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Research Article

PREVALENCE OF DIABETIC NEUROPATHY AND FACTORS ASSOCIATED WITH IT: EXPERIENCE FROM A RURAL TERTIARY CARE HOSPITAL IN WESTERN INDIA

Jyoti G Mannari[1]., Alpa C Leuva[2] and Ajay G Phatak[3]

[1]Department of Medicine. Pramukhswami Medical College. Gokal Nagar, Karamsad, Anand, Gujarat - 388325
[2]Department of Medicine. Pramukhswami Medical College. Gokal Nagar, Karamsad, Anand, Gujarat - 388325
[3]Manager, Central Research Services,CharutarArogya MandalGokal Nagar, Karamsad, Anand, Gujarat - 388325

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ABSTRACT

India has become 'World Capital' of diabetes and coupled with the fact that Indians are genetically weak against metabolic disorders, prevention and management of diabetes pose a formidable challenge.A cross sectional study was conducted to determine the extent of diabetic neuropathy & associated factors as well as its association with other long term complications of diabetes in patients attending diabetes clinic of tertiary care rural teaching hospital in Gujarat, India. Out of 307 consecutive patients attending diabetes clinic from April 2006 to Dec 2007, 287 patients were included in the study. 'Diabetic Neuropathy' was identified when there was loss of vibration sense using 128 MHz tuning fork. Diabetic retinopathy and nephropathy were identified using standard methods.

Of the 287 diabetic patients assessed (169 Males, 118 Females, mean age(SD) 57.8(11.1)), Neuropathy was seen in 128(44.6%) patients. Retinopathy [18% vs.6.4%, Odds Ratio(OR) 3.2, 95% Confidence Interval (1.6, 7.0)] and Nephropathy [10.9% vs. 1.9%., Odds Ratio(OR) 6.3, 95% Confidence Interval (1.8, 22.3)] were more common in patients with Neuropathy as compared to patients without Neuropathy. A multi-variable logistic regression analysis revealed that Duration of diabetes, poor glycemic control and presence of nephropathy are significantly associated with Diabetic neuropathy [Adjusted OR (95% CI) are 1.06 (1.02, 1.1), 1.9(1.1, 3.3) and 6.1(1.3, 28.5)] respectively.

This study indicates high prevalence of diabetic neuropathy. Further studies to find out the hurdles and possible solutions in maintaining good glycemic control are due as it is the only modifiable factor coupled with the fact that diabetic neuropathy is irreversible.

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INTRODUCTION

The twentieth century has experienced unmatched transformation in human health as a result of demographic transition followed by epidemiological transition which started in Europe and subsequently spread across the world. While the disease pattern has shifted from communicable diseases to non-communicable diseases in developed countries, the countries in transition, like India, are facing a double burden in the form of presence of both types of diseases simultaneously (World Health Report, 1999). Diabetes took the form of a pandemic to the extent that people are referring to it as "Diabesity", a syndrome rather than a disease. As per the latest report, there are 285 million people with diabetes in 2010 while projections indicate this figure to reach 439 million in 2030. Unfortunately, 70% of the diabetes patients are from low and middle income countries and largest increase in diabetes population is expected in developing economies (International Diabetes Federation report, 2010).

India has become the 'World Capital' of diabetes. Coupled with the fact that Indians are genetically weak against the metabolic diseases, diabetes and its management pose a public health challenge of the 21st century (Bhatnagar *et al*, 1995; Nakagami *et al*, 2003). Number of people with diabetes in India currently is around 40.9 million and is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken (International Diabetes Federation report, 2010). A national

*Corresponding author: **Jyoti G Mannari***
Department of Medicine. Pramukhswami Medical College. Gokal Nagar, Karamsad, Anand, Gujarat - 388325

survey of diabetes conducted in six major cities in India in the year 2000 has shown that the prevalence of Diabetes in urban Indian adults was 12.1% (Ramachandran *et al*, 2001).

Both micro-vascular and macro-vascular complications cause significant morbidities and mortality among diabetes subjects (Zagar *et al*, 1999).

Diabetic neuropathy is a common complication that causes considerable mortality and morbidity in diabetic patients (Duby *et al*, 2004). A large study done in South India showed 26.1% prevalence of diabetic neuropathy in south Indian type 2 diabetics (Pradeepa*e t al*, 2008). It also increases the risk of other complications like amputations and foot ulcers (Adler *et al*, 1997). The prevalence of diabetic foot was reported to be 3.6% in a Indian clinic based study (Pendsey *et al*, 1994). Further a study from South India revealed that patients without foot problems spent 9.3% of the total income whereas patients with foot problems spent 32.3% of the total income towards treatment (Shobhana *et al*, 2000). It is thus important to prevent this complication of diabetes.

