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**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**<http://doi.org/10.5281/zenodo.1117221>Available online at: <http://www.iajps.com>**Research Article****PROSPECTIVE AND OBSERVATIONAL STUDY OF
COMPLICATIONS OF TYPE 2 DIABETES MELLITUS AT
TERTIARY CARE TEACHING HOSPITAL****Meraj Fatima, Nikhath Begum, Syeda Fathima Sultana Safura, Syeda Saleha Farheen
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Abstract:

Background: Type 2 Diabetes Mellitus Patients develop chronic complications, which are the leading causes of premature mortality among them. The contribution of poor glycemic control and other risk factors must be identified so that preventive strategies can be considered. This observational study was undertaken to determine the prevalence of complications in Type 2 Diabetes Mellitus and identify the various risk factors for these complications.

Methodology: A Prospective observational non-invasive study carried out with established type 2 Diabetes Mellitus patients in the Department of General Medicine in Osmania General Hospital, for a period of 6 months. In patients and Out patients of either gender with more than 30 years of age were included. Patients with Type 1 diabetes mellitus, any other severe illness and pregnant diabetics were excluded. The selected patients were observed for presence of Microvascular and Macrovascular complications by making enquiries and collecting data in a data collection form designed for the recording all the relevant parameters and diagnosis. Morisky Medication Adherence scale MMAS-4 was used for assessing medication adherence.

Results and Observations: During the study period a total of 200 Diabetic Patients were enrolled. Amongst the total participants, 135 subjects were with Diabetes Mellitus complications Out of which 115 were males and 20 were females and remaining 65 subjects with Diabetes Mellitus are without complications. The Cerebrovascular disease (32.8%) has highest prevalence followed by Coronary Artery Disease (28%) Diabetic Nephropathy (14.8%), Diabetic Foot (13.3%), Diabetic Neuropathy (7.4%) and Diabetic Retinopathy (4%) which are associated with various risk factors.

Conclusion: This study highlights the high prevalence of Macrovascular complications in Type 2 Diabetes Mellitus patients. It is found that cerebrovascular disease and Coronary artery disease were the most prevalent of all the complications of diabetes in the study population. Low medication adherence, Body Mass Index (BMI), Family History of type 2 Diabetes Mellitus, History of Hypertension are the significant risk factors in our study. The progression of most complications can be halted or delayed if detected early and appropriate therapy is instituted.

Keywords: Diabetes Mellitus Complications, Macrovascular, Micro vascular and Risk Factors.

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INTRODUCTION:

Diabetes mellitus (DM) is a syndrome characterised by chronic hyperglycaemia and disturbance of carbohydrate, fat and protein metabolism associated with absolute or relative deficiencies in insulin secretion and/or insulin action [1].

The longer duration of diabetes the less controlled of blood sugar levels leads to development of diabetic complications which are divided into Microvascular (damage to small blood vessels) and Macrovascular (damage to large blood vessels).

The Micro vascular complications are Long term complications that affect retina, kidney and nervous system. Diabetic eye disease, particularly retinopathy, has become a major cause of blindness throughout the world. The Macro vascular complications which include coronary artery disease, cerebrovascular disease, peripheral vascular disease and Diabetic foot also occur with higher frequency in Diabetes [1].

According to International Diabetes Federation, India has 40.9 million diabetic patients in the year-2006, 50.8 million in 2010, 60 million in 2014 and it is expected to raise up-to 69.9 million by the year 2025. According to the epidemiological study in India, Hyderabad is known as diabetic capital of India with the prevalence of 16.6 % [10].

Diabetes mellitus is the commonest metabolic disorder and has a high prevalence in India. The prognosis of the diabetic patients largely depends on the complications seen in the natural course of illness. This study was undertaken to define more clearly the risk factors influencing susceptibility to such complications in diabetic patients.

Poor glycemic control and Non-adherence to medications in Type 2 DM patients is significantly associated with increased incidences of complications of Diabetes Mellitus.

METHODOLOGY:

Study Design: A Prospective observational non-invasive study.

Study Location: The study was conducted in Department of General Medicine in Osmania General Hospital, a tertiary care teaching hospital.

Study Population: All patients attending General Medicine department with established type 2 Diabetes Mellitus

Study Duration: 6 months.

Sample Size: 200

Study Criteria**Inclusion Criteria:**

- Patients with either sex of more than 30 years of age group
- In Patients and Outpatients already diagnosed of Type 2 diabetes mellitus and on treatment.

