



## RESEARCH ARTICLE

**Prevalence of Micro and Macrovascular Complications and Assessment of Risk Factors in Diabetic Patients: A Prospective Observational Study****D Jothieswari<sup>1,\*</sup>, R M Soniya<sup>1</sup>, R S Vinuthna<sup>1</sup>, P Venkatesh<sup>1</sup>, V Hari<sup>1</sup>**<sup>1</sup>Sri Venkateswara College of Pharmacy, RVS Nagar, Chittoor, 517127, Andhra Pradesh, India

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## ABSTRACT

Diabetes is a chronic metabolic disorder of heterogeneous type. Diabetic complications are mostly associated with condition of vascular penetrability that affects different tissues & kidneys, retina, nerves which involve the body organs. The aim of study was to assess the prevalence of micro and macro diabetic complications and risk factors of diabetic patients. The prospective observational study was conducted in Raghu Diabetes and general clinic, Chittoor, Andhra Pradesh. A sample size of 200 subjects was recruited for the study. The study was conducted from December 2020 to May 2021. Patients with age group of 30-90 years and diabetic complications were included in the study. Patients below 30 years of age were excluded from study. The patient details were collected using questionnaire form. It contains sociodemographic data and medical history including smoking, alcohol, family history of diabetes mellitus, and treatment and management of diabetes. The statistical analysis was carried out using SPSS version 25.0. The study results showed 1.5% of patients had more than two co-morbidities, which was significantly higher among elderly (5.04%), females (5.2%) and urban residence (6.31%), physical inactivity (3.15%) and house wife (2.1%). The statins prescribed patients were 160 (80%) whereas patients on other medications, insulin in combination with OHA 38 (19%), and multivitamins prescribed patients 181 (90.5%). The study showed the patient's age of 51-70 years was mostly affected by diabetes. Regular exercise, intake of more vegetables and fruits and adopting a healthier life-style can reduce the prevalence of diabetes.

**Keywords:** Diabetic complications; physical inactivity; smoking; alcohol; statins; Insulin

## INTRODUCTION

Diabetes is a chronic metabolic disorder of heterogeneous type. Its Aetio-pathology lacks in secretion of insulin, and its actions in body along with disturbances in carbohydrate, proteins and fat metabolisms. Over the past 10 years, diabetes mellitus incidence increased by 50% and to be noted as major epidemic in 540 century. Egypt, Indian, Persian civilization records shows that world's oldest disease as diabetes. According to World Health Organization diabetes incidence can be estimated to be doubled by 2030<sup>1</sup>. Insufficient insulin production or the cells inability to use insulin properly and efficiently leads to hyperglycemia and Diabetes. Diabetic microvascular complications are mostly associated with condition of vascular penetrability that affects different tissues & kidneys, retina, nerves which involve the body organs. Macro vascular includes peripheral and coronary arterial disease and the main manifestation is HG, which in

turn can impair function of many tissues in the body and the structure especially the vascular system HG can severely damage the vascular system via MGO and other mediator, when it becomes chronic with time. Diabetes mellitus is also associated with production of ROS excessively, which in turn can induce vasoconstriction with accelerated lipid peroxidation and inflammations reactions leads to atherosclerosis<sup>2-4</sup>. The diabetes is associated with multiple metabolic risk factors such as age, sex, family history, alcohol consumption, cigarette smoking, sleep, obesity, physical activity. Use of anti-inflammatory drugs and lowering low-density lipoprotein cholesterol (LDL-C) levels are also useful. Intensive diabetes control designed to achieve normal blood sugar level has a significant impact on lowering the risk for developing microvascular complications. For prevention of macrovascular complications, a multipronged approach with tight diabetic control, adequate control of blood pressure and lipid lowering along with life style

modifications would reduce the diabetic complications<sup>5-10</sup>.

## AIMS AND OBJECTIVES

### *Aim*

The aim of study was to assess the prevalence of micro and macro diabetic complications and risk factors of diabetic patients.

### *Objectives*

- To study the prevalence between ages, duration of disease, co-morbidity among the total study population.
- To evaluate the risk factors associated in diabetic patients.
- To find out the independent relationship of the following risk factors especially Age, BMI, Diet, Gender, Family history, Social history.
- To assess the risk factor associated complications in patients.

## METHODOLOGY

### *Study site*

The study was conducted in Raghu diabetes & general clinic, Chittoor, Andhra Pradesh.

