EPIDEMIOLOGY OF DIABETIC NEPHROPATHY IN THE POOR PATIENTS FROM RURAL SOUTH-EAST INDIA

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Abstract: Diabetic nephropathy has become a highly prevalent health problem in the poor patients. Left untreated, it progresses inexorably to greater levels of severity at variable rates. The aim of this study was to assess primary care processes and clinical characteristics of nephropathy with type2 diabetes in representative sample of Warangal city in south-east India who were receiving their routine treatment in government hospital. A structured questionnaire was used to obtain details on demography, occupation, family income, medical history, depression, physical activity, dietary pattern, laboratory test which includes blood glucose test, blood pressure, microalbuminuria test, etc. The prevalence of diabetic nephropathy in poor patients was found to be 17.14%. The first analysis was carried out using occupation and employment status as a marker for socio-economic status. About 80.6% and 69.9% patients were uneducated and unemployed respectively. Those who are employed, 88.3% of them had a monthly income of <100 US$. The frequency table for gender showed 59.2% of female patients with diabetic nephropathy. The study has revealed many risk factors found in these poor patients associated with the treatment adherence of diabetic nephropathy and were compared with the progression of microalbuminuria, which includes intake of crude alcohol & animal protein, tobacco chewing, smoking, poverty, poor medicine compliance. The treatment regimen in these patients showed a significant decrease of P< 0.05 in microalbuminuria with antihypertensive drugs like ACE Inhibitors and antidiabetic drugs like glibenclamide. These preliminary data suggest that prevalence of diabetic nephropathy in poor patients is increased due to lack of patient care and reduced quality of life. The data can be used as an excellent tool for local quality improvement and to advice the government on diabetic care in poor patients.

Keywords: Diabetic nephropathy, microalbuminuria, poor patients, medicine compliance.

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INTRODUCTION:

India today bears the burden of both communicable and non-communicable diseases. Along with the wide prevalence of infectious diseases like tuberculosis, malaria, pneumonia, HIV/AIDS, hitherto neglected ailments like diabetes are likely to assume endemic proportions. It is expected that the country would have a population of around 57.2 million diabetic patients by the year 2025, many of whom would be adults in the working age. (Pradeepa R., et al., 2002)

In India, diabetic nephropathy is expected to develop in 6.6 million of the 30 million patients suffering from diabetes. Diabetic nephropathy is a complication of diabetes that is caused by uncontrolled high blood sugar. It is a clinical syndrome, typically defined by either macroalbuminuria-that is, a urinary albumin excretion of greater than 300mg in 24-hour collection, or by abnormal renal function as represented by an abnormality in serum creatinine, calculated by creatinine clearance, or glomerular filtration rate(GFR). (Diabetic Nephropathy, 2004) Indians have a highest prevalence of diabetes in world and an excess of avoidable complications and early death. Many of these complications can be reduced with appropriate community-based primary health care interventions. (Ranjith U., et al., 2007; Prakash J., et al., 2006; Ramchandran A., et al., 2002.)

There is growing evidence that a structured approach to caring for people with chronic conditions can significantly improve patient satisfaction and quality of life which in fact improves the clinical outcomes. A number of studies have addressed this issue in western countries. (DCCT, 1998; UKPDS 33, 1998; UKPDS 34, 1998.) In India, there are wide social and economic disparities, but the profile of diabetes in the low income groups or the patients from below poverty line have not been studied in detail. However a pilot study in Asian countries has been reported by Cockram C., (1999). Epidemiological data from India by Ranjith U., (2007) had shown a rising prevalence of diabetes with overt nephropathy and microalbuminuria to 2.2% and 26.9% respectively. Similarly Ramachandran A., (1988, 1992, 1997, 1999.) reported rising prevalence of diabetes (15% - 40%) in the adult population in the past two decades. However, there is no much detail study which has focused on the impact of poverty on the profile of diabetic nephropathy. This study was therefore designed to look at the patients of below poverty line who were receiving treatment for Diabetic Nephropathy in government hospital in Warangal district, Andhra Pradesh, India.

The objective was to examine the progression of diabetic nephropathy in poor patients. To study the effects and interactions of potential risk factors on micro albumin excretion. To observe the current health care provide to these patients. To study the health related quality of life of patients from below poverty line.

