

Original Research Article

Detection of microvascular complications of diabetes by EZSCAN method and their correlation with metabolic indices

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ABSTRACT

Background: EZSCAN is a new, non-invasive technique to detect sudomotor dysfunction and thus neuropathy in diabetes patients at an early stage. It further predicts chances of development of other microvascular complications. In this study we evaluated EZSCAN for detection of microvascular complications in Type 2 diabetes patients and assessed their correlation with various metabolic parameters.

Methods: 104 known diabetes patients, 56 males and 48 females, were studied. All cases underwent the EZSCAN test, Body mass index measurement, fasting and postprandial blood glucose, HbA1c tests. Diabetes related complications were thereafter correlated with various metabolic indices.

Results: Strong correlation was found between HbA1c, body mass index (BMI), fasting blood glucose (FBG) and post-prandial blood glucose (PPBG) with diabetes related microvascular complications assessed by EZSCAN, strongest being with FBG ($r=0.755$) and weakest with BMI ($r=0.232$).

Conclusions: Microvascular complications of diabetes as detected by EZSCAN method correlate strongly with metabolic indices of the patient and thus EZSCAN can be used as a simple, non-invasive and quick method to detect microvascular complications of diabetes.

Keywords: EZSCAN, Metabolic indices, Microvascular complications, Type 2 diabetes

INTRODUCTION

Type 2 diabetes often progresses silently, without developing clinically evident symptoms. It frequently remains undiagnosed until complications appear. So, as soon as a patient is diagnosed with diabetes, she/he must be screened for the complications of the disease simultaneously because by this time the disease would have already progressed pretty long in its course. Timely screening and early detection of diabetes and its complications will enable clinicians to intervene early in the course of the disease, preventing adverse outcomes and possible regression of the complications associated with the disease.

There are a number of macro as well as microvascular complications of diabetes, among which neuropathy is considered to be the earliest to occur.^{1,2} Autonomic neuropathy develops very early in the course of the disease and it may be either clinically evident or subclinical with dysfunctions of cardiovascular, gastrointestinal, genitourinary systems and sudomotor or ocular functions. Among these, sudomotor dysfunction has been regarded as the initial component of autonomic neuropathy. In the presence of neuropathy, the possibility of nephropathy and retinopathy is increased too.

The conventional methods used to screen for microvascular complications are time taking and

invasive. Moreover, multiple tests are needed for different complications which might reduce the patients, compliance. This creates a need for methods which quick, safe, non-invasive and can be used to screen all the three complications by a single test. EZSCAN is one such method which has already proven its effectiveness in detecting diabetes and pre-diabetes at mass level and can be used further to detect the presence of microvascular complications in the persons having diabetes.³⁻⁷

The Aims and Objectives of this study to use of EZSCAN for detection of microvascular complications in patients of Type 2 diabetes and correlate these with various metabolic parameters.

METHODS

Study design

This single point cross sectional study was conducted over 104 subjects at MLN Medical College, Allahabad and its associated SRN Hospital, Allahabad during a period from March 2017 to July 2018. Subjects ≥18 years who were already diagnosed with diabetes according to American Diabetes Association 2014 guidelines were selected as cases.

There was no separate control group for the study. Patients having secondary diabetes due to chronic pancreatitis, hemochromatosis, cystic fibrosis, drug- or chemical-induced (such as in the treatment of HIV/ AIDS or after organ transplantation) and Gestational diabetes mellitus were excluded from the study.

Procedures

A detailed history, clinical examination and relevant investigations were done in each subject to assess the disease progression and presence of microvascular complications. Each subject also underwent EZSCAN to assess the presence of microvascular complications of diabetes. History included duration of diabetes, symptoms of neuropathy and other related complications, any drug intake, any concurrent or chronic illness. Fasting blood glucose (FBG), Post-prandial blood glucose (PPBG) and HbA1c level were measured in the hospital laboratory.

EZSCAN test

EZSCAN is being used for early screening and assessment of early diabetes, devised by Impeto Medical (Paris, France). It is non-invasive and provides immediate results, without any need for patient preparation, fasting or a blood draw.

It uses reverse iontophoresis and chronoamperometry methods to assess the sudomotor dysfunction. Data processing results in a score representative of the

individual’s risk to show pre-diabetes (IGT), diabetes and complications.⁸ EZSCAN risk score was recorded which ranges from 0 to 100% and risk assessment was done as: no risk (<25 %), intermediate risk (25-50%) and high risk (>50%).

These threshold values were issued from the previous clinical studies. 37% was taken as the cut off for detection of the microvascular complications (optimal according to Youden index).