### *Sample size*

Sample size of 200 subjects was recruited for the study

### *Study design*

It was prospective observational study.

### *Study duration*

The study was conducted from December 2020 to May 2021.

### *Inclusion criteria*

- Both the genders and age group of 30-90 years were included
- Patients with diabetes have been recruited into the study
- Patients with diabetic complications were included

### *Exclusion criteria*

- Patients below 30 years of age were excluded from study
- Pregnant women
- Patients with end stage renal failure

## *Patient data collection*

The patient details were collected using questionnaire form. It contains sociodemographic data and medical history including smoking, alcohol intake, family history of diabetes mellitus, and treatment and management of diabetes. Patient enrollment into the study was done by interacting with the patients.

## *Statistical analysis*

Data was presented as mean and standard deviation, and numbers with percentages. The variables like age, gender, BMI, smoking status, alcoholic status, and biochemical parameters were considered as risk factors. Multivariate logistic regression was performed to estimate odds ratio (OR) for assessing the risk factors associated with presence of micro & macro vascular complications with 95% confidence interval (CI). Two-tailed value of less than 0.05 was considered as significant. Prescribing pattern of different anti-diabetic drugs was also reported in the form of percentages. All the analyses were carried out using SPSS version 25.0.

## *Ethical approval*

The protocol was reviewed and approved by Institutional Ethics Committee (IEC) of RVS Institute of medical sciences (Ref. No.: IEC / RVSIMS / 2021 / 04).

## RESULTS

### *Socio demographics and co-morbidities*

Overall the prevalence of co-morbid DM (Diabetes Mellitus) and HTN (Hypertension) was 6.5% with significant high prevalence among (66.3%) and females (70.4%). But no rural - urban difference was noted. In 5% of respondents, DM, HTN & Dyslipidemia co-existed. Around 1.5% of respondents had more than 2 morbidities, which was significantly higher among elderly (5.04%), females (5.2%) and urban residence (6.31%), physical inactivity (3.15%) and housewife (2.1%). It was shown in Table 1.

In our study the risk factor for Neuropathy were found to be Age group (71- 90 yrs) [OR, 0.090, 95% CI, P= 0.022], marital status for widow [OR, 0.578, 95% CI, P= 0.005] and for married [OR, 17.304, 95% CI, P= 0.005], education for illiterates [OR, 0.238, 95% CI, P= 0.28] and for primary education [OR, 6.319, 95% CI, P= 0.016], working status (retired) [OR, 0.214, 95% CI, P= 0.050], comorbidities for foot ulcer [OR, 9.337, 95% CI, P= 0.034] and [OR, 0.120, 95% CI, P= 0.047] for hypothyroid, CAD [OR, 0.050, 95% CI, P= 0.003], cataract (yes) patients [OR, 0.116, 95% CI, P= 0.004] and for no patients [OR, 8.608, 95% CI, P= 0.004], Habit of smoking (yes) [OR, 0.124, 95% CI, P= 0.006] and no patients [OR, 16.135, 95% CI, P= 0.007], Intake of alcohol (yes) [OR, 0.145, 95% CI, P= 0.011] and no patients [OR, 4.565, 95%

**Table 1:** Patient socio demographic details

Parameters	Total	Co-morbidities DM & HTN	DM, HTN & Dyslipidemia	More than 2 Morbidities
Age group				
31-51	56	29	03	00
51-70	119	79	06	02
71-90	25	22	01	01
Gender				
Male	85	49	04	01
Female	115	81	06	02
Residence				
Rural	105	66	04	01
Urban	95	65	06	02
working status				
Jobless	03	01	00	00
Housewife	94	67	06	02
Business/private	45	29	02	00
Government	07	04	00	00
Retired	23	13	01	00
Cooli	28	16	01	01
Physical activity				
Yes	105	68	05	00
No	95	63	05	03

CI, P= 0.019]. The risk factors for having nephropathy were found to be comorbidities (no) patients [OR, 0.162, 95% CI, P= 0.093], In complications of Neuropathy patients [OR, 0.072, 95% CI, P= 0.011], Intake of alcohol (no) patients [OR, 13.834, 95% CI, P= 0.011], Intake of water (3-5 lit) [OR, 7.217, 95% CI, P= 0.065] and 5 lit [OR, 0.162, 95% CI, P= 0.093]. The risk factors for having CVD were found to be gender (male) [OR, 4.664, 95% CI, P= 0.050] and female [OR, 0.214, 95% CI, P= 0.050], BMI [OR, 0.106, 95% CI, P= 0.034], DM duration of 11-14 years [OR, 0.162, 95% CI, P= 0.093], Intake of alcohol (yes) [OR, 0.214, 95% CI, P= 0.050] and no [OR, 0.9377, 95% CI, P= 0.034]. The study results were shown in Table 2.

