

# Prevalence of Certain Chronic Complications of Diabetes among Type 2 Diabetic Patients in Rural Population of Kancheepuram District, Tamil Nadu- A Cross Sectional Study

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## ABSTRACT

**Background:** Nearly 50% of diabetics in India are undiagnosed and that the newly diagnosed diabetes patients are often found to have signs of complications. **Objectives:** To estimate the prevalence of diabetic complications, other than retinopathy and peripheral vascular disease, among known diabetic patients treated at healthcare centers in Kancheepuram district of Tamil Nadu; and to analyze the associations between chronic complications and patient's demographics, T2DM characteristics. **Methodology:** A cross sectional study was carried out in sixteen out of fifty six health care centers in Kancheepuram district in Tamil Nadu by cluster sampling method using the semi-structured questionnaire, with medical record, physical examination and biochemical investigation to identify chronic kidney disease and co-morbid conditions of type 2 diabetes. A Disability Neuropathy Score (DNS) of more than zero and negative monofilament/vibration tests were used to classify patients as having signs of peripheral neuropathy. **Results:** Prevalence of Ischemic heart disease and stroke were 7.8% and 0.5% respectively. Prevalence of stage I kidney disease based on the KDO-QI guidelines using the estimated GFR and urine PCR values was 30.7% , while chronic kidney disease (i.e., stage II or III or PCR>0.2) was seen in 10.4% patients. Based on the DNS scoring chart 59% of them had peripheral neuropathy while 19% of them had signs of peripheral neuropathy. Participants with at least one chronic complication of diabetes (excluding retinopathy) were 32.8 percent. Prevalence of hypertension was 61.4%. and Hyperlipidemia was 85.9% ,while high LDL, TGL was seen with 60.9% and 64.6% respectively, low HDL among 83.9 % of patient. **Conclusion:** The high prevalence of undiagnosed microvascular complications in known diabetics treated at primary care emphasis a strong need for routine screening for complications of diabetes and to create awareness on its early detection and prevention of progression.

**Key words:** Prevalence, Type 2 diabetes complications, peripheral neuropathy, chronic kidney disease, primary health centre.

## INTRODUCTION

The type 2 diabetes (T2DM) being the most common type of diabetes has a relatively asymptomatic phase between the actual onset of the condition and its clinical diagnosis which is estimated to 4-7 years.<sup>1,2</sup> The diabetics in low and middle income countries who contribute to 70% of diabetics have limited access to diabetic care.<sup>3</sup> As a progressive disease diabetic patients are frequently diagnosed with chronic complications including cardiovascular disease, nephropathy, coronary heart disease, retinopathy, and neuropathy. The prevalence of these complications of diabetes is generally expected to be proportional with the duration of diabetes and degree of glycemic control.<sup>4</sup> This is of concern as 50% of diabetics in India are undiagnosed<sup>5</sup> and that the newly diagnosed diabetes patients are often found to have signs of these complications. Late or undiagnosed cases become victims of diabetic complications early in their life which are directly

responsible for poor quality of life, economical catastrophe, premature death and incur heavy burden to the health care system.<sup>3</sup> Diabetes mellitus basically produces changes in the blood vessels and therefore affect almost every part of the body. Diabetic nephropathy has become a world epidemic accounting for one third of all cases of End Stage Renal Disease worldwide.<sup>5</sup> More than half of non-traumatic amputations are due to diabetic complication. About 11% of total health expenditure for adults in the world is spent on diabetics.<sup>6</sup> A significant economical burden is imposed on both the state and the individual for treatment of diabetic complications.

India has a prevalence of 8.7%, higher than the world prevalence. Every seventh type 2 diabetes patient in the world is an Indian.<sup>7</sup> A quarter of all diabetic deaths happen in India. Study by Mohan *et al* (CUPS study) has shown that mortality rates are twofold higher in diabetic people when compared to non-

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diabetics in India<sup>8</sup> and two studies done in India showed that diabetes related deaths in India is dominated by infections and renal failure unlike cardiovascular or cerebrovascular causes which dominate the developed countries.<sup>9, 10</sup> The type 2 diabetes burden in India is escalating, more prevalent in the southern region of the country primarily due to changes in socioeconomic conditions, dietary habits and reduced physical activity.<sup>11</sup> South India is a high carbohydrate consuming region with rice being their predominant food intake. Studies by Mohan *et al* in 1998 showed that complications were quite high even at the time of diagnosis of diabetes probably due to its insidious onset and long duration of asymptomatic disease before symptoms develop. In most cases the first presentation of diabetes would be associated with its complication.

