able to perceive sensations, he or she was labelled as having LOPS (Lost Of Protective Sensations on feet) and labelled high risk feet for ulceration accordingly.

Similarly patients having any other risk for foot ulceration, e.g., foot deformity (e.g., Halux Valgus, Claw Toes, hammer Toes or any other Deformity), very dry skin, callus, previous ulcerations or amputations etc., were also labelled as having high risk feet.^{33,34}

The above methodology for screening and examination was based on risk classification system of the International Working Group on the Diabetic Foot, as shown in Table-1.

All data were analyzed using computer software statistical package SPSS version 12 for Windows Copyright SPSS Inc USA. Variables of interest, i.e., neuropathy, high risk foot, Retinopathy status and HbA1c values were selected for the study. Data were summarised using descriptive statistics. For categorical variables, frequencies and percentages were used. Frequency table was made for the summary of the complications and patients' demographic characteristics with descriptive statistics for continuous variables. Box Plots were used to show the relation between HbA1c with vibration perception, neuropathy status, high risk foot and retinopathy. Chi-square test was used to show the relation and significance ($p < 0.05$) between the two variables, i.e., high risk foot and retinopathy.

RESULTS

Total 333 patients were examined in the present study categorised with respect to literacy, gender, type of diabetes and their foot-wear conditions. Their results have been described in Table-2.

The results regarding the frequency of categorisation of patients examined for the occurrence and non-occurrence of retinopathy,

neuropathy and associated problems have been presented in Table-3.

The results regarding the average values of age, duration of diabetes and associated common factors, i.e., HbA1c have been presented in Table-4.

The results regarding SPSS analysis for obtaining the relationship of HbA1c with neuropathy, associated sensory problems and retinopathy have been presented in box plots as Figure-1 to 4. According to these results the level of HbA1c was significantly higher with loss of vibration sense, neuropathy, high risk foot and both the proliferative and non-proliferative retinopathies.

Table-1: Simplified risk stratification, considered in the examination of Diabetic Foot

Risk Category	Risk Profile	Evaluation Frequency
0	Normal	Annual
1	Peripheral Neuropathy LOPS	Semi-annual
2	Neuropathy, Deformity and/or PAD	Quarterly
3	Previous Ulcer or Amputation	Monthly to Quarterly

Table-2: Frequencies for the categorization of patients with respect to literacy, gender, type of diabetes and the condition of foot-wears

Parameters	Description with n (%)	
	Literate	Illiterate
Literacy	254, (76.3)	79, (23.7)
Gender	Male	Female
	252, (75.7)	81, (24.3)
Type of Diabetes	Type-1	Type-2
	31, (9.3)	302, (90.7)
Condition of Foot-Wear	Poor	Acceptable
	221, (66.4)	112, (33.6)

Table-3: Frequency categorisation of patients examined for the occurrence and non-occurrence of Retinopathy Neuropathy and associated problems

Variables of Frequency	Number	%
No Retinopathy (WNL)	161	48.3
No Neuropathy (Without foot problem)	189	56.8
Non-Proliferative Retinopathy	147	44.1
Proliferative Retinopathy	25	7.5
Neuropathy	144	43.2
Currently with Diabetic Foot	34	10.2
High Risk Foot	105	31.5
Foot Deformities	31	9.3
Previous foot amputation	8	2.4
Loss of protective sensations in foot	38	11.4
Loss of vibration sensations in foot	112	33.6
History of Previous Ulcer	22	6.3
Peripheral Vascular Disease	6	1.8

Table-4: Average values of age, duration of diabetes and associated common factor, HbA1c

Variable	Mean±SD	Minimum	Maximum
Age	56±14.5	21	97
Duration of diabetes	13±7.94	1	37
HbA1c	9.9±2.34	5.7	17.6