### Chemical & biochemical characteristics

The low HDL (High Density Lipoprotein) cholesterol levels were seen among 29.19% (n=41) of patients and high LDL (Low Density Lipoprotein) cholesterol levels were seen in 25.71% (n=36) of the population, 27.14% (n=38) had high TG levels, 14.29% (n=20) had high cholesterol and 19.29% (n=27) had VLDL (Very Low Density Lipoprotein). The mean & standard values of PCV(36.43%), MCV(28.57%), MCH(27.14%), MCHC(22.86%) significantly decreased in the T2DM, the respective values were  $33.39 \pm 4.31$ ,  $73.47 \pm 12.70$ ,  $27.98 \pm 8.73$  and  $35.21 \pm 4.91$ . The T4 levels were seen among 10% (n=14), TSH levels were seen among

9.29% (n=13) and T3 levels were seen among 8.57% (n=12). It was shown in Table 3.

**Table 3:** Chemical & biochemical characteristics of diabetic patients

Parameters	N	Mean	Std deviation	N %
Age	140	70	15	100
Gender	140	70	15	100
TG	38	197.67	60.90	27.14
Cholesterol	20	179.75	51.69	14.29
HDL	41	38.07	15.78	29.29
LDL	36	107.87	29.88	25.71
VLDL	27	47.83	22.52	19.29
Total cholesterol/Hdl ratio	17	5.25	0.79	12.14
T3	12	1.21	0.20	8.57
T4	14	10.30	2.16	10
TSH	13	2.73	1.81	9.29
Total Bilirubin	6	1.29	0.58	4.29
Direct Bilirubin	5	0.492	0.23	3.57
Blood Urea	16	29.48	13.82	11.43
Sr. Creatinine	31	1.54	1.55	22.14
Sr. Uric acid	16	7.59	10.64	11.43
Albumin	-	-	-	-
Sugar	-	-	-	-
PCV	51	33.39	4.31	36.43
NCV	40	73.47	12.70	28.57
MCH	38	27.98	8.73	27.14
MCHC	32	35.21	4.91	22.86

### Anti – hyperglycemic & concurrent medications

Diabetic patients 167 (83.5%) were prescribed combination of Biguanides and Sulfonylureas followed by Biguanides 44 (22%), Sulfonyl ureas 17 (18.5%),  $\alpha$ -Glucosidase inhibitors 83 (41.5%), Thiazolidinediones 02 (1%), Meglitinide 04 (2%), insulin in combination with OHA 38 (19%). About 108 (54%) patients were prescribed with anti-hypertensives, 33 (16.5%) patients

were prescribed with cardiovascular drugs, 34 (17%) were prescribed with statins, 160 (80%) were prescribed multivitamins and 181 (90.5%) were prescribed with other drugs that includes (antibiotics, painkillers, PPI, antipyretics). It is shown in Figure 1.