Information on the prevalence of T2DM related complications is helpful in aiding adjustments in policies and practices in diabetic care management to gain better control of T2DM and this study was aimed at describing the prevalence of diabetic complications, other than diabetic retinopathy and peripheral vascular disease, among known diabetic patients treated at healthcare centers in Kancheepuram district of Tamil Nadu; and to analyze the associations between chronic complications and patient's demographics, T2DM characteristics.

## METHODOLOGY

A cross sectional study was carried out in sixteen out of the total fifty six health care centers in Kancheepuram district in Tamil Nadu using cluster sampling method, considering each primary care centers as a cluster. Twelve consecutive outpatients in each of the hospital who were willing to participate in the study and fulfilled the inclusion criteria of being a known case of diabetic and treated at the hospital were included in the study making into the required sample size of 192 estimated with assumption of proportion of 27% {Prevalence and risk factors for diabetic neuropathy in an urban south Indian population: the Chennai Urban Rural Epidemiology Study (CURES-55) Pradeep *et al*, 2008}, CI-95% and an absolute precision of  $\pm 7$  percent and 20% non response rate. The study was done between February-April 2013. The participants were given detailed information about the study. The subjects were interviewed using the semi-structured questionnaire to capture information about demographics, personal and medical history. Medical records and prescription review were done to know if they had cardiovascular and cerebrovascular complications. We also took their anthropometric measurements and blood pressure. Blood samples (5ml) were collected from all the subjects for testing blood sugar levels, serum creatinine and lipid levels. Also spot urine was collected to test for urine sugar and protein. Those samples which tested positive for urine protein were transported to laboratory for further investigation. Testing for retinopathy was not included in the study.

The complications of Ischemic Heart Disease and Stroke were identified from Patient's past medical history and review of medical records. To identify patients with Chronic Kidney Disease measurements of both serum creatinine and protein positive urine samples were taken and used the serum creatinine levels to calculate eGFR using the MDRD (Modification of Diet in Renal Disease) formula<sup>12</sup>. Urine levels of protein and creatinine were also used to calculate Protein-Creatinine Ratio (PCR). The KDOQI guidelines were used for staging of renal disease and chronic kidney disease.<sup>13</sup>

To identify Peripheral Neuropathy, patient were interviewed in person about their symptoms such as feeling of pins and needles, sharp pain, aching pain, numbness in their legs/feet and examined for vibratory sensation perception using 128-Hz tuning fork placed on bony prominence at the dorsum of great toe and both malleoli. Superficial sensation was tested using the 10-g Semmes-Weinstein monofilament over six

areas of feet for all the study participants. A Disability Neuropathy Score (DNS) of more than zero and negative monofilament/vibration tests were used to classify patients as having signs of peripheral neuropathy.

Patients with TGL levels >150 mg/dl or calculated LDL levels >100 mg/dl or HDL <40 mg/dl for males and <50 mg/dl for females were classified as having dyslipidemia.

Patients with known history of hypertension or with a systolic blood pressure of  $\geq 140$  mm of Hg or with a diastolic blood pressure of  $\geq 90$  mm of Hg, measured using a standard sphygmomanometer on the right arm in sitting position after making sure the patient had at least rested 10- 15 minutes on reaching the hospital, were considered as those with hypertension. All individuals included in the study provided written informed consent. The study was approved by the Institutional Ethics Committee.

Data were analyzed using Microsoft excel and Epi info 3.5.3. Descriptive data were presented as mean and proportion. A univariate analysis was used to derive at unadjusted odds ratios (OR) to measure the strength of association with 95% confidence intervals and multivariate analysis to derive at the adjusted odds ratio with 95% confidence interval. Chi-square test was used to lend statistical support to prove associations between categorical variables. Mann-Whitney test and modified t test were used to the relationship between continuous variable.