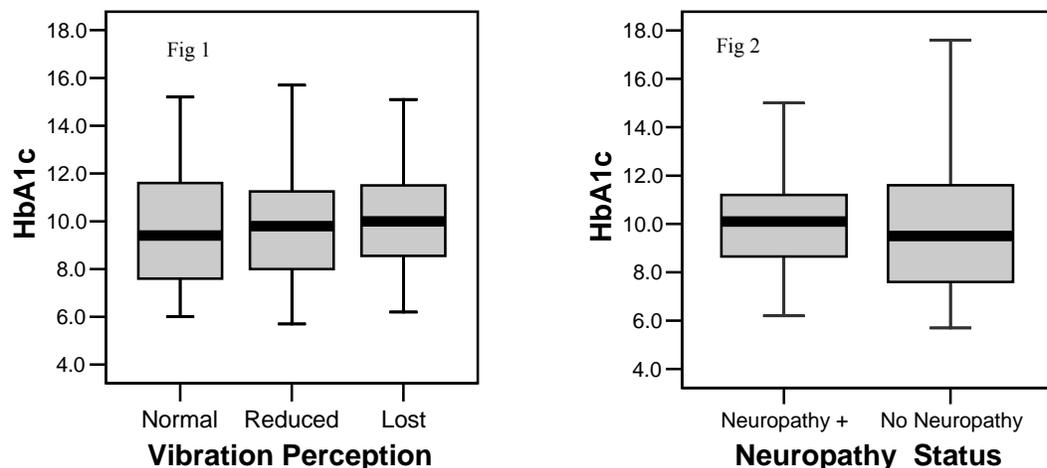


Figure-1 & 2: Box plots showing the relationship of HbA1c with vibration perception and status of neuropathy (high risk foot)

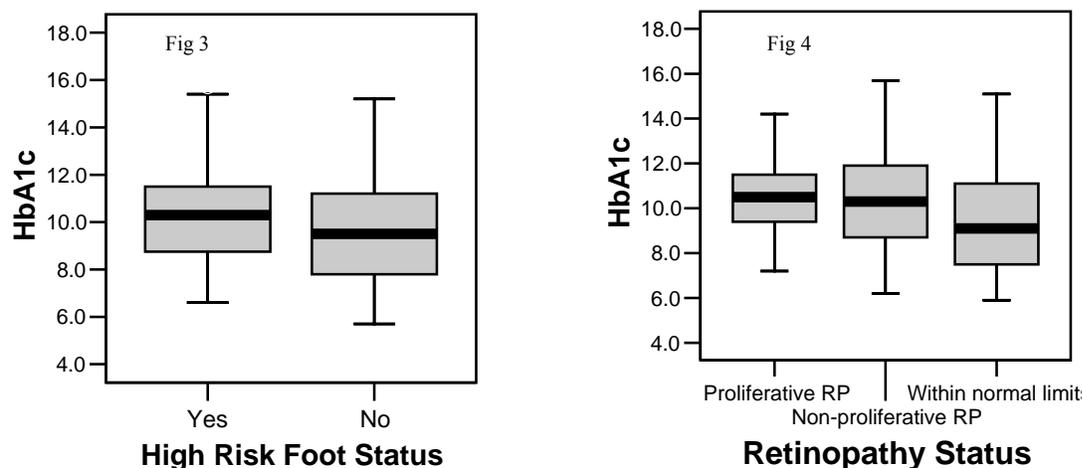


Figure-3 & 4: Box plots showing the relationship of HbA1c with the status of high risk foot and retinopathy

The result of Pearson Chi-square statistic performed for the determination of association between high risk foot and retinopathy demonstrated association between high risk foot and retinopathy, which was highly significant ($p < 0.0001$).

DISCUSSION

On the basis of results of present study it is suggested that the risk stratification should be followed (Table-1), while examining the diabetic patient with or without foot ulceration. According to results shown in Table-2, 23.7% of the patients were illiterate and obviously their foot wear or shoes were inappropriate which accounts 66.4%, being significant. The poor or inadequate foot wear leads ultimately to neuropathic foot ulceration & higher HbA1c levels (uncontrolled diabetes) itself, which leads to neuropathy again, creating a vicious circle for pathology to develop again and again. This

can be prevented at least by educating the patient at diabetic educator clinic and diabetic foot clinic, and regular foot examination by health care professional.

In addition, according to the obtained results, it is clear that as HbA1c levels are increasing and hence, there is a progressive loss of vibration sensations (Figure-1). For those patients in whom HbA1c levels are 10 or more, they definitely have loss of vibration sensations. This reflects their poor glycemic control at the time of examination or presentation. Further, as shown in Fig. 2, it is clear that those patients, in whom HbA1c levels are 10 or more, have developed neuropathy. Similarly, Fig. 3 demonstrates that HbA1c levels of more than 10 are associated with high risk foot and diabetic foot deformities, again reflecting poor glycemic control. This pathological association of poor glycemic control is also demonstrated in Fig. 4. Accordingly, rise in HbA1c from and above level 10,

patients have developed non-proliferative and proliferative retinopathy, indicating severity of retinopathy with uncontrolled diabetes. But, those patients who were having average HbA1c levels 9 or less; they are within normal limits or have not yet developed retinopathy, when examined in the current study. In other words, diabetic complications will occur if blood sugars remain high for long time, and may occur at any level of the disease process, but those patients whose HbA1c was 10 or more, have definitely developed the chronic complications as has been shown by the results in the present study.