MATERIALS AND METHODS

Setting and subjects

This was the cross sectional descriptive study carried out in the diabetic clinic of Mahatma Gandhi Memorial (M.G.M) general hospital, Warangal district, Andhra Pradesh (A.P), India. We followed all patients diagnosed with diabetes with nephropathy complication from August 2006-July2007.During this period out of 694 Diabetes patients 119 were diagnosed with early status of Nephropathy complication. The patients attended the outpatient clinic

every two or three months. No special intervention or attempt was made to influence the patient care practices in the centre. The classification of Diabetic Nephropathy was based on clinical judgment of the hospital's endocrinologists and nephrologists.

Data was collected by reviewing patient medical records, through interviews and laboratory assessments. (Lee, et al., 2001) The data collection form was used to record patient-demographics, type and duration of Diabetes, risk factors (i.e. smoking, alcoholic consumption, other micro vascular complication, etc). Data fields were left blank if no data were available. The results of laboratory assessments and clinical examinations, performed during the 12 months of recruitment, were used for analysis.

A Clinical Pharmacy branch was setup in M.G.M general hospital by Prof. Dr. Krishna, Kakatiya University, which endow with voluntary free service for the diagnosis of Diabetes in patients recruit for treatment in that hospital. All measurements & laboratory assessments were carried out by the research students of Kakatiya University, Warangal, A.P, India. BMI was calculated by measuring Weight and height (kg/m^2). Blood pressure was measured at each visit. Serum samples were collected in the morning after the subject had fasted 12 hours. Measurements included Fasting plasma glucose (FPG), Post lunch plasma glucose (PLPG). Urinary albumin excretion for the screening of microalbuminuria was performed on an early morning spot urine specimen. Similarly, for proteinuria conventional dipstick test was performed. Persistent microalbuminuria and macroalbuminuria were defined as a urinary albumin excretion rate between 20 and 200mg/dl and >200mg/dl respectively[16], in at least two or three consecutive samples, with an increase of at least 30% above the baseline

level. Patients were classified as smokers if they smoked more than one cigarette a day. Ethical approval was made by the local hospital authorities as per study needed.

Statistical analysis

Statistical analysis was performed using SPSS13.0 (SPSS, Inc, Chicago). The results were expressed as means, standard deviations and percentages. Descriptive statistics was computed separately. The collected data was screened properly and the groups were compared by one way ANOVA, Bornferroni test.

RESULTS AND DISCUSSIONS

A total of 694 diabetic patients from across the rural Warangal region were recruited for the treatment within 12 months in MGM hospital. Out of which 119 patients were diagnosed as Diabetic nephropathy. This shows that the prevalence of nephropathy in diabetic patients is about 17.14%. However 16 patients were excluded from the statistical analysis due to missing data on patient information, errors in micro albumin readings or any inconsistency between basic data fields. Thus 103 patients with diabetic nephropathy were constituted for the final study. The prevalence of diabetic nephropathy in type 2 diabetic subjects is reported to be 5-9% from various Indian studies. (Ranjit, et al., 2007) A study conducted in Italy by Boero R., et al., (2003) reported the prevalence of the microalbuminuria was found to be 33.3%.

The patient demographics and characteristics are summarized in Table 1. The first analysis was carried out using occupation and employment status as a marker for socio-economic status. A majority of patients (69.9%) from government hospital

Table1:   Patients Demographics in Government Hospital (INDIA)

Groups	Total Diabetic patients (694) in % (n)	
	Without Microalbuminuria (591)	With Microalbuminuria (103)
Gender:		
Male	34.01 (201)	40.8(42)
Female	65.98 (390)	59.2 (61)
Age of Patients (years):		
31-40	47.88 (283)	15.5 (16)
41-50	26.56 (157)	42.7 (44)
51-60	16.07 (095)	31.1 (32)
61-70	08.79 (052)	09.7 (10)
>70	00.67 (004)	01.0 (01)
Employment status:		
Employed	36.20 (214)	29.2 (31)
Unemployed	63.79 (377)	69.9 (72)
Monthly Income (US $):		
<100	—	88.3 (91)
100-200	—	11.7 (12)
Education:		
Uneducated	—	80.6 (83)
Primary	—	15.5 (16)
Secondary	—	03.8 (04)
Heredity:		
Yes	12.35 (073)	38.8 (40)
No	87.64 (518)	61.2 (63)
Duration of Diabetes (years):		
1-3	66.15 (391)	34.9 (36)
4-7	26.22 (155)	43.6 (45)
8-11	06.09 (036)	14.5 (15)
>11	01.52 (009)	06.8 (07)
Body Mass Index (BMI kg/m^2):		
Normal (20-25)	—	80.6 (83)
Overweight (25-30)	—	14.6 (15)
Obese (>30)	—	04.9 (05)