Due to the complex mechanisms involved in the pathogenesis, therapeutic interventions are not much successful making diabetic neuropathy almost irreversible (Pop-Busui *et al*, 2006). This study was conducted to find out the extent of the problem and determine associated factors of diabetic neuropathy in a rural tertiary care teaching hospital viz. Shree Krishna Hospital, Karamsad, Gujarat, India.

The study was approved by the Human Research Ethics Committee of the CharutarArogya Mandal.

MATERIALS AND METHODS

Setting

A cross sectional study was conducted to determine the prevalence of diabetic neuropathy (hereafter referred to as neuropathy) and the associated factors in consecutive patients attending diabetes clinic during April 2006 to December 2007 in a rural tertiary care teaching hospital viz. Shree Krishna Hospital, Karamsad, Gujarat. As the investigations were part of routine care, a verbal consent was obtained from the participants to use the data maintaining confidentiality of the participants.

Study Procedure

Detailed clinical and family history was recorded for each participant. Diabetic peripheral neuropathy was checked by 10 g monofilament (Semmes Weinstein monofilament) and vibration using 128-Hz tuning fork. Monofilament was applied on base of 1st, 3rd and 5th metatarsal heads and planter surface of distal hallux. Area affected by callus and ulceration was avoided. Inability to perceive sensations at one or more than one site was considered abnormal. Assessment of vibration was done with a 128 MHz tuning fork applied over the sole of great toe and the plantar aspect of the 1st ,3rd & 5th metatarsal head in both feet & the dorsum of the great toe. Two out of 5 areas showing loss of vibration sense was labelled as neuropathic feet.

The response was considered abnormal when the patient loses the vibratory sensation but examiner still feels it while holding the tuning fork on the tip of his/her own toe.

Diabetic Nephropathy was diagnosed by presence of Microalbuminuria by Immunoturbidometry method using COBAS in 3 hrs urine collected after discarding the first morning urine sample. Diabetic Retinopathy was diagnosed by a fundus examination done by an Ophthalmologist and patients were graded according to International classification of diabetic retinopathy and diabetic macular oedema severity scale.

The glycemic control was assessed by an HbA1c, using COBAS. HbA1c ≤ 7 was considered as good glycemic control while HbA1c ≥ 7 was considered as poor glycemic control (AMERICAN DIABETES ASSOCIATION position statement - Standards of Medical Care in Diabetes, 2009). Blood pressure was recorded in the sitting position after resting for at least 5 minutes in the right arm to the nearest 2 mmHg with a mercury sphygmomanometer (Diamond Deluxe BP apparatus; Diamond Deluxe, India). Hypertension was diagnosed if subjects were on anti-hypertensive medication or had systolic blood pressure (SBP) $\geq$ 130 mmHg or diastolic blood pressure (DBP)$\geq$80 mmHg (National High Blood Pressure Education Program, 2003).

The information regarding history of walking bare foot and the type of foot-wear was recorded based on the participant's response to the question what he/she generally wear outside home. The type of foot-wear was classified as open (Chappal), semi-open(sandles) or well protected(shoes).

Statistical Analysis

Out of 307 patients who visited the diabetes clinic during the study period, 11 patients refused to participate in the study despite counseling while 9 patients did not turn up for the laboratory investigations. These 20 patients were not included in the analysis. Descriptive statistics were used to portray the socio-demographic and clinical profile of the participants. Associations were examined using student's t test or Chi square test depending upon the nature of the variables involved. Multi-variable logistic regression analysis was performed to segregate the independent effect of each factor with diabetic neuropathy. The analysis were performed using STATA(14.2) and P-values <0.05 were considered significant.

RESULTS

Out of 307 participants, all relevant information could be elicited for 287 participants. The baseline attributes of the non-participants were similar to the participants. Out of the 287 participants, 18 had type 1 diabetes while 269 had type 2 diabetes. The participants included 169 males and 118 females. The mean (SD) age of the participants was 57.81 (11.1) years whereas the range was 20 - 89 years. The median duration of the diabetes was 7 years with only 25% participants had diabetes diagnosed for more than 12 years.