## RESULTS

### *Socio-demographic profile of the study participants*

A total of 192 patients were included in the study based on the inclusion criteria, of which 77.1 % ( 148/192) were women and 22.9 % ( 44/192) were men. About 81% (183/192) were above the age of 40 years. While 42.7 % ( 82/192) of them were uneducated, the retired/jobless and homemakers combined to make up 76 % ( 146/192) of the study population. Although tobacco usage and alcohol consumption were 21.8% (42/192) and 12.5 % ( 24/192) respectively, there was a higher percentage (around 63%) of them who persisted with their habits even after being diagnosed with diabetes. A positive family history of diabetes was seen with 35.4% (68/192) of the study population. About 85 % ( 164/192) said it took not more than 30 minutes to reach their health care center from home and 45% came by walk. Nearly 44.8 % ( 86/192) of the study population had a body mass index (BMI) of over 25kg/m<sup>2</sup> thus getting classified as obese. About 54.7 % ( 105/192) of them said they adhered to diabetic diet and 34.9 % ( 67/192) had said they have increased their physical activity after being diagnosed with diabetes.

### *Prevalence of chronic complications of diabetes and co-morbidities*

Table 1 depicts the prevalence of chronic complications of diabetes and co-morbidities. The prevalence of Ischemic heart disease and stroke were 7.8% (95% CI= 4.02-11.60) and 0.5% (0.17-3.33) respectively. The prevalence of kidney disease based on the KDOQI guidelines using the estimated GFR and urine PCR values, 30.7% ( 95% CI= 23.52-37.92) of the study population had stage I disease while chronic kidney disease (i.e., stage II or III or PCR>0.2) was seen in 10.4% patients. Based on the DNS scoring chart 59% ( 95% CI= 51.62 - 67.13) of the study population interviewed fell into the category of having symptoms of peripheral neuropathy while the monofilament/vibration test done on each of the study participants gave prevalence of 19% (95% CI= 10.89-26.61) for peripheral neuropathy. The total number of study participants with at least one chronic complication of diabetes (excluding retinopathy) was 32.8 percent. The prevalence of co-morbid hypertension among the diabetic study population was 61.4% (95% CI= 53.21-69.70) out of which 13 % (95% CI= 7.18- 18.86) were newly diagnosed during the study. Hyperlipidemia was prevalent among 85.9% (165/192) of the study

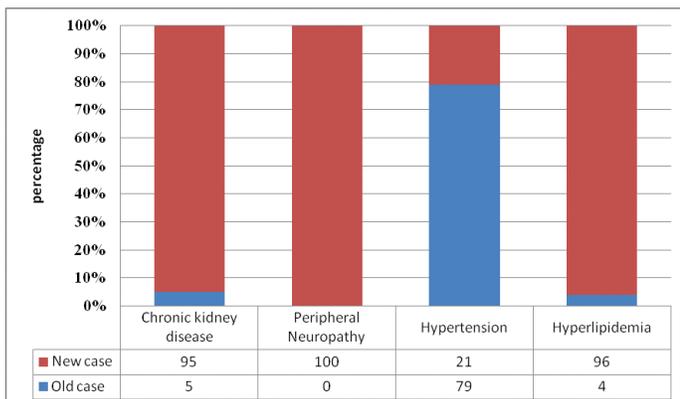
**Table 1: Prevalence of chronic complications and co-morbidities among type 2 diabetes patients (n=192)**

Complications/Co-morbidities	No.	Prevalence (%)	95% CI
Ischemic heart disease	15	(7.8)	4.02-11.60
Stroke	2	(0.5)	0.17-3.33
<b>Kidney disease</b>			
Stage I (eGFR 60-89)	59	(30.7)	23.52-37.92
Stage II (eGFR 30-59)	10	(5.2)	2.45-7.95
Stage III (eGFR 15-29)	1	(0.5)	0.02-2.49
PCR>0.2	11	(5.7)	2.60-8.85
eGFR<60 or PCR>0.2	20	(10.4)	4.68-16.14
<b>Peripheral neuropathy</b>			
Positive Monofilament/ Vibration test	36	(18.8)	10.89-26.61
DNS score>0 (only)	114	(59.4)	51.62-67.13
<b>Hypertension</b>			
Known hypertensive's	93	(48.4)	40.13-56.74
Newly detected hypertensive's	25	(13.0)	7.18-18.86
Total hypertensive's	118	(61.5)	53.21-69.70
<b>Dyslipidemia</b>			
High Total Cholesterol( ≥200 mg/dl)	87	(45.3)	36.73-53.88
High TGL( ≥150 mg/dl)	117	(60.9)	53.55-68.31
High LDL (≥100 mg/dl)	124	(64.6)	61.27-76.50
High Non-HDL (≥130 mg/dl)	138	(71.9)	62.86-80.88
Low HDL ≤ 40 for males and ≤ 50 for females	161	(83.9)	76.16-91.54
<b>Any one complication#</b>	63	(32.8)	26.20-39.90

