Original Research Article

A prospective study on risk of diabetic foot in diabetes with micro and macro vascular complications

Faisal KK[1]

Associate professor,Department of Medicine,Government Medical college Calicut,India

Received: 02-04-2021 / Revised: 10-06-2021 / Accepted: 15-07-2021

Abstract

Introduction: Diabetes mellitus is found in as many as 13 million people nationally. Many of the clinical complications of diabetes may be ascribed to alterations in vascular structure and function, with subsequent end-organ damage and death. Specifically, two types of vascular disease are seen in patients with diabetes: micro and macro vascular complications. The former is relatively unique to diabetes, whereas the latter lesions are morphologically similar in both nondiabetic and diabetic patients.**Objectives:** To estimate the incidence of diabetic foot in patients of diabetes with micro and macrovascular complications.**Methods:** In this study, total330 subjects (M:F 170: 160), attending the diabetic clinic, were analysed. The study sample look like the population sample in anthropometric, age and socioeconomic factors. All patients had undergone the test for retinopathy by fundus examination, nephropathy by microalbuminuria, serum creatinine and blood urea, neuropathy by monofilament and biothesiometer, peripheral vascular disease (PVD) by colourdoppler and cardiovascular disease by ECG.**Results:** Among 330subjects, nephropathy was present in 9%, coronary heart disease (CHD) was present in 12.5% and peripheral vascular disease (PVD) (diabetic foot) was present in 12.4% of the subjects. Duration of diabetes had significant association with the neuropathy, nephropathy and PVD ($p<0.05$). Higher HbA1C increases the risk of neuropathy, and nephropathy.**Conclusion:** The study highlights the high incidence of diabetic foot in patients of vascular complication.

Keywords: diabetes, diabetic foot, ulcer, neuropathy, nephropathy, intermittent claudication

Introduction

Diabetes mellitus is growing in incidence both in urbanand rural population in India.[1,2,3] The main penalties, inthe long term, of uncontrolled diabetes are microvascular(nephropathy, retinopathy, and neuropathy) and macrovascular (coronary artery disease, cerebrovascular, and peripheralvascular disease) complications.[4] The latter has resulted indiabetes being declared as vascular disease and it is theforemost cause of cardiovascular death worldwide.[5]The clinical supervision of the patient with diabetes contains not only addressing hyperglycemia but also screening for the angiopathic problems andevaluating the other risk factors.[6]Studiesfrom India stated an incidence of 5% to 37% of macrovascular and microvascular complications midst diabetespatients.Patients with diabetes and related microvascular complications are at higher risk of enhanced atherosclerosis which ultimately concludes in cerebrovascularand cardiovascular events and premature death.[6]

A multicentric study in India stated a high incidence of microvascular complications like diabetic neuropathy (26.1%) andnephropathy (26.9%).[7] The incidence of hidden complications is more in rural area when associated to urbanarea, due to poor control of diabetes, lack of awareness, andlimited access to health care.Population information on diabetes complications are obtainablein urban India. Data on the load of vascular complications of diabetes, its incidence and severity are uncommon fromthe rural setting in India. Indiabeing a developing country and with mainstream of the population being in rural area, complete assessment of diabetic patients and classifying the complications becomesthe need of the hour. Screening for both macro and microvascular complications in type 2 diabetes patients having diabetic foot will helpin understanding the burden of the problem. The rationale behind the study is to determine the risk of diabetic foot in patients of diabetes having vascular complications.

**Correspondence*
Dr. Faisal KK
Associate Professor,Department of medicine,Government Medical college Calicut,India
E-mail: faisalkkdr@gmail.com

Materials and Methods

This hospital based prospective study was conducted in diabetic clinic of medical college from Jan 2019 to December 2019. Based on study done by Agarwal et al, on vascular complication of diabetes (incidence of neuropathy—32.5%), the minimum sample size was calculated to be 324 subjects at 95% confidence level and 5% of allowable error. So, the total sample size used was 330.