Exclusion Criteria:

- Type 1 diabetes mellitus
- Any other severe illness
- Refusal to be a part of the study
- Pregnant diabetics

Procedure for data collection

All the relevant and necessary data is collected from

- Patient's case notes.
- Prescription prescribed by the physician.
- Laboratory reports
- Interviewing patient or patients care taker(s) and health care professionals.

All patients were screened for type 2 Diabetes Mellitus and its complications. Each subject's details regarding risk factors like age, sex, Duration of Diabetes, B.M.I, socioeconomic status, family history, History of hypertension, Fasting Blood Sugar level, postprandial blood sugar level, Systolic and diastolic blood pressure, medical adherence and exercise and diet control is collected for all the patients. For measuring medical adherence Morisky Medication Adherence (MMAS-4) scale is used.

The selected patients were observed for presence of vascular (micro and macro) complications who had undergone the test for Retinopathy by fundus examination, Nephropathy by micro albuminuria, serum creatinine and blood urea, Neuropathy by history of numbness paraesthesia, tingling sensation, burning sensation and confirmed by touch sensation¹, Peripheral vascular disease (PVD) by colour Doppler, Cardiovascular disease by ECG, Chest X-ray and by history of myocardial infarction or angina [4], Cerebrovascular disease by CT Scan of brain, Impaired speech, inability to see in one eye or double vision Inability to walk and Paralysis on one side of the body and Diabetic foot problems known by foot ulcers or amputation [6].

Unpaired t test was used for comparison between males and females patients and Regression analysis

for finding the scientific risk factor's association with various complications.

RESULTS:

In our study, 200 Diabetic patients were enrolled. Amongst the total participants, 135 subjects had developed Diabetes Mellitus complications, out of which 115 were males and 20 were females and remaining 65 subjects has Diabetes Mellitus without complications. Macrovascular complications (73.8%) are more prevalent when compared to Microvascular complications which (26.2%).

Out of 135 patients with Diabetes Mellitus complications, 44 subjects were with Cerebrovascular Disease (32.8%) has significantly higher prevalence of complications compared to other vascular complications. Coronary Artery Disease is the second most prevalent complication with 38 subjects (28%) Third most prevalent complication is Diabetic Nephropathy 20 (14.8 %),

followed by Diabetic Foot in 18 (13.3%) subjects, Diabetic Neuropathy in 10 (7.4%) subjects and Diabetic Retinopathy in 5 (4%) subjects were detected in the study population.

Table no.1 shows the Demographic profile of study population. Patients with Diabetic complications are having average age of 57 years, Duration of diabetes 8 years, B.M.I is 22.2, FBS is 170.5 mg/dl ,PPBS is 315 mg /dl, Systolic B.P is 130mm/hg, Diastolic B.P is 90 mm/hg, family history is found in 73 patients, High medication Adherence in 24, Medium medication Adherence in 53, Low Medication Adherence in 58 patients, smoking status in 62 patient and exercise and diet control in 53 patients. Males are more prevalent for developing the type 2 Diabetes Mellitus vascular complications compared to females. The result is found to be statistically significant from unpaired t test with P Value of 0.0177.

Table 1: Demographic profile of study population

(n = number of patients, BMI = Body mass index; CAD = Coronary Artery Disease; CVD = Cerebrovascular

Parameters	Diabetic complications n=135 Mean			CAD n=38			CVD n=44			DN n=20			DNE n=10			DR n=5			DF n=18			PVD n=0
	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	
Age in yrs	57			58.48			60.27			54.7			54.8			48			52.24			-
Duration of DM yrs	8			7.37			8.87			11.5			9.23			6			6.8			-
B.M.I	22.2			22.1			19.6			21.3			21.5			21			22.04			-
FBS	170.5			162.47			177.3			145.5			141.3			190			160.8			-
PPBS	315.25			235.33			320			217.02			236.83			305			288.7			-
Systolic B.P	132.5			136.2			130			140			130			120			127.5			-
Diastolic B.P	90			85.1			88.9			89.8			78			82			89.1			-
Family History	73			20			24			13			4			2			10			-
Medication adherence	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	H	M	L	-
	24	53	58	8	12	18	7	18	19	2	10	8	1	5	4	1	2	2	5	6	7	-
Smoking Status	62			18			24			9			6			2			3			-
History of Hypertension	81			24			27			2			15			5			8			-
Exercise and diet control	53			13			17			9			4			2			8			-

Disease; PVD = Peripheral vascular disease; DN = Diabetic Nephropathy; DNE = Diabetic Neuropathy; DR = Diabetic Retinopathy; DF=Diabetic Foot; FBS = Fasting blood sugar; PPBS = Postprandial blood sugar; H=High Medication adherence; M= Medium Medication adherence; L= Low Medication adherence.)