Statistical analysis

The data were analysed and assessed with appropriate statistical methods within different groups. Software used is SPSS-IBM version 21. Student t-test was applied to correlate various metabolic parameters with diabetic microvascular complications. Confidence interval used is 95% and p value <0.05 was taken as significant.

RESULTS

Out of 104 subjects studied, 56 were males and 48 females. Mean age of subjects was 53.5±11.4 (years) with a range between 24 to 76 years. 49 subjects were found to have microvascular complications by EZSCAN method. Strong correlation between HbA1c, BMI, FBG and PPBG with microvascular complications were seen, strongest being with FBG (r=0.755) and weakest with BMI (r=0.232) (Table 1 and 2).

Table 1: Correlation of microvascular complications with various metabolic parameters signifying severity of diabetes (quantitative variables).

Parameter	Pearson correlation coefficient[r]	p value	Inference
HBA1c	0.617	<0.001	Positive, significant
BMI	0.232	0.018	Positive, significant
FBG	0.755	<0.001	Positive, significant
PPBG	0.712	<0.001	Positive, significant

Mean BMI in subjects having complications was 26.30±4.18 kg/m² while in subjects devoid of complications, it was 24.43±3.60 kg/m². This difference is statistically significant (p=0.016); (Table 2, Figure 1).

Mean HbA1c, FBG and PPBG in population having microvascular complications, were 8.08±1.36%, 143.98±21.81 mg/dl and 211.08±47.99, respectively. While in population not having any complication, these were 6.67±0.92%, 109.04±19.86 mg/dl and 150.15±30.40 mg/dl, respectively. And these differences were statistically significant with p <0.001; (Table 2, Figure 2-4).

Table 2: Comparison of microvascular complications with means of quantitative variables metabolic parameters).

Variables (metabolic parameters)	EZSCAN Results (Microvascular complications absent) [n=55]		EZSCAN Results (Microvascular complications present) [n=49]		p value
	Mean	± SD	Mean	± SD	
BMI (kg/m ²)	24.43	3.60	26.30	4.18	0.016
HbA1C (%)	6.67	0.92	8.08	1.36	<0.001
FBG (mg/dl)	109.04	19.86	143.98	21.81	<0.001
PPBG (mg/dl)	150.15	30.40	211.08	47.99	<0.001

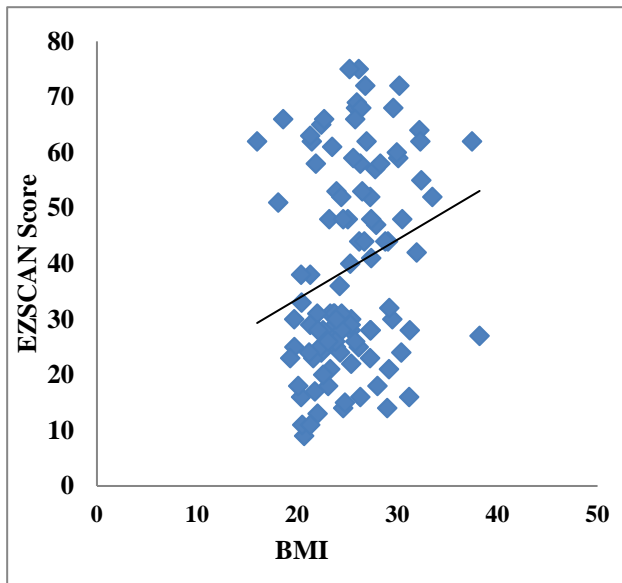


Figure 1: Correlation of BMI with microvascular complications (EZSCAN score).

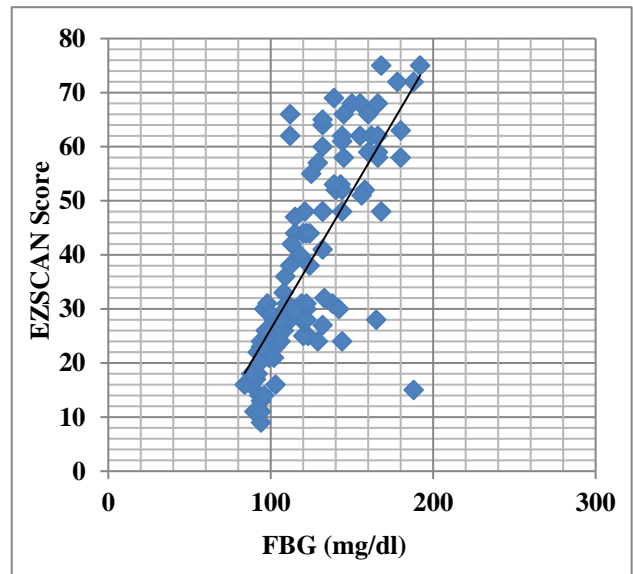


Figure 3: Correlation of microvascular complications (EZSCAN risk score) with FBG.