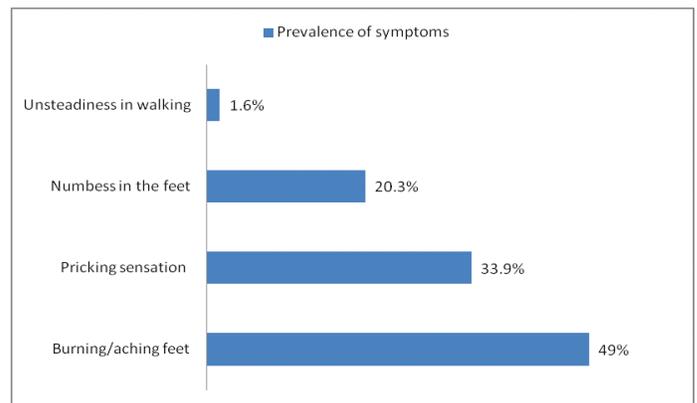
#- IHD or stroke or CKD or peripheral neuropathy

population. While high LDL, TGL was seen with 60.9% and 64.6% respectively, low HDL was seen among 83.9 % of these diabetics.

Figure 1 depicts newly detected complications and co-morbidities among diabetes patients. A large proportion of diabetic complications such as chronic kidney disease 19 out of 20 cases of chronic kidney diseases were newly detected cases (95%), all 36 peripheral neuropathy cases detected were new cases (100%) and 96% of hyperlipidemia cases detected were new cases while a large proportion of the total hypertensive's were known/ old cases.



**Figure 1:** The proportion of newly detected diabetic complications and co-morbidities among all T2DM patients treated at health care centers



**Figure 2:** Prevalence of symptoms of peripheral neuropathy among T2DM patients treated at health care centers

Table 2 shows the mean parameters of diabetic patients with and without peripheral neuropathy and chronic kidney disease. While increasing age ( $60 \pm 10.59$ ) was significantly associated with peripheral neuropathy, high total cholesterol ( $220 \pm 69.78$ ) high TGL (248) and Non-HDL levels ( $182.65 \pm 65$ ) were significantly associated with chronic kidney disease. Patients with higher duration of diabetes and those who had longer duration of travel to the health care center had significantly higher association with chronic kidney disease. The mean duration of diabetes was seen to be higher both in those who had peripheral neuropathy and chronic kidney disease when compared to those who did not, although not statistically significant.

**Table 2: Mean parameters of patients with peripheral neuropathy and chronic kidney diseases among T2DM patients treated at the health care centers**

Variables	Peripheral neuropathy		Chronic kidney disease	
	Present (n=36)	Absent (n=156)	Present (n=20)	Absent (n=172)
Age, yrs	60.13 ± 10.59 <sup>s</sup>	54.98 ± 10.15	56.40 ± 10.35	55.9 ± 10.44
BMI, kg/m <sup>2</sup>	24.00 ± 4.52 <sup>s</sup>	25.04 ± 4.02	24.13 ± 3.37	24.93 ± 4.20
SBP, mm Hg	133.22 ± 20.10	128.76 ± 18.51	130.5 ± 20.89	129.5 ± 18.65
DBP, mm Hg	80.72 ± 10.55	79.20 ± 11.12	79.4 ± 11.57	79.5 ± 10.97
DM duration, months	48 <sup>*</sup>	36	48 <sup>*s</sup>	36
TC, mm/dl	198.97 ± 56.56	195.09 ± 45.49	220 ± 69.78 <sup>*s</sup>	193 ± 43.76
LDL, mm/dl	109.93 ± 28.63	116.72 ± 36.96	121.93 ± 63.55 <sup>#</sup>	114.89 ± 32.17
TGL, mm/dl	242.75 ± 232.74 <sup>*</sup>	203.58 ± 110.93	248 <sup>s</sup>	179
Non-HDL, mm/dl	158.69 ± 54.96	156.63 ± 42.93	182.65 ± 65.05 <sup>*s</sup>	154.04 ± 41.64
Travel time to PHC, minutes	26.94 ± 22.1	24.13 ± 16.79	32.5 ± 27.26 <sup>*s</sup>	23.75 ± 16.33