Methodology-

Information on background demographic features like age, gender, education, occupation, etc. was calm using a pretested structured questionnaire. Details of co-morbidities were obtained from records as well as from history. The content validity of the questionnaire was examined by an expert team. The questionnaire was translated to English by language experts. Data collection was done by co-investigators.Anthropometric assessment of study population was done using standard procedures.[8]Foot examination was complete to look for signs of gangrene, absence of toes, past healed/unhealed ulcers, deformity, absent peripheral pulses (dorsalispedis, posterior tibial). Touchsensation in lower limbs was assessed using 10 g monofilament. The monofilament was held perpendicular to the skin and pressure was applied until the filament just bends with a contact time of 2 seconds. Vibration and touch were verified at 5 areas—plantar surface of distal hallux, heads of first metatarsal, presence or absence of ankle reflex was patterned using percussion hammer.[8]

Blood was examined for plasma glucose (fasting and postprandial), HbA1c, and serum creatinine. Urine was examined for glucose, albumin, pus cells, and RBCs. A 12-lead electrocardiogram resting ECG was taken. Nephropathy was assessed using estimated

glomerular filtration rate (eGFR) which was calculated by the abbreviated MDRD equation (Modification of Diet in Renal Disease).18 Based on the patient's history, physical examination and laboratory findings, vascular complications of diabetes were diagnosed by an endocrinologist (SM).

Operational Definition

Macrovascular Complications

Coronary artery disease (CAD): History of angina or myocardial infarction or/and documented in medical records or abnormal ECG findings indicating the presence of ischemia or infarction indicating coronary artery disease.Cerebrovascular disease (CVD): History of stroke or transient ischemic attack/hemiplegia or/and documented in medical records.Peripheral vascular disease (PVD): Definitive history of intermittent claudication or if one or more peripheral pulses absent in any one foot.[9]

Microvascular Complications

Peripheral neuropathy: Ankle reflex absent or 10 g monofilament for touch is<3/5 or 128 Hz vibration sense is <3/5 in any 1 foot.Nephropathy: Estimated Glomerular filtration rate less than 60 mL/ min/1.73 m^2.Diabetic foot: Presence of ulcer/old healed ulcer/ gangrene/ deformity/amputation in either foot.[10]

Statistical Analysis-

Data analysis of the variables was done using Statistical Package for Social Sciences (SPSS) version 22 (IBM Corporation, Somers, New York, USA) software after checking for completeness. Qualitative variables such as socio-demographic characteristics were articulated as frequency and percentages. The incidence of vascular complications of diabetes was calculated as percentages and 95% Confidence Interval. Chi- Square test was used and P value of <.05 was statistically significant.

Results

Table 1- Demographic details of the study participants (N=330)

Variables	Number	Percentage (%)
Age		
<50	85	26
50-70	220	67
>70	25	7
Gender		
M	170	51
F	160	49
Education		
Less Than High School	200	61
High School And Above	130	39
Smoking		
Yes	167	51
No	163	49
BMI		
Normal	226	68
Overweight	77	24
Obesity	27	8
Waist Circumference		
Normal	100	30
High	230	70
Duration of Diabetes		
<5 years	193	60
>5 years	137	40

As per table 1 The socio-demographic characteristics of the study subjects are given in Table. The mean (SD) age of studypopulation was 56.3±10.1 years. About 51% of the studypopulation were males. About 61% of study population were educated less than primary school level. The mean (SD) BMI was 26.9±11.4 kg/m^2 and more than 30%of the study population were overweight/obese. The mean(SD) duration of diabetes was 6.3±6.1years. Based on the HbA1c value about 55.4% of study population had theirdiabetes under control (HbA1c<7%).

Table 2: Signs and Symptoms with incidence of Microvascular complications and Diabetic foot

Complications	Percentage (%)	p-value
Peripheral neuropathy		0.11
Vibration <3/5	16.3	
Monofilament <3/5	31.3	
Absence ankle reflex	21.1	
Nephropathy		0.09
Urine albumin >1+	9	
s.creatinine>1.4	9	
Diabetic foot		0.001*
Gangrene	0.9	
Ulcer	3.5	
healed ulcer	4.5	
Deformity	6.1	

As per table 2 among the symptoms of peripheral neuropathy, diminished touch sensation (31.3%) was most prevalent followed by absent ankle reflex (21.1) and diminished vibration (16.3). About 9% of study subjects hadabnormal urine albumin and serum creatinine. The findings of diabetic foot among the study participants were presenceof ulcer (3.5%), healed ulcer (4.5%), gangrene (0.9%), and deformity (6.1%) the p value was found to be significant ($p<0.05$) only for diabetic foot. Which concludes that diabetic foot was common in diabetic patient as the significant microvascular complication but the most common was peripheral neuropathy.