are unemployed and had very less income. From the patients who are employed, 88.3% of them have income of less than 100 US $ which is just enough to cope up with the basic needs of the family. A similar study conducted by Ramchandran, et al., (2002) has reported the impact of poverty on prevalence of diabetes and its complications in India, where the patients were compared based on high income and low income. Thus in the current study, the patients are described as poor patients or patients from the below poverty line who are unemployed without any income or with low income (monthly income <100US$). These patients are from the rural surroundings of Warangal district and most of them are female patients, comprised about 59.2% and male patients made up 40.8%. The overall mean age of patients was 52.32±8.86 years with the majority (73.5%) of the patients in the age group of 41-60 years. Overall duration of Diabetes was 5.76±3.69 years. Majority of these patients (61.2%) have diabetes as non-hereditary. This shows the prevalence of diabetes is increasing among the poor patients due to stress and poverty. There was a high illiteracy rate among these patients, about 80.6% were uneducated and have very poor knowledge of the disease. Generally variation in weigh/height (Body Mass Index) effect the treatment, but in these patients BMI was normal ($<25kg/m^2$) in almost all the patients (80.6 %).

The major risk factors found in the patients is given in Table -2. Because of the low health related quality of life style maintenance the patients in Government Hospital has many risk factors. Majority of them (61.2%) had poor or average medicine compliance. The patients either miss the dose or cannot complete the duration of treatment course due to unavailability of the source

Table 2: Risk Factors found in the patients

Social characteristics	Percentage (%)
Smoking or tobacco chewing:	
Yes(males& females)	(63)
Alcohol consumption:	
Yes(males)	(35)
Medicine Compliance	
Good	38.8 (40)
Poor	30.1 (31)
Average	31.1 (32)
Exercise	
Yes	19.4 (20)
No	80.6 (83)
Complications	
Retinopathy	09.7(10)
Foot	15.5(16)
Macro vascular	0

or poor financial conditions. In this region chewing of betel leaves or tobacco (ghutka) was common among males and females with about 62.7% of the patients were smokers or tobacco chewers or had habit of chewing betel leaves, where as crude alcohol intake was common in almost all the males. Apart from these, some of the patients had retinopathy and feet complications, which was evaluated by patient's medical records. The presence of severe late complications or macro vascular complications which include legal blindness, myocardial infraction/ coronary artery/bypass graft/angioplasty, stroke and leg amputation was found to be zilch among these patients which is in contrast with the western studies. (Mc Neely, et al., 1995; Reiber, et al., 1992)

Based on the 1996 WHO classification criteria for hypertension (WHO technical report series 862), mentioned the target blood sugar for renal patient should be 130/90. In this study the majority had very high blood pressure (Table-3), while just 19.41% had normal blood pressure (<130/90 mmHg).

Table 3: Disease status in the patients N=103

Parameters	Observed mean Values	Total patients % (n)
Fasting Blood Glucose (mg/dl)	**151.53**	100 (103)
80–110	—	
110–140	128.74	31.06(32)
>140	163.29	68.93(71)
Post lunch Blood Glucose (mg/dl)	**228.90**	100 (103)
125–150	—	—
150–200	182.32	39.81(41)
>200	259.91	60.19(62)
Systolic Blood pressure (mmHg)	**132.22**	100 (103)
125–130	128.34	19.41 (20)
130–135	133.46	52.42 (54)
>135	142.13	28.15 (29)
Diastolic Blood Pressure (mmHg)	**82.62**	100 (103)
75–80	76.46	17.47 (18)
80–85	80.21	59.22 (61)
>90	99.23	23.31 (24)
Microalbuminuria (mg/dl)	**102.16**	100 (103)
<20	18.56	22.33 (23)
20–200	132.48	65.04 (67)
<200	212.71	12.62 (13)

The overall mean FBG and PLBG level for these patients was 151.53 and 228.90 mg/dl respectively. From the 103 patients who had albumin excretion assessed, 22.33% had normal-albuminuria, defined as urine albumin concentration < 20mg/dl, while 65.04% and 12.62% had microalbuminuria and overt proteinuria respectively (Urine albumin concentration 20-200mg/dl and > 200mg/dl respectively).