\*- Mann-Whitney test

#- Modified t test

\$- Significant value

**Table 3: Association between presence of at least one complication and risk factors for complication among the T2DM patients treated at health care centers**

Characteristics	At least one complication		Crude OR	95% CI	P value	Adjusted OR	95% CI	P value
	Present (n=63)	Absent (n=129)						
		Age						
>56 yrs	38	54	2.10	1.13-3.92	0.017	1.28	0.59-2.77	0.52
≤56 yrs	25	75						
		Sex						
Male	16	28	1.22	0.59-2.48	0.568	0.76	0.27-2.19	0.61
Female	47	101						
		BMI						
<23 kg/m <sup>2</sup>	30	42	1.87	1.00-3.49	0.044	0.53	0.84-3.62	0.14
≥23 kg/m <sup>2</sup>	33	87						
		Duration of Diabetes						
>36 mths	39	56	2.10	1.14-3.94	0.017	2.05	0.97-4.34	0.06
≤36 mths	24	73						
		Tobacco Usage						
Yes	16	26	1.34	0.64-2.74	0.410	1.57	0.63-3.90	0.33
No	47	103						
		Glycemic control						
No	45	83	1.38	0.72-2.70	0.328	1.09	0.52-2.31	0.81
Yes	18	46						
		High LDL						
Yes	34	90	0.631	0.32-1.24	0.175	0.52	0.24-1.11	0.09
No	21	35						
		High TGL						
Yes	43	74	1.59	0.84-3.05	0.147	1.64	0.80-3.78	0.18
No	20	55						
		Low HDL						
Yes	53	108	1.03	0.45-2.43	0.942	0.92	0.35-2.44	0.86
No	10	21						
		LSM advice						
Not given	19	22	2.09	1.02-4.27	0.039	2.38	1.01-5.61	0.04
Given	44	107						
		Adherence to diabetic food						
No	30	57	1.14	0.62-2.10	0.653	0.83	0.39-1.78	0.64
Yes	33	72						

Table 3 shows the association between presence of at least one complication and risk factors for diabetic complications. The univariate analysis with risk factors for diabetic complications showed that elderly (over 56 years) had two times the odds of getting at least one complication of diabetes, similarly those with increased duration of diabetes (more than 36 months) had two times the odds and those who did not get any advice on life style modification also had twice the odds of getting at least one complication of diabetes. Strangely, those with lower BMI had significantly higher chances of getting at least one complication of diabetes. But on adjusted odds ratio, only those who did not receive any advice on life style modification were found to be significantly associated to have at least one complication of diabetes.

## DISCUSSION

The chronic complications have a significant role in the T2DM related morbidity and mortality, and the burden it impinges on the health care resources.<sup>3</sup> Hence it is important to understand the epidemiology of T2DM complications and its co-morbidities. This paper looks into the prevalence of chronic complications of diabetes (excluding retinopathy) among type 2 diabetic patients treated at health care centers in Kancheepuram district of Tamil Nadu. To our knowledge, this could be the first report made for estimating the prevalence of complications of diabetic in health care centers in rural areas of Tamil Nadu.