Table 3:Signs and Symptoms with incidence of Macrovascular complications

Complications	Percentage (%)	p-value
CVD		0.18
Abnormal ECG	12.5	
h/o CAD	3.4	
PVD		0.02*
Intermittent claudication	4.1	
Absent peripheral pulse	12.4	
CVD		**0.21**
h/o CVD	3.5	

According to table 3 About 12.5% of study subjectspresented with abnormal ECG findings. History of CADand CVD was observed in 3.4% and 3.5% of study subjectsrespectively. About 4.1% and 12.4% of study subjects presented with history of intermittent claudication and absentperipheral pulses. Which further concludes that absence of peripheral pulse is the significant factor for diabetic foot ulcer ($p<0.05$).

Discussion

In this study easily available screening tools were used to measure the incidence of vascular complications of diabetes in a hospital setting. It revealed high incidence of both micro and macrovascular complications in the population. The implications of the study findings are: (1) burden of vascular complications is quite high in our population.Among the macrovascular complications, the incidence of CAD and PVD was high (12.5%) followed by CVD (3.5%). Studies done in rural India detected the incidence of Ischemic heart disease and stroke to be 7.8% to 11.4% and 0.5% respectively.[11] Study complete by Agarwal et al observed that the incidence of PVD by both clinical examination to be 18.1% which was close to our study conclusions.[12] Incidence of claudication (likelihood ratio LR—3.30) and any pulse abnormality (LR, 3.10) are the most beneficial clinical findings in diagnosis of PVD. PVD is one of the hazardous complications of diabetes, a simple history of intermittent claudication and examination of peripheral pulses will help in early detection of PVD and patients can be referred to higher centers for additional diagnosis and action.[13]Among the microvascular complications, peripheral neuropathy (57.9%) had the highest incidence followed by nephropathy (9%) and diabetic foot (10.2%). Studies have exposed the incidence of peripheral neuropathy in South India to range from 10.5% to 60.4%. The high incidence in rural areas could be due to interruption in diagnosis, poor self-care, poor health-seeking conduct.[14,15] In the current study doctors were trained to use these simple tools like monofilament and VibraTip for early detection of peripheral neuropathy which can be applied country wide. Awareness program on foot care was directed with special training to patients identified with peripheral neuropathy.A multicentric study done in India to screen diabetic patients for occurrence of diabetic foot exposed 8.7% of study population agonized from foot ulcers and blisters which was close to our study findings (10.2%).[16] In our study complete assessment of foot along with peripheral vascular disease and peripheral neuropathy was done which helped in classifying at -risk foot too. Doctors were trained to educate the patients on simple self-foot examination which is a very real preventive strategy to reduce this serious complication.

Studies have experiential that lower the education higher is the risk of CAD.The danger of PVD in diabetic patients increased 2.2 times in those with high waist circumference which is a degree of abdominal obesity. Study done by Rao et al detected that abdominal obesity measured by waist-hip ratio and waist circumference were autonomous and significant risk factor of PVD like our study findings.[17]

A meta-analysis on diabetic neuropathy observed that duration of diabetes, HbA1c are significantly associated with amplified risks of DPN amongst diabetic patients.[18,19]Studies done in India detected that poor glycemic control and increased duration of diabetes were significantly related with diabetic neuropathy which was like our study findings. Males have higher risk of evolving diabetic foot than females. Study done by Dinh et al also observed similar results.[20] Poor glycemic control was also related with incidence of diabetic foot.

Conclusion

High prevalence of vascular complications especially diabetic foot was observed inthis study. Simple, effective, and easily available tools may suffice to screen for the complicationsfacilitating early diagnosis and referral. Factors such ase ducation, hypertension, HbA1c, and postprandial bloodsugar were strongly associated with increase in vascular complications of diabetes.

