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

Ashok Gopinath[1], Vivin Thomas Varghese[2], Aquib Shaick[2] and SM Rajapradeep[1,*]

[1] Professor, Department of General Surgery, SUT AMS Hospital, Trivandrum Kerala, India.
[2] Associate professor, Department of General Surgery, SUT AMS Hospital, Trivandrum Kerala, India.
* Correspondence: rajapradeepsm@gmail.com

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Abstract: Diabetes mellitus affects approximately 13 million people and is associated with various vascular complications. Microvascular and macrovascular problems are common in diabetes, with the latter being similar in both diabetic and non-diabetic patients. The study aimed to estimate the incidence of diabetic foot in patients with diabetes and vascular complications. The study included 330 patients (M:F 170:160) who underwent tests for retinopathy, nephropathy, neuropathy, peripheral vascular disease (PVD), and cardiovascular disease. The results showed that nephropathy was present in 9% of patients, CHD in 12.5%, PVD (diabetic foot) in 12.4%, and neuropathy in 12.5%. Diabetes duration was significantly correlated with neuropathy, nephropathy, and PVD, while higher HbA1C levels were associated with an increased risk of nephropathy and neuropathy. The study highlights the high incidence of diabetic foot in patients with vascular complications.

Keywords: Diabetes; Diabetic foot; Ulcer; Neuropathy; Nephropathy; Intermittent claudication.

1. Introduction

Diabetes mellitus is becoming increasingly prevalent in both urban and rural areas of India [1–3], and it can lead to microvascular (nephropathy, retinopathy, and neuropathy) and macrovascular (coronary artery disease, cerebrovascular, and peripheral vascular disease) complications [4]. Diabetes has been classified as a vascular disease due to its association with macrovascular complications, making it the leading cause of cardiovascular death worldwide [5]. In addition to managing hyperglycemia, diabetic patients require clinical monitoring for angiopathic issues and assessment of additional risk factors. The incidence of macrovascular and microvascular complications in diabetes patients in India has been reported to range from 5% to 37% in six studies [6].

In India, a multicentric study found that diabetic nephropathy (26.1%) and diabetic neuropathy (26.9%) were common microvascular complications [7]. However, due to inadequate diabetes management, lack of awareness, and limited access to medical treatment, the incidence of hidden complications is higher in rural areas than in urban areas [1]. While data on the prevalence and severity of diabetes-related vascular problems are available for metropolitan areas, statistics for rural India are scarce [7]. As the majority of the Indian population lives in rural areas, a comprehensive evaluation of diabetic patients and classification of their complications is urgently needed [7].

Screening for both macrovascular and microvascular complications in type 2 diabetes patients with diabetic foot can help understand the burden of the problem. The objective of this study is to estimate the incidence of diabetic foot in patients with diabetes and vascular complications, with a focus on identifying the risk factors associated with this complication.

2. Materials and Methods

This prospective hospital-based study was conducted at SUT AMS Hospital, Trivandrum, Kerala from January 2021 to December 2021. The minimum sample size was calculated to be 324 subjects at a 95% confidence level and 5% of allowable error based on the study done by Agarwal *et al.,* [11] on vascular complications of diabetes (incidence of neuropathy-32.5%). Therefore, the total sample size used was 330.

2.1. Methodology

A pretested structured questionnaire was used to collect data on background demographic variables such as age, gender, education, occupation, etc. Co-morbidities were assessed using records and history. The questionnaire's content validity was reviewed by an experienced panel, and language specialists translated the survey into English. Co-investigators were involved in the data collection process. Standard methods were used to conduct an anthropometric assessment of the research population.

The entire foot was examined for any evidence of gangrene, missing toes, previously healed or unhealed wounds, deformities, or absent peripheral pulses (dorsalis pedis, posterior tibial). Touch sensitivity in the lower limbs was evaluated using a 10 g monofilament. Pressure was applied while holding the monofilament perpendicular to the skin for a contact time of two seconds. Five points were tested for vibration and touch: the distal hallux plantar surface, the heads of the first metatarsal, and the presence or absence of the ankle reflex, which was modeled using a percussive hammer [8].

Blood was collected to measure HbA1c, serum creatinine, and plasma glucose (fasting and postprandial). A urine sample was collected to detect RBCs, albumin, pus cells, and glucose. A 12-lead resting electrocardiogram was recorded. Estimated glomerular filtration rate (eGFR), which was determined using the condensed MDRD equation, was used to evaluate nephropathy (Modification of Diet in Renal Disease). An endocrinologist identified the patient's vascular problems of diabetes based on the patient's medical history, physical examination, and test results.

3. Operational Definition

3.1. Macrovascular Complications

Coronary artery disease (CAD): History of angina or myocardial infarction or 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 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].