Table-4 & 5 shows the treatment regimen in government hospital. These patients had average Glycemic control, just with the limited available drugs in government hospital. These patients were treated with the only available drugs which are supplied by the government such as metformin, glibenclamide, Enalapril, CCB and thiazides. Metformin is prescribed for 76.69% of the patients including combination with Glibenclamide and Glibenclamide is used only for 55.33% of the patients including combination with Metformin for the treatment of Diabetes. The antihypertensive and antihypoglycemic therapy received in Government Hospital was inadequate. The effect of different Antihypoglycemic drugs were compared and assessed by decrease in the Fasting blood glucose and Post lunch blood glucose from the last diagnosed values. Sulphonylureas like Glibenclamide

Table 4:   Effect of Antihypertensive agents

Drugs	N	B.P (mmHg)		Decrease in Microalbuminuria (mg/dl)
		Systolic	Diastolic	
Enalapril (ACEI)	32	133.23	85.33	–36*
Amlodipine(CCB)	20	137.81	84.21	–14
Furosemide(DIU)	16	135.36	87.27	+09
Chlorthiazide(DIU)	09	133.48	85.69	–05
ACE+DIU	18	132.62	84.14	–41*
CCB+DIU	08	134.21	86.78	–16

Bornferroni test,* P<0.05,

(BP- Blood Pressure, ACEI-Angiotensin Converting Enzyme Inhibitors,CCB-Calcium Channel Blockers, DIU-Diuretics)

Table 5:   Effect of Antihypoglycemic agents

Drugs	N	Decrease in Blood Sugar level(mg/dl)	
		FBS	PLBS
Metformin	46	–24	–36
Glibenclamide	24	–31	–43*
Met + Glib	33	–46*	–32

Bornferroni test, P<0.05

(FBS- Fasting Blood sugar, PLBS- Post Lunch Blood Sugar, Met-Metformin, Glib-Glibenclamide)

showed good response in controlling blood sugar levelsThe effect of different Antihypertensive drugs were compared and assessed by blood pressure control and decrease in the Microalbuminuria from the last diagnosed values. There was no significant different in treatment of hypertension among different class of drugs but Enalapril showed good response as monotherapy and combination with diuretics in patients both on blood pressure control and microalbumin control. CCB & Diuretics showed good response in blood pressure control but could not decrease Microalbuminuria.

The result clearly shows that there are number of risk factors among the patients from below poverty line which even had impact on treatment adherence. The different risk factors which increase the progression of microalbuminuria such as old age, poor medicine compliance, intake of crude alcohol, animal protein, smoking, tobacco chewing, lack of exercise, lack of knowledge on diabetic nephropathy, inappropriate use of drugs. (Giovanni, et al., 2005)

The income of these patients is so less that they can hardly survive with the basic needs. Therefore it is very difficult for these patients to have an advance treatment in private hospitals. But still the physicians in the government hospital are trying there best to treat these patients with minimum availability of laboratory assessment and limited supply of drugs. The use of glycated hemoglobin (HbA_{1c}) assessment, lipid profile assessment, measurement for serum creatinine and other potential laboratory test were very expensive for these patients which are lacking in the government hospitals. Metformin is not excreted in overt proteinuria cases, but still it is prescribed to the patients. Thiazides or calcium channel blockers just can control blood pressure but cannot slowdown the progression of microalbumin. Patients with

poorer mobility as a result of renal failure or more severe eye disease might arguably also have been less likely to see their doctors for diabetes care. This might account for nil reports of some severe late complications. This study presents the status of diabetic control, management and complications in poor patients.

CONCLUSION

These preliminary data suggest that prevalence of Diabetic nephropathy in poor patients is increased due to lack of patient care and reduced quality of life. Free health care facilities are available for the economically backward classes, but due to the low level of education and occupational problems, the facilities are not always used. These findings call for efforts at establishing and maintaining improved diabetes management with regards to control and screening for microalbuminuria for every six months for a new patient. In addition, our study also suggests the importance of empowering the patients for diabetes self care skills, diabetes and nephropathy education.

The data can be used as an excellent tool for local quality improvement and help the government strategies on diabetic care in poor patients. Resources for treatment to these patients should be increased by partnership between health care providers, pharmaceutical industries and pharmacist. Proper counseling with detailed description and co-operation with these patients in therapy is highly recommended.

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