In this study, the observation that nearly 9% of the participants were below 40 years of age has stood by the fact that Indians have a higher chance of getting diabetes at an earlier age when compared to other population in the world.<sup>14</sup>

Prevalence of peripheral neuropathy diagnosed using the monofilament and vibration tests of 18.75%, consistent to the study done by Ashok among patients attending a diabetic clinic in south India using biothesiometry<sup>15</sup> while it was lower than in Pakistan which gave a higher prevalence of 39.6%.<sup>16</sup> The mean age of those patients with neuropathy was older (60.13 years compared to patients without neuropathy (54.98 years) it was statistically significant ( $p < 0.05$ ). The DNS score chart that scores the patient based on his/her symptom of peripheral neuropathy gave a prevalence of 59.3% among the study population which was higher than a similar study done in 2011 at Benghazi, Libya which showed a prevalence of 47.1% for peripheral neuropathy,<sup>17</sup> Detecting neuropathy earlier will prevent varying number of foot complications and hospitalization.<sup>18</sup> In our current study we observed that none of the patients who were screened and diagnosed with neuropathy had previously been diagnosed. Studies by Litzelman and Rith-Najarian reported that in intervention groups there was significant reduction of serious foot ulceration.<sup>19,20</sup>

The prevalence of chronic kidney disease (eGFR < 60 ml/mt per 1.73m<sup>2</sup> and/or urine PCR > 0.2)<sup>[21,22]</sup> was 10.41% and that of early stage renal disease (Stage I)<sup>23</sup> was 30.72%. Asian studies done among general population had shown prevalence of CKD to be 3-5% in southern China, 13% in southern Taiwan, 9.2% in Japan and 5.2% in Indonesia.<sup>24</sup> The community in Delhi on the prevalence of low eGFR was 4.2%.<sup>25</sup> Study done by Weiping Jia among diabetic patients in China revealed a prevalence of 29.6%<sup>26</sup> and a global prevalence of 22%<sup>27</sup> for CKD. A similar study done by Chadban *et al* in Australia<sup>28</sup> had a prevalence of 11.2% for eGFR < 60 ml/mt per 1.73m<sup>2</sup>. Most of the studies on nephropathy had been done using microalbuminuria and macroalbuminuria measurements or by calculating the urine albumin creatinine ratio. With diabetic nephropathy being the leading cause of end-stage renal disease worldwide and microalbuminuria being considered an important predictor for cardiovascular disease,<sup>29</sup> it is vital therefore to catch them early and treat to prevent any progression of the condition. The prevalence of ischemic heart disease of

7.8% was less compared to 14.9% stated by a study done in Libya,<sup>17</sup> 22% in a study done in Pakistan<sup>14</sup> and 32.3% as in a study done at Goa.<sup>28</sup> The CUPS study done in Chennai revealed a prevalence of 21.4% for coronary artery disease.<sup>29</sup> The prevalence of stroke was also seen high in the Pakistan study<sup>16</sup> when compared to the current study which has given a prevalence of 1.02%. Hypoglycemia is not just a problem for that day of its occurrence, the counter regulatory response it initiates has shown to increase cardiac risk, cerebral ischemia, stroke.<sup>30</sup> Recent studies by Khunti *et al* and Hanfeld *et al* in diabetic care have identified hypoglycemia to have a strong association with macrovascular events, unfavorable clinical outcomes and mortality. Prevalence of at least one diabetic complication is 32.8% in our study. The age and duration of diabetes was significantly higher ( $p < 0.05$ ) among those with at least one complication. This study has observed that people who did not get LSM advice had statistically significant association of developing at least one of the chronic complications of diabetes.

## CONCLUSION

In summary, our study has observed that the prevalence of diabetic neuropathy among patients treated at health care centers 59% based on DNS scoring chart. The prevalence of diabetic nephropathy was 30.7 percent. More than 90% of both these microvascular complications in our study population were newly diagnosed. It is thus quite evident that there is a strong need for routine screening mechanism at the primary care level, not only for early detection but also for prevention of their progression. Also the fact that lack of LSM advice is a significant risk factor advocates the need for promoting more awareness on complications of diabetes and ways to prevent them.

## Limitations

Taking into consideration of the cost constraints certain diabetic complications such as peripheral vascular disease and diabetic retinopathy were not covered in this study.

## ACKNOWLEDGEMENT

Nil

## CONFLICT OF INTEREST

Nil

## ABBREVIATIONS USED

KDOQI: Kidney Disease Outcomes Quality Initiative; DNS: Diabetic Neuropathy Symptom Score; LDL: Low Density Lipids; HDL: High Density Lipids; TGL: Triglycerides; EGFR: Estimated Glomerular Filtration rate.

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