3.2. 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 one 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].

4. Statistical Analysis

The statistical analysis was performed using SPSS for Windows version 22.0 software on Mac and Linux. The findings were presented in numbers and percentages and analyzed by frequency, percent, and Chi-square test. The Chi-square test was used to find the association among variables. The critical value of P indicating the probability of significant difference was taken as less than 0.05 for comparison.

5. Results

The socio-demographic characteristics of the study population are summarized in Table 1. The mean age (SD) of the study population was 56.3±10.1 years, and 51% of the participants were male. Majority of the study population (61%) had an education level below primary school. The mean BMI (SD) was 26.9±11.4 kg/m^2, and more than 30% of the participants were overweight or obese. The mean duration of diabetes (SD) was 6.3±6.1 years. Based on the HbA1c value, 55.4% of the study population had their diabetes under control (HbA1c<7%).

Table 2 presents the symptoms of peripheral neuropathy observed in the study population. Diminished touch sensation (31.3%) was the most prevalent symptom followed by absent ankle reflex (21.1%) and diminished vibration (16.3%). About 9% of study subjects had abnormal urine albumin and serum creatinine. The findings of diabetic foot among the study participants were presence of 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.

Table 3 shows the prevalence of macrovascular complications in the study population. About 12.5% of study subjects presented with abnormal ECG findings. The history of CAD and CVD was observed in 3.4% and 3.5% of study subjects, respectively. About 4.1% and 12.4% of study subjects presented with a history of intermittent claudication and absent peripheral pulses.

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

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

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

Table 3. Signs and Symptoms with incidence of Macrovascular complications

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

6. Discussion

Among the macrovascular complications, the highest incidence was observed for CAD and PVD (12.5%), followed by CVD (3.5%). Studies conducted in rural India reported the incidence of ischemic heart disease and stroke to be between 7.8% and 11.4%, and 0.5%, respectively [11]. In a study by Agarwal *et al.*, the incidence of PVD by clinical examination was found to be 18.1%, which is in line with our study's findings [12]. The most helpful clinical symptoms for the diagnosis of PVD are the frequency of claudication (likelihood ratio LR-3.30) and any irregularity of the pulse (LR, 3.10). Given that PVD is one of the dangerous consequences of diabetes, patients with a simple history of intermittent claudication and evaluation of peripheral pulses should be referred to higher facilities for further diagnosis [13].

Peripheral neuropathy (57.9%) had the highest incidence of microvascular complications, followed by nephropathy (9%) and diabetic foot (10.2%). Studies in South India have reported a prevalence of peripheral neuropathy ranging from 10.5% to 60.4%. The high occurrence in rural areas may be due to delayed diagnoses, inadequate self-care, or ineffective health-seeking behavior [14,15]. In our study, physicians were trained to use inexpensive, widely applicable equipment such as monofilament and VibraTip for early identification of peripheral neuropathy. Patients diagnosed with peripheral neuropathy received specific training and an awareness program on foot care [16].

Doctors taught patients a practical preventive method to reduce the risk of diabetic foot by instructing them on easy self-foot examination. Studies have shown that the risk of CAD increases with lower education levels, and in diabetic patients, the risk of PVD increases 2.2 times with high waist circumference, a level of abdominal obesity. Similar to our findings, a study found that abdominal obesity indicated by the waist-hip ratio and waist circumference was a significant and independent risk factor for PVD [17]. According to a meta-analysis on diabetic neuropathy, the length of diabetes and HbA1c levels are significantly linked to increased risks of DPN in diabetic individuals [18,19]. In our study, we found a strong relationship between diabetic neuropathy and poor glycemic control and longer duration of diabetes, consistent with studies conducted in India. Men were found to be more likely than females to develop diabetic foot, as noted in a study by Dinh *et al.* [20]. Diabetic foot occurrence was also associated with poor glycemic control.

7. Conclusion

In this study, a high prevalence of vascular complications, particularly diabetic foot, was observed. Simple, efficient, and readily available tools may be adequate for screening for these complications, enabling early detection and referral. The incidence of vascular complications in diabetes was significantly associated with factors such as education level, hypertension, HbA1c, and postprandial blood sugar.

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Conflicts of Interest: "The authors declare that they do not have any conflict of interests."

References

[1] Deepa, M., Bhansali, A., Anjana, R. M., Pradeepa, R., Joshi, S. R., Joshi, P. P., ... & Kaur, T. (2014). 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 4. *Indian Journal of Endocrinology and Metabolism, 18*(3), 379-385.