The overall prevalence of diabetic neuropathy was 44.6% (95 % Confidence Interval [CI]: 38.76, 50.55). Males had higher prevalence of neuropathy as compared to females (50.3 vs. 36.4%, P = 0.02). Overall prevalence of neuropathy in participants with known diabetes was 47.6 % (95%CI: 41.23, 53.99) while it was significantly lower 25.6% (95%CI: 13.04, 42.13) in participants who were diagnosed for diabetes during the study (p = 0.014). **[Table 1]**

Table-1 Prevalence of Diabetic Neuropathy

	Male				Female			
	N	Patients with Neuropathy	%	95% CI	N	Patients with Neuropathy	%	95%CI
Total (287)	**169**	**85**	**50.3**	**42.52, 58.07**	**118**	**43**	**36.4**	**27.78, 45.80**
Known Diabetic (248)	147	78	53.06	44.66, 61.33	101	40	39.6	30.01, 49.83
Newly Detected Diabetics (39)	22	7	31.82	13.86, 54.87	17	3	17.65	3.80, 43.43

The age wise overall prevalence of microvascular complications are shown in **Figure 1**. The overall prevalence of diabetic nephropathy was 5.9% (95% CI: 3.49, 9.31) whereas the overall prevalence of diabetic retinopathy was 11.5% (8.05, 15.77). Diabetic neuropathy was commonest microvascular complication in the study participants and an increasing trend was observed in its prevalence with respect to age.

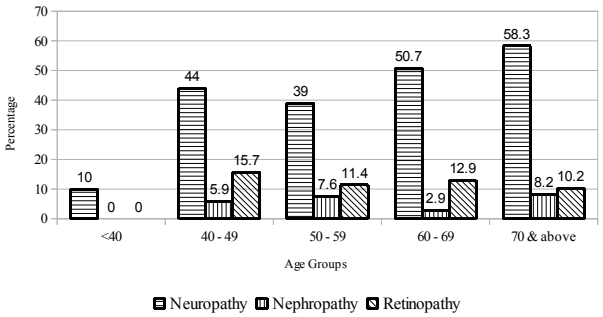

Figure 1 Age wise prevalence of microvascular complications in diabetes.

Diabetic participants with neuropathy were older (p=0.01) and longer duration of diabetes (p <0.001). The prevalence of diabetic retinopathy (18 vs. 6.4%, p=0.002) and nephropathy (10.9 vs 1.9%, p=0.001) was higher in participants with neuropathy as compared to those without, whereas the difference in the prevalence of hypertension failed to attain statistical significance. Participants with good glycemic control had lower prevalence of diabetic neuropathy as compared to those who had unsatisfactory glycemic control (29.1 vs. 47.1%, p=0.002). The practice of bare foot walking was not significantly different in the participants with or without neuropathy (p = 0.59). **[Table 2]**

Table 2 Demographic and clinical profile of the participants

Variables	Participants with Diabetic Neuropathy	Participants without Diabetic Neuropathy	P value
	Mean (SD)	**Mean (SD)**	
Age	59.76 (10.82)	56.17 (11.11)	0.01
Duration	10.84 (8.96)	6.96 (7.14)	<0.0001
	N (%)	**N (%)**	
History of walking barefoot	27 (22.3)	37 (25.2)	0.59
Hypertension	77 (60.2)	76 (48.7)	0.054
Retinopathy	23 (18)	10 (6.4)	0.002
Nephropathy	14 (10.9)	3 (1.9)	0.001
Glycemic Control (Good)	37 (29.1)	73 (47.1)	0.002

Only 111 (39%) out of 287 participants had good glycemic control. Very few participants (23.7%) without neuropathy used semi open or closed foot-wear. Surprisingly this proportion was similar (28.9%) in participants with neuropathy. Multivariable logistic regression using 'Diabetic neuropathy' as a dependent variable reveled that duration of diabetes (p=0.001), glycemic control (p=0.022) and Nephropathy (p=0.021) were significantly associated with neuropathy even after adjusting for possible confounders. The predictive power of the logistic model was quite fair with about 70% overall correct classification rate. **[Table 3]**

Table 3 Logistic Regression Analysis using neuropathy as a dependent variable

Factors	Adjusted OR*	95% CI	P value
Duration of DM	1.06	1.02 , 1.1	0.001
Glycemic Control:			
Good	1	Reference category	
Poor	1.9	1.1-3.3	0.022
Nephropathy:			
No	1	Reference category	
Yes	6.1	1.3-28.5	0.02

* Odds Ratios adjusted for Age, Sex, Duration of Diabetes, Glycemic control, Retinopathy, Nephropathy, Hypertension, Type of foot wear, History of walking bare foot.