References

1. Deepa M, Bhansali A, Anjana RM et al. Knowledge and awareness of diabetes in urban and rural India: the Indian Council of Medical Research India Diabetes Study (Phase I): Indian Council of Medical Research India Diabetes. Indian J Endocrinol Metab. 2014;18(3):379-385.
2. Nanditha A, Snehalatha C, Satheesh K et al. Secular TRends in DiabEtes in India (STRiDE–I): change in prevalence in 10 years among urban and rural populations in Tamil Nadu. Diabetes Care Mar. 2019;42:476-485.
3. Little M, Humphries S, Patel K, Dewey C. Decoding the type 2 diabetes epidemic in rural India. Med Anthropol. 2017;36:96-110.
4. Kumar HK, Kota S, Basile A, Modi K. Profile of microvascular disease in type 2 diabetes in a tertiary health care hospital in India. Ann Med Health Sci Res. 2012;2:103-108.
5. Einarson TR, Acs A, Ludwig C, Panton UH. Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017. CardiovascDiabetol. 2018;17:83.
6. Chawla A,Chawla R, Jaggi S.Microvascular and macrovascular complications in diabetes mellitus: distinct or continuum? Indian J EndocrinolMetab. 2016;20:546-551.
7. Pradeepa R, Anjana RM, Unnikrishnan R, Ganesan A, Mohan V, Rema M. Risk factors for microvascular complications of diabetes among South Indian subjects with type 2 diabetes–the Chennai Urban Rural Epidemiology Study (CURES) Eye Study- 5. Diabetes TechnolTher. 2010;12:755-761.

8. Casadei K, Kiel J. Anthropometric measurement. https://www.ncbi.nlm.nih.gov/books/NBK537315/, 2020.
9. Goyal A, Kahlon P, Jain D et al. Trend in prevalence of coronary artery disease and risk factors over two decades in rural Punjab. Heart Asia. 2017;9:e010938.
10. Tesfaye S, Boulton AJ, Dyck PJ et al. Diabetic neuropathies: update on definitions, diagnostic criteria, estimation of severity, and treatments. Diabetes Care. 2010;33:2285-2293.
11. Mohan V, Venkatraman JV, Pradeepa R. Epidemiology of cardiovascular disease in type 2 diabetes: the Indian scenario. J Diabetes Sci Technol. 2010;4:158-170.
12. Agarwal PR, Ranka M, Beniwal R. Prevalence of micro and macro vascular complications in type 2 diabetes and their risk factors. Int J DiabDev Countries. 2004;24:11-16.
13. Khan NA, Rahim SA, Anand SS, Simel DL, Panju A. Does the clinical examination predict lower extremity peripheral arterial disease? JAMA. 2006;295:536-546.
14. Pradeepa R, Rema M, Vignesh J, Deepa M, Deepa R, Mohan V. Prevalence and risk factors for diabetic neuropathy in an urban south Indian population: the Chennai Urban Rural Epidemiology Study (CURES-55). Diabet Med. 2008;25:407-412.
15. D'Souza M, Kulkarni V, Bhaskaran U et al. Diabetic peripheral neuropathy and its determinants among patients attending a tertiary health care centre in Mangalore, India. J Public Health Res. 2015;4:450.
16. Dixit S, Kumar S. Awareness of diabetic foot complications in type 2 diabetes population in Rural India: are we doing enough? J Diabetes Metab. 2014;5:363.
17. Dégano IR, Marrugat J, Grau M et al. The association between education and cardiovascular disease incidence is mediated by hypertension, diabetes, and body mass index. Sci Rep. 2017;7:12370
18. Liu X, Xu Y, An M, Zeng Q. The risk factors for diabetic peripheral neuropathy: a meta-analysis. PLoS One. 2019;14:e0212574.
19. Bansal D, Gudala K, Muthyala H, Esam HP, Nayakallu R, Bhansali A. Prevalence and risk factors of development of peripheral diabetic neuropathy in type 2 diabetes mellitus in a tertiary care setting. J Diabetes Investig. 2014; 5:714-721.
20. Dinh T, Veves A. The influence of gender as a risk factor in diabetic foot ulceration. Wounds. 2008;20:127-131.

Conflict of Interest: Nil
Source of support:Nil