[2] Nanditha, A., Snehalatha, C., Satheesh, K., Susairaj, P., Simon, M., Vijaya, L., ... & Ramachandran, A. (2019). Secular TRends in DiabEtes in India (STRiDE-I): change in prevalence in 10 years among urban and rural populations in Tamil Nadu. *Diabetes Care, 42*(3), 476-485.

[3] Little, M., Humphries, S., Patel, K., & Dewey, C. (2017). Decoding the type 2 diabetes epidemic in rural India. *Medical Anthropology, 36*(2), 96-110.

[4] Kumar, K. H., Kota, S. K., Basile, A., & Modi, K. D. (2012). Profile of microvascular disease in type 2 diabetes in a tertiary health care hospital in India. *Annals of Medical and Health Sciences Research, 2*(2), 103-108.

[5] Einarson, T. R., Acs, A., Ludwig, C., & Panton, U. H. (2018). Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017. *Cardiovascular Diabetology, 17*(1), 1-19.

[6] Chawla, A., Chawla, R., & Jaggi, S. (2016). Microvasular and macrovascular complications in diabetes mellitus: distinct or continuum?. *Indian Journal of Endocrinology and Metabolism, 20*(4), 546-551.

[7] Pradeepa, R., Anjana, R. M., Unnikrishnan, R., Ganesan, A., Mohan, V., & Rema, M. (2010). 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 Technology & Therapeutics, 12*(10), 755-761.

[8] Casadei, K., & Kiel, J. (2019). Anthropometric measurement. Published January 28, 2020.

[9] Goyal, A., Kahlon, P., Jain, D., Soni, R. K., Gulati, R., Chhabra, S. T., ... & Wander, G. S. (2017). Trend in prevalence of coronary artery disease and risk factors over two decades in rural Punjab. *Heart Asia, 9*(2), e010938.

[10] Tesfaye, S., Boulton, A. J., Dyck, P. J., Freeman, R., Horowitz, M., Kempler, P., ... & Toronto Diabetic Neuropathy Expert Group. (2010). Diabetic neuropathies: update on definitions, diagnostic criteria, estimation of severity, and treatments. *Diabetes Care, 33*(10), 2285-2293.

[11] Mohan, V., Venkatraman, J. V., & Pradeepa, R. (2010). Epidemiology of cardiovascular disease in type 2 diabetes: the Indian scenario. *Journal of Diabetes Science and Technology, 4*(1), 158-170.

[12] Agrawal, R. P., Ranka, M., Beniwal, R., Sharma, S., Purohit, V. P., Kochar, D. K., & Kothari, R. P. (2004). Prevalence of micro and macro vascular complications in type 2 diabetes and their risk factors. *Age, 50*, 12-14.

[13] Khan, N. A., Rahim, S. A., Anand, S. S., Simel, D. L., & Panju, A. (2006). Does the clinical examination predict lower extremity peripheral arterial disease?. *Jama, 295*(5), 536-546.

[14] Pradeepa, R., Rema, M., Vignesh, J., Deepa, M., Deepa, R., & Mohan, V. (2008). Prevalence and risk factors for diabetic neuropathy in an urban south Indian population: the Chennai Urban Rural Epidemiology Study (CURES-55). *Diabetic Medicine, 25*(4), 407-412.

[15] D'Souza, M., Kulkarni, V., Bhaskaran, U., Ahmed, H., Naimish, H., Prakash, A., ... & Kumar, A. (2015). Diabetic peripheral neuropathy and its determinants among patients attending a tertiary health care centre in Mangalore, India. *Journal of Public Health Research, 4*(2), 120-124.

[16] Dixit, S., & Kumar, S. (2014). Awareness of diabetic foot complications in type 2 diabetes population in Rural India: are we doing enough. *Diabetes & Metabolism Journal, 5*(4), 1-2.

[17] Dégano, I. R., Marrugat, J., Grau, M., Salvador-González, B., Ramos, R., Zamora, A., ... & Elosua, R. (2017). The association between education and cardiovascular disease incidence is mediated by hypertension, diabetes, and body mass index. *Scientific Reports, 7*(1), 12370.

[18] Liu, X., Xu, Y., An, M., & Zeng, Q. (2019). The risk factors for diabetic peripheral neuropathy: a meta-analysis. *PloS one, 14*(2), e0212574.

[19] Bansal, D., Gudala, K., Muthyala, H., Esam, H. P., Nayakallu, R., & Bhansali, A. (2014). Prevalence and risk factors of development of peripheral diabetic neuropathy in type 2 diabetes mellitus in a tertiary care setting. *Journal of Diabetes Investigation, 5*(6), 714-721.

[20] Dinh, T., & Veves, A. (2008). The influence of gender as a risk factor in diabetic foot ulceration?. *Wounds: A Compendium of Clinical Research and Practice, 20*(5), 127-131.