Table 2: B.M.I and its prevalence with vascular complication of type 2 diabetes mellitus

B.M.I	CAD n=38	CVD n=44	DR n=5	DN n=20	DNE n=10	DF n=18
Obese >30	1 (2.63%)	0	0	0	0	1 (5.5%)
Over weight 25-30	14(36.84%)	24 (54.6%)	2 (40%)	10(50%)	4 (40%)	9 (50%)
Normal weight 18.5-25	13 (34.2%)	12(27.27%)	1 (20%)	4(20%)	3 (30%)	5 (27.7%)
Under weight <18.5	10 (26.3%)	8 (18.18%)	2 (40%)	6 (30%)	3 (30%)	3 (16.6%)

(BMI = Body mass index; CAD = Coronary Artery Disease; CVD = Cerebrovascular Disease; DN = Diabetic Nephropathy; DNE = Diabetic Neuropathy; DR = Diabetic Retinopathy; DF=Diabetic Foot)

Table No.3: Family History and its prevalence with vascular complications of type 2 diabetes mellitus

Complications	Family History n=73
CAD	20 (27.39%)
CVD	24 (32.8%)
DR	2 (2.73%)
DN	13 (17.8%)
DNE	4 (5.47%)
DF	10 (13.6%)

Table No.4: Results of regression analysis showing association of various risk factors with microvascular complications

Risk variables	Diabetic Retinopathy		Diabetic Nephropathy		Diabetic Neuropathy	
	Odd ratio	95% CI	Odd ratio	95%CI	Odd ratio	95%CI
Age in yrs	5.00	0.79-31.33	1.75	0.63-4.82	1.60	0.4412-5.83
Duration of DM	1.54	0.25-9.56	0.63	0.24-1.66	1.01	0.28-3.68
B.M.I	0.75	0.12-4.66	1.16	0.4-3.02	0.74	0.2-2.772
Treatment Adherence	0.85	0.138-5.28	0.65	0.24-1.75	0.84	0.22-3.15
Family History	0.55	0.09-3.42	1.70	0.63-4.57	0.63	0.171-2.361
History of Hypertension	0.43	0.06-2.665	2.22	0.75-6.54	0.64	0.177-2.343
Smoking Status	1.00	0.165-6.19	1.00	0.3-2.63	1.55	0.42-5.637
Exercise and diet control	1.03	0.16-6.3	1.32	0.5-3.44	1.0	0.277-3.852

(CI is confidence interval)

Table 5: Results of regression analysis showing association of various risk factors with macrovascular complications

Risk variables	Coronary Artery Disease		Cerebro Vascular Disease		Diabetic Foot	
	Odd ratio	95% CI	Odd ratio	95%CI	Odd ratio	95%CI
Age in yrs	0.843	0.38-1.84	1.69	0.810-3.54	1.65	0.61-4.49
Duration of DM	1.18	0.55-2.50	1.33	0.65-2.75	0.95	0.32-2.56
B.M.I	0.57	0.26-1.23	1.6	0.75-3.301	1.16	0.43-3.148
Treatment Adherence	1.0	0.47-2.32	1.11	0.53-2.29	1.03	0.38-2.81
Family History	0.9	0.4-1.9	0.71	0.34-1.47	1.07	0.39-2.907
History of Hypertension	1.3	0.6-2.8	1.088	0.52-2.27	0.48	0.17-1.31
Smoking Status	1.4	0.7-3.0	1.2	0.64-2.45	0.15	0.03-0.71
Exercise and diet control	0.7	0.3-1.6	0.96	0.4-2.01	1.28	0.47-3.48

Table No.2 shows the association of BMI with Type 2 DM complications. Out of 135 patients with type 2 Diabetes Mellitus complications, 24 Patients with Cerebrovascular disease, 14 Patients with Coronary artery disease, 10 Patients with Diabetic nephropathy, 9 with Diabetic foot and 4 Patients with Diabetic neuropathy are overweight (B.M.I between 25-30) .