**Table 2:** Risk factors for complications in patient with DM

Risk Factors	Neuropathy		Retinopathy		Nephropathy		Cerebro-Vascular disease		Cardio-vascular disease	
	Odds ratio	P-value	Odds ratio	P-value	Odds ratio	P-value	Odds ratio	P-value	Odds ratio	P-value
Age group										
31-50	0.531	0.222	1.000	1.000	0.244	0.209	0.500	0.572	0.492	0.321
51-70	1.891	0.218	-	-	0.434	0.172	-	-	2.030	0.321
71-90	0.090	0.022	-	-	2.201	0.195	2.000	0.572	0.492	0.321
Gender										
Male	0.636	0.360	1.000	1.000	0.750	0.600	0.500	0.572	4.664	0.050
Female	1.571	0.360	-	-	1.333	0.600	2.000	0.572	0.214	0.050
BMI										
Under weight (<18.5)	-	-	-	-	-	-	-	-	-	-
Normal weight (18.5 – 24.9)	0.852	0.778	-	-	1.206	0.760	0.497	0.569	.106	0.034
Over weight (25 – 29.9)	1.414	0.559	1.000	1.000	2.030	0.321	2.010	0.569	4.664	0.050
Obese (>30)	0.829	0.760	1.000	1.000	0.492	0.321	-	-	2.010	0.569
Marital status										
Widow	0.578	0.005	-	-	0.387	0.114	0.497	0.569	0.086	0.019
Married	17.304	0.005	5.050	0.296	2.578	0.114	2.010	0.569	11.582	0.019
Unmarried	1.000	1.000	-	-	-	-	-	-	-	-
Genetic										
Yes	1.064	0.338	1.000	1.000	1.347	0.587	0.497	0.569	2.041	0.250
No	0.632	0.338	1.000	1.000	0.742	0.587	2.010	0.569	0.489	0.250
Residence										
Rural	1.263	0.630	1.000	1.000	0.742	0.587	2.010	0.569	1.414	0.559
Urban	0.791	0.630	1.000	1.000	1.347	0.587	0.497	0.569	0.829	0.760
Education										
Illiterates	0.238	0.028	-	-	0.489	0.520	-	-	0.593	0.479
Upto primary education	6.319	0.016	5.050	0.296	8.291	0.471	2.010	0.569	5.012	0.138
Upto secondary education	2.010	0.569	-	-	1.000	1.000	-	-	0.330	0.338
Higher education	0.330	0.338	-	-	1.000	1.000	0.497	0.569	1.000	1.000
working status										
Jobless	2.308	0.169	-	-	1.777	0.365	1.000	1.000	2.030	0.321
Housewife	0.134	0.703	-	-	1.340	0.703	1.000	1.000	1.507	0.654
Business/private	-	-	-	-	-	-	-	-	2.010	0.569
Government	1.507	0.654	1.000	1.000	-	-	1.000	1.000	0.162	0.093
Retired	0.214	0.050	1.000	1.000	0.419	0.213	-	-	-	-

***Distribution of the study group according to age, sex and mean FBS (Fasting Blood Sugar), PPBS (Post Prandial Blood Sugar), HbA1c (Glycated Haemoglobin)***

The mean  $\pm$  SD FBS levels of subject in the study was  $147.93 \pm 18.89$  mg/dl. The subjects belonging to 30-50 age group had mean  $\pm$ SD FBS levels of  $174.17 \pm 64.79$  mg/dl, 51-70 yrs was  $139.20 \pm 45.33$  and 71-90 yrs was  $130.43 \pm 53.22$  mg/dl. The mean  $\pm$  SD PPBS levels of subject in the

study group were  $230.96 \pm 23.33$  mg/dl. PPBS levels in subjects belonging to 30-50 age group had mean  $\pm$  SD  $260.78 \pm 80.73$ , 51-70 ( $228.29 \pm 64.75$ ) and 71-90 years ( $203.81 \pm 65.20$ )mg/dl. The mean HbA1c level in the study group was  $8.43 \pm 1.00\%$ . The mean  $\pm$  SD of HbA1c levels was higher in 30-50 age group  $9.33 \pm 1.35$ , 51 – 70 years was  $8.93 \pm 2.18$  and 71-90 years was  $7.03 \pm 0.70$ . as presented in Figure 2.

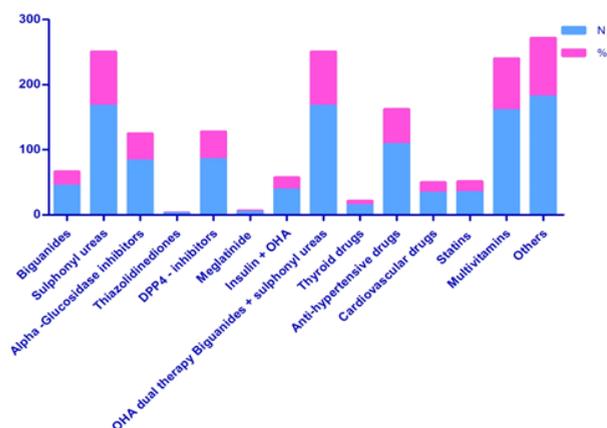


Fig. 1: Prescribed medications among adult diabetic patients on monthly review

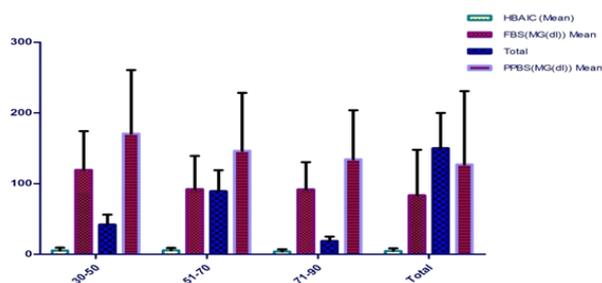


Fig. 2: Distribution of study group according to the age and mean FBS, PPBS & HbA1c