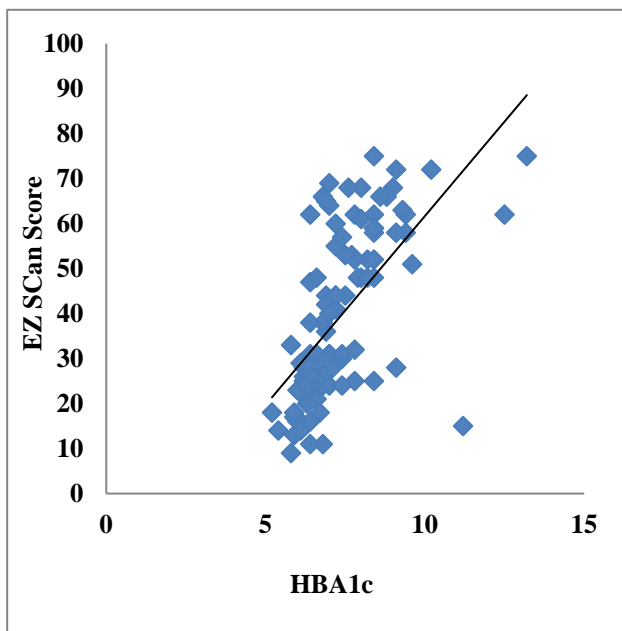


Figure 2: Correlation between microvascular complications (EZSCAN risk score) and HbA1c levels.

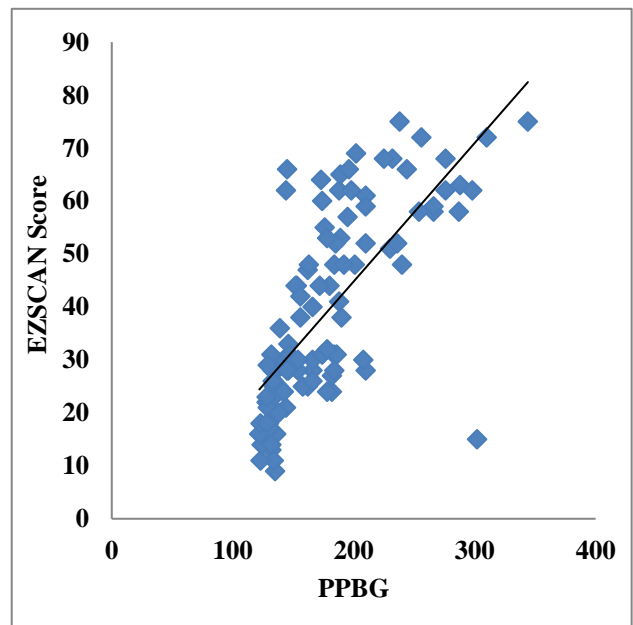


Figure 4: Correlation between microvascular complications (EZSCAN risk score) and PPBG levels.

DISCUSSION

In the present study when HbA1c was correlated to the prevalence of microvascular complications, a positive significant correlation was found. It is strongly supported by many studies done previously like Zoungas S and et al, showed in their study that with every 1% increase in HbA1c level above the threshold (6.5%), there was a 40% higher risk of a microvascular complication.⁹ In study done by Ji Kim and et al, HbA1c was found to be a strong independent predictor for microvascular complications.¹⁰ Similar results were found in the study of Adler AI and et al, FBG as well as PPBG were found to be strongly and positively correlating to the microvascular complications in diabetic subjects, though FBG correlated a little more strongly than PPBG [$r(\text{FBG})=0.755$, $r(\text{PPBG})=0.712$].¹¹ In study done by Deepa DV and et al, $r(\text{FBG})$ was 0.56, while it was 0.82 in DCCT in a study conducted by Nathan and et al, it was 0.89.¹²⁻¹³ So, all these studies support observations seen in the present study. As far as BMI of subject is considered, it was significantly correlated with the complications. According to study done by M Tomic and et al, the prevalence of nephropathy and polyneuropathy was significantly related to BMI, whereas the prevalence of retinopathy increased significantly with higher body weight.¹⁴ Many other studies too support this observation.¹⁵⁻¹⁷ The strongest correlation to microvascular complications among all these parameters was shown by FBG($r=0.755$)and weakest by BMI ($r=0.232$).

CONCLUSION

Diabetes is now recognized as an immense and growing public health challenge worldwide, especially India and other South East Asian countries. EZSCAN is a quick non-invasive patient friendly device to detect microvascular complications in diabetes patients at an early stage and correlates strongly with various metabolic parameters. It can be used to detect microvascular complications at an early stage and halt their progression. Further studies are required to establish the role of EZSCAN as a useful tool to detect diabetic complications.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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