Among the total participants, there are 73 Patients with family history, out of which nearly 33% of Patients are with a family history of Cerebrovascular Disease, 27% with Coronary Artery Disease, nearly 18% with Diabetic Nephropathy with, 13% with Diabetic Foot, 5% with Diabetic Neuropathy and 3% of Patients with Diabetic Retinopathy has family history.

Among the total participants, there are 81 patients with History of Hypertension. Majority is

Cerebrovascular Disease with 33% Patients and Coronary Artery Disease with 30% Patients.

Among Total patients of type 2 Diabetes Mellitus with complications, Diabetic Neuropathy has highest smoking status compared to other vascular complications. Among Total patients of type 2 Diabetes Mellitus with complications Diabetic Neuropathy has highest smoking status compared to other vascular complications.

Total patients with Type 2 Diabetes Mellitus complications with exercise and diet control are 53. 32% Patients, With Cerebrovascular Disease, 25% patients with Coronary Artery Disease, 17% patients with Diabetic Nephropathy, 15% patients with Diabetic Foot, 8% Patients with Diabetic Neuropathy and 4% patients with Diabetic Retinopathy are having exercise and diet control.

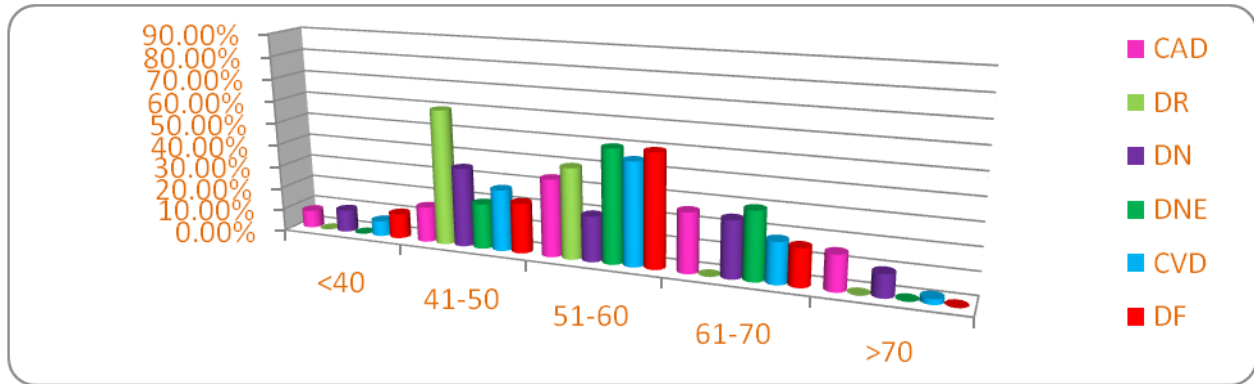


Fig.1: Age of patients and its prevalence with various vascular complications of type 2 diabetes mellitus

It is found that patients with Coronary Artery Disease (CAD), Cerebrovascular Disease (CVD), Diabetic Neuropathy (DNE) and Diabetic foot (DF) Complications are high in age group 51-60, Diabetic nephropathy (DN) and Diabetic retinopathy (DR) patients are prevalent in age group 41-50, shown in Figure no.1.

Patients with type 2 Diabetes Mellitus complications were divided according to Duration of Diabetes in Figure no.2. Patients were grouped into 4 groups i.e. < 5 years, 6-10years, 11-15 years and more than 15 years. All Macrovascular and Microvascular complications are more prevalent with 6-10 years of Duration of Diabetes.