In this study 57.5% were females and 42.5% were males. The mean  $\pm$  SD of FBS among females was  $149.83 \pm 50.14$  mg/dl and among males was  $145.28 \pm 60.93$  mg/dl. The mean  $\pm$ SD PPBS levels of females were  $234.53 \pm 67.21$  mg/dl and among males was  $234.53 \pm 78.02$  mg/dl. The mean  $\pm$ SD of HbA1c was  $9.44 \pm 1.33\%$  in females and  $8.33 \pm 2.20\%$  in females. It is shown in Figure 3.

**DISCUSSION**

DM is a complex disease. The time lag between the onset of DM & clinical diagnosis results in the development of chronic micro & macro vascular complications. Based on our study results this proposition might be higher in developing countries like India.<sup>11-15</sup> In this study, we assessed the prevalence of micro & macro vascular complications in 200 DM patients and found 17% presented with microvascular complication and 11.5% presented with macrovascular complication.<sup>16-19</sup> Similar cross-sectional studies have been done in India reporting prevalence rates ranging from 13 to 30%. This study revealed that about 9% of subjects suffer from moderate to severe neuropathy

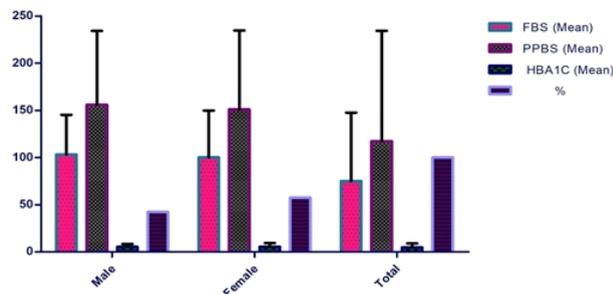


Fig. 3: Distribution of the study group according to gender and mean FBS, PPBS & HbA1c

which needs immediate attention, as they are at high risk of foot infection and amputation.<sup>20</sup> Also in this study, age, obesity, and lipids parameters were the main significant risk factors for the development of diabetic retinopathy. A high prevalence of obesity, poor glycemic control and cardiovascular events were reported in previous studies to be major causes of co-morbidities in patient, especially in middle and old age group.<sup>21</sup>

The key findings of the present study include:

1. The prevalence of DM and HTN are found to be 65% in the general adult population.
2. DM, HTN and Dyslipidemia exist together in 5% of the population.
3. Factors strongly correlated with co-morbid DM & HTN such as, age-group, dyslipidemia, obesity and family history of DM.<sup>22</sup>

Obesity is an emerging global problem giving rise to increase in Diabetes, HTN, Dyslipidemia & CVD. Weight reduction achieved between life-style interventions like dietary regulations & regular physical activity will help overweight individuals accomplish higher BP & glucose control & thereby reduce their complications.<sup>23</sup> Regarding medications sulfonylureas was most utilized medication alone or in combination with other Anti-diabetic medication. Diabetic patients with chronic health issues require extensive healthcare which can be fulfilled by providing the healthcare terms with sufficient, comprehensive, reliable, compactible & co-relating patients information across the different health sectors.<sup>24</sup> Thus study reported the prevalence of diabetes is more in the subjects of sedentary life-style, obese, Hypertensive & smokers.<sup>25</sup>

**CONCLUSION**

The study reported the prevalence of DM progression, comorbidities, risk factors and associated micro & macro complications. This study shows the prevalence of diabetes is high in the subjects having overweighted, gender,



hypertensive and also found that females & patients aged 51-70 years were most affected by diabetes. Apart from glycemic control there is a need of tight lipid management in DM patients as TG, LDL and HDL, total cholesterol were shown as significant risk factors for micro & macro vascular complications. Regular exercise, intake of more fibrous diet, vegetables and fruits can reduce the prevalence of diabetes in subjects with poor literacy status and use of educational attainment promote an interest in own health and acquisition of knowledge that strongly influence people's ability to reduce risk by successfully adopting a healthier lifestyle. Future research studies are need to be conducted for an in-depth analysis and understanding of the possible causal and risk factors. Thus research in the field of diabetes needs to be intensified.

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