DISCUSSION

High prevalence and implications

In this study population, the overall prevalence of diabetic neuropathy (44.6%) was very high. This prevalence may be argued to be inflated due to study settings (clinic based study) and at the same time counter argued to be underestimated due to study tool (Tuning Fork). It is thus difficult to compare the prevalence between studies due to differences in study settings, study populations and diagnostic criteria used to diagnose neuropathy. Despite the fact that Nerve Conduction Studies (NCS) using high fidelity gadgets are most accurate methods of diagnosing diabetic neuropathy as of today, these methods have their own limitations with respect to cost, infrastructure requirements and simplicity. Although NCS may be essential in controlled clinical trials, simple, rapid and cheaper methods are well established for screening diabetic patients for neuropathy (Olaleye *et al*, 2001). Vibration sensation with a tuning fork and Semmes-Weinstein Monofilament are validated for detecting neuropathy both in Western and Indian populations. The characteristics like sensitivity, specificity and predictive values are comparable between these methods (Perkins *et al*, 2003; Jayprakash *et al*, 2011).

But beyond minute discrepancies related to study settings, study tools and study populations, prevalence studies provide a reasonable estimate of the magnitude of the problem in the society. In a similar study in Karachi, Pakistan, the prevalence of neuropathy was estimated to be 39.6% which is very close to estimated prevalence in this study (Shera *et al*, 2004). Interestingly, a "Clinic Based" study in 1999 in Chennai reported prevalence of neuropathy to be 27.5% which was attained in a population based study by conducted in 2003 (Joshi *et al*, 2008). In this region the population is predominantly vegetarian and vitamin B_{12} deficiency is rampant. This may explain at least in part the high prevalence

of neuropathy but because of cost constraint, we were unable to check B_{12} levels in the participants. The high prevalence of diabetic neuropathy is of concern although Indians have lower rates of diabetic neuropathy as compared to Europeans (15% vs. 20%), despite having greater risk of cardiovascular diseases as reported by Abbott CA *et al*. in a population based sample (Abbott *et al*, 2010). Coupled with the fact that India is a diabetes capital of the world, diabetes complications pose a formidable public health challenge for decades to come.

Associated factors

There had been efforts to identify the associated factors for various micro-vascular complications. Comparison of such studies involve the same challenges like study setting, diagnostic tool etc. In the present study; duration of diabetes, glycemic control and nephropathy came up as significantly associated factors with neuropathy while similar study from Karachi, Pakistan (Shera *et al*, 2004) reported gender and glycemic control as significantly associated factors with neuropathy. Janghorbani M *et al*. (Janghorbani*et al*, 2006) concluded age, duration of diabetes and nephropathy to be associated with neuropathy while a population based study from Chennai reported age, duration and glycemic control to be associated with neuropathy (Pradeepa *et al*, 2008). It is indeed difficult to explain biological pathways for the association between nephropathy and neuropathy found in the present study. Probably both are the effects of poor glycemic control over a long duration. It is clear that duration of diabetes and glycemic control are the common factors reported by most of the studies. Moreover only glycemic control is the modifiable factor which may help in averting microvascular complications.

Status of diabetes control and future direction

Overall glycemic control was very poor in the present study with 61% participants having unacceptable glycemic control. This finding is neither new nor unexpected. Similar finding is reported by many studies conducted in Asia. Raheja *et al*. reported poor glycemic control in more than half participants in 2001 (Raheja *et al*, 2001] and situation did not change much till date (Pradeepa *et al*, 2008; Janghorbani *et al*, 2006; Shera *et al*, 2004; Jayprakash *et al*, 2011). Joshi SR *et al*. (Joshi *et al*, 2008) hinted at *clinical inertia* for the lack of tight control but socio-political inertia also contributed a lot in this regard. Diabetes care and management is an artful combination of pharmacotherapy and lifestyle modification. The later part is very hard to achieve as it requires sustained behavioral changes. Kapur K *et al*. (Kapur *et al*, 2008) concluded that barriers in modifying dietary behavior that are related to life circumstance are mostly non-modifiable and advocated improving counseling skills of health care provider. Behavior change requires diligent motivation and conducive environment. Clinicians need to come out of their closets (clinic) and try to develop and establish models for sustainable behavioral change by including dieticians, physical therapists and social scientists in the care giving team. At a societal level persistently advocating food labeling, pricing, availability and nutritional quality control is needed.

A diabetes club has been established to develop one such model at Shree Krishna Hospital where diabetes care is decentralized from the clinic and the clinicians work in a team to achieve tight control in patients suffering from diabetes mellitus through sustainable behavior change. The initial results are encouraging suggesting replicability of such hospital based model and viability of developing such model in the population.

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