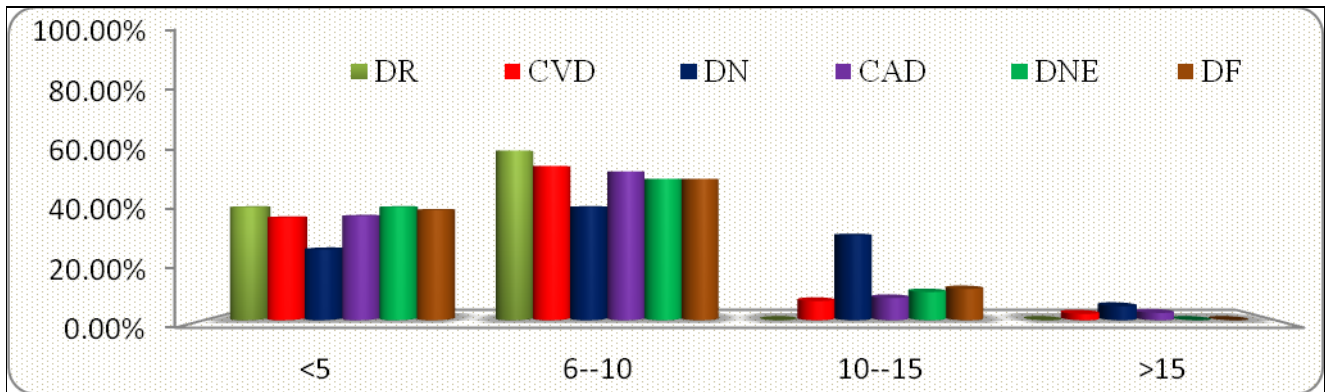


Fig.2: Duration of diabetes and its prevalence with complication of type 2 diabetes mellitus

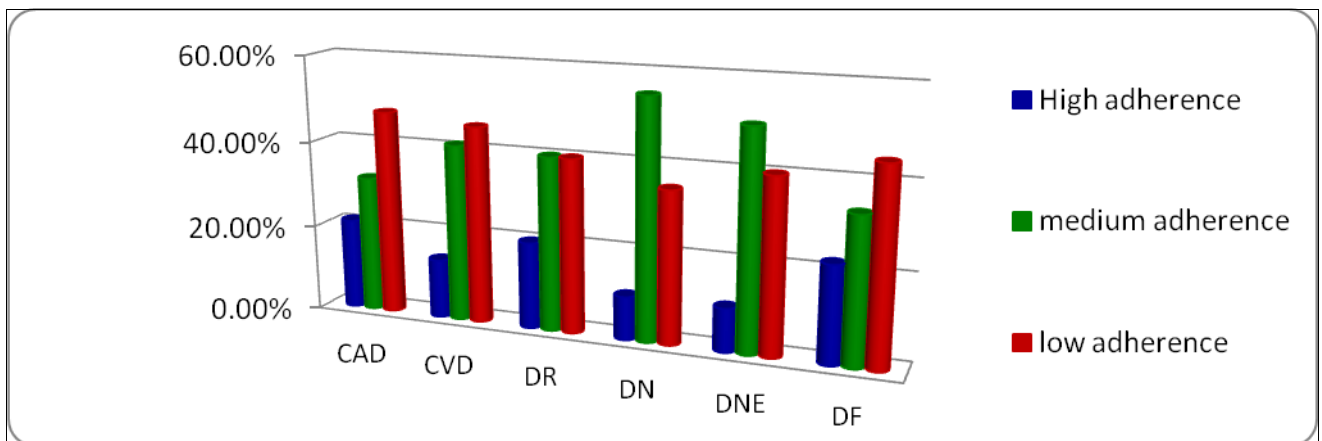


Fig. 3: Medication adherence and its prevalence with vascular complications of type 2 diabetes mellitus

Among total patients of type 2 Diabetes Mellitus complications studied, 24 patients are with High medication adherence, 54 with Medium medication adherence and 58 with Lower medication adherence as shown in figure no.3

The details of relationship between risk variables with various vascular complications are shown in table 4 and 5.

DISCUSSION:

In present study evidence of type 2 Diabetes Mellitus were observed in 200 patients. Amongst the total participants, 65 subjects have DM without complications and 135 subjects have DM complications out of which 115 (85.19%) were males and 20 (14.81%) were found to be females, among which microvascular complications were found in 35 patients (25.9%) and macrovascular complications in 100 patients (74.1%).

Among 135 patients with diabetic complications 44 subjects are with CVD (32.8%) has significantly higher prevalence of complication compared to other vascular complications, CAD is second most prevalent complication with 38 subjects (28%) then Diabetic nephropathy 20 (14.8 %) ,diabetic foot in 18 (13.3%) subjects, Diabetic neuropathy in 10 subject (7.4%) and Diabetic Retinopathy in 5 (4%) subjects were detected in the study population. which are associated with risk factors like age, Duration of type 2 DM, gender (males are more prevalent than females), B.M.I, History of Hypertension, family history, socioeconomic status, smoking status, medication adherence and exercise and diet control.

Significant risk factors for most of the complications in our study are Low medication adherence B.M.I., history of hypertension, Family history of type 2 DM, and smoking.