The most important aspect of this study was to determine the association between the two complications i.e., the high risk foot and the development of the progressive retinopathy. According to Table 3, and Pearson chi square statistics, this association was found to be highly significant at the level of p -value of < 0.001 .

One of the important assessments from the present study is that, diabetic patients cannot well examine their feet daily because of the occurrence of retinopathy or visual loss, and need assistance of other persons at home. It should also be noted that visual impairment is one of the risk factors for the development of diabetic foot ulcers, because of associations and their coincidence in diabetes. In addition, by identifying high-risk patient and tailoring a total foot care prevention program accordingly, the incidences of ulceration and lower extremity amputations can be reduced.^{35,36}

Diabetic patients at risk for foot lesions must be educated about risk factors and the importance of foot care,^{37,38} including the need for self-inspection and surveillance, monitoring foot temperatures, appropriate daily foot hygiene, use of proper footwear, good diabetes control, and prompt recognition and optimal evidence based treatment of newly discovered lesions. In the current study 66.2 % of the patients overall were wearing poor foot wear which may further predispose them to ulcerations or injury. In addition, 23.3 % of the patients were illiterate i.e., they cannot even read or write. Although education should be targeted at all patients, but these illiterate patients need multiple sessions of education so that they really can understand the ongoing diabetes disease process & foot complications or problems. This emphasizes the importance of diabetic educator and the foot care specialist nurse. Also there is a need for multidisciplinary team including the diabetologist, the podiatrist, the vascular surgeon, the radiologist, ophthalmologist and the infectious disease specialist for better management and care for diabetic patients.

Therefore, the results of the present study clearly indicates that two of the most important complications of diabetes (retinopathy and neuropathy)

finally leads to the Diabetic Foot Syndrome, which occur together as glycemic control worsens.^{39,40} In other words, to prevent the complications, the blood sugars should be controlled to the target levels as recommended by American Diabetes Association and other associations and others as well. Lowering HbA1C to below or around 7% has been shown to reduce micro-vascular and neuropathic complications of type-1 and type-2 diabetes. Therefore, for micro-vascular disease prevention, the HbA1C goal for non-pregnant adults in general is 7%.¹⁹

Further, HbA1c is now considered also a diagnostic tool, as has been recommended by American Diabetes Association in 2010 because now its methodology is standardized. Nevertheless in the past and still now it has been a good tool for monitoring diabetes and its complications. It is easy to measure and gives reliable evidence for the past control of diabetes. In our study and data, we have used this tool also and have related its association with other complications.⁴⁰⁻⁴² This obviously implies that keeping HbA1c in acceptable range (by intensifying treatment, education and counselling) will prevent the complications and will have greater impact on reducing the burden and health cost at National as well as International levels.

RECOMMENDATIONS

Early referral of the diabetic patient from primary health care centre to the tertiary health care Diabetic Centre so that they can be screened early for the diabetic complications by multidisciplinary specialist team.

Early detection and screening for the various complications is essential and to document HbA1c levels so that to initiate tight glycemic control to prevent or at least to delay further complications. This strategy has great impact on health care planning and cost effective management. The above mentioned statistics once again emphasizes the importance of diabetes education not only at the patient's level but also at the physician's level, so that early education for the patients can be started when they first arrive to their general practitioner in primary health care units.

Future strategies are required for early diagnosis and referral to a diabetologist and other multidisciplinary diabetes care team for early detection of complications so that to prevent the blindness or the visual impairment and amputations. There is also need to train the physicians for diabetes and the society is in great need for the diabetologists (the trained physician who is specialist in diabetes management and its related disorders).

Furthermore, studies are also required to analyze and compare such data regarding diabetic neuropathy and retinopathy between various diabetic centers of a region, to associate these complications and

their impact on health planning strategies especially in developing countries.

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