In our study it is found that CVD is highly prevalent complication compared to other type 2 DM vascular complications and the risk factors associated with CVD is age, duration of diabetes, family history, smoking status, low medication adherence and exercise and diet control which is less in patients. Our results are consistent with Khudhair SA et al (2009) [8] who found there was significant relationship between the prevalence of long term complications and degree of diabetic control and duration of diabetes mellitus.

In present study CAD is found to be second most prevalent complication (28%) of type 2 DM and the risk factors associated with it are age, history of hypertension, duration of diabetes, smoking status,

lower medication adherence, socioeconomic status, and family history Our results are consistent with Hashim R et al (1999) [6] according to which the macro vascular complications Ischaemic heart disease increased with age and duration of diabetes were more prevalent in uncontrolled diabetics.

Our results are consistent with AL Maskari F et al (2007) [11] found that there is a significant association between hypertension and presence of macro vascular disease among diabetic patients which is similar to our findings. Deepa DV et al. (2014) [4] concluded that there was a significant correlation between prevalence of diabetes with increased weight and body mass index, which is consistent with our results

Diabetic Nephropathy is third most prevalent complication found in 14.8% study population associated with risk factors age, family history, exercise and diet control and lower medication adherence which was similar to that of studies reported by Mohammed AK et al (2015) [10] who found that the patients on uncontrolled diet Causes hyperglycemia developed diabetic nephropathy.

In our study Diabetic foot is found to be fourth prevalent complication in 13.3% and the risk factors associated with these complications are age, B.M.I, Duration of diabetes Our results are considered with Knuiman MW et al (1986) [9] which indicate most complications of diabetes show a strong association with some time-related variable, e.g., age and duration of diabetes.

In our study least prevalent complications is Diabetic Neuropathy in 7.4% and Diabetic retinopathy is found in 4%, risk factors associated with this complications is age, gender (males are more Prevalent than females), exercise and diet control, duration of diabetes, history of hypertension, family history and socioeconomic status . Our results are consistent with Ashok S et al (2002) [3] who found that the Prevalence of Neuropathy in Type-2 Diabetic patient increases with increase in age and duration of diabetes and study population has neuropathy. Raman R et al. (2009) [12] who found that the prevalence of diabetic retinopathy in the population with diabetes mellitus were significantly associated with risk factors included gender (men at greater risk) longer duration of diabetes.

In our study the details of relationship between risk variables with various vascular complications are observed on regression analysis It is observed that with type 2 DM vascular complications, Risk factors

like age, Duration of type 2 DM, smoking, B.M.I, History of Hypertension shared the strongest association with the vascular complications, which was similar to that of studies reported by Agrawal RP et al. (2004) [1] Regression analysis revealed that age, duration of diabetes and hypertension was significantly associated with all these complications.

Some of the studies reported in literature review which are not similar to our studies are Vaz NC et al (2011) [14] concluded that The prevalence of the associated diabetic complications were as follows neuropathy (60%), retinopathy (15.4%), peripheral vascular disease (11.5%) and cerebrovascular accidents (CVAs) (6.9%) A significant rising trend in the prevalence of all diabetic complications was observed with advancing duration of diabetes. Kung K et al (2014) [7] concluded that a high prevalence of microvascular complications among Chinese primary care patients despite achieving adequate HbA1c levels, highlighting the importance of managing all aspects of diabetes including weight, lipid and blood pressure. Ramachandran A et al (1999) [13] concluded that there is high prevalence of microvascular complications in Type 2 diabetes in India. Retinopathy and neuropathy were the commonest complications of diabetes.

Ergul A et al (2012) [5] concluded that cerebrovascular complications make diabetic patients 2–6 times more susceptible to a stroke event and this risk is magnified in younger individuals and in patients with hypertension and in other vascular complications.

CONCLUSION:

This study highlights the high prevalence of vascular complications in Type 2 Diabetes mellitus patients. It is found that cerebrovascular disease and Coronary artery disease were the commonest complications of diabetes in the study population.

Macrovascular complications are detected in 100 patients and Microvascular complications in 35 patients with Type 2 DM. Macro vascular complications are found to be more prevalent when compared Microvascular complications, which are associated with risk factors like age, Duration of type 2 DM, gender, B.M.I, History of Hypertension, family history, socioeconomic status, smoking status, medication adherence and exercise and diet control. Males are more prevalent for developing the type 2 DM vascular complications when compared to Females. Low medication adherence, B.M.I, Family History of type 2 DM, History of Hypertension are the most significant risk factors in our study.

The progression of most complications can be halted or delayed if detected early and appropriate therapy instituted.

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