

## Prescribing Patterns and Treatment Outcomes of Newer Anti-Diabetic Medication As Add On To Metformin in Type-2 Diabetes Mellitus-A Prospective Observational Study

Sk.Abdul Saleem, Ch.Vani, K.Umatejaswi, P.Sireesha, Y.Jemimah  
*Department of Pharmacy Practice, NIPS College, Narasaraopet, Guntur dist., INDIA.*

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### ABSTRACT

**Objective :** The aim of the study was to evaluate the prescription pattern & To assess the safety and efficacy of newer anti-diabetic medication as add on to metformin in patients with type 2 diabetes mellitus.

**Methodology:** A prospective observational study was conducted in department of endocrinology in private hospital Guntur for a period of 6 months. Patients of either sex aged  $\geq 18$  years and above, patients who were diagnosed as diabetic were included in the study. The records of all the patients with in given period was isolated and screened and relevant data was extracted by using patient data and collection form were analysed. **Results** A total of 177 patients were recruited for the study, 47.5% of the patients were males and 52.5% of the patients were females. Most of the patients were in the age group of 61-70 years i.e. 35.6 % (n=63) . In the present study, nearly two-third of the patients had a diabetic history of 6-10 years. This study also revealed the common predominant co-morbidity with DM and others like Anemia, CVA, retinopathy etc., of 34.4 %.. In this study, the patients were treated with monotherapy, dual therapy, and triple therapy. The dual therapy Antidiabetic drugs are in combination of Biguanides & DPP4 Inhibitors, by 69 (87.34%) patients. triple therapy drugs are accounted to manage uncontrolled diabetes, these combinations were prescribed to 93 (53.1%) patients Among fixed drug combinations the most prescribed drugs anti-diabetic agents are Biguanides (metformin) followed by DPP4 Inhibitors (Teligliptin) 30.5%.(n=54). **Conclusion :** In conclusion monotherapy with Sulphonylureas, metformin and toward combination therapies to achieve better glycemic control with increased use of Biguanides and DPP-4 inhibitors.

**Key words :** prescribing, Diabetes, glycemic control, Anti-diabetic medication.

### I. INTRODUCTION

Diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys, and nerves. The most common is type 2 diabetes, usually in adults, which occurs when the body becomes resistant to insulin or doesn't make enough insulin. In the past three decades the prevalence of type 2 diabetes has risen dramatically in countries of all income levels. Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin by itself<sup>[1]</sup>. Diabetes is fast becoming the epidemic of the 21st century. Type 2 diabetes, which is more prevalent (more than 90% of all diabetes cases) and the main driver of the diabetes epidemic, now affects 5.9% of the world's adult population with almost 80% of the total in developing countries . Nowhere is the diabetes epidemic more pronounced than in India as the World Health Organization (WHO) reports show that 32 million people had diabetes in the year 2000. The International Diabetes Federation (IDF) estimates the total number of diabetic subjects to be around 40.9 million in India and this is further set to rise to 69.9 million by the year 2025 Epidemiology of diabetes in India has an extensive history<sup>[2]</sup>. The management of type-1 diabetes depends on insulin mainly, whereas the management of type-2 diabetes is mainly managed using oral hypoglycaemic agents (OHAs) .Diabetes, if uncontrolled, leads to several acute and chronic complications . The chronic complications of diabetes make it necessary to prescribe drugs for these patients life long. Moreover, a good number of diabetes patients suffer from cardiovascular disease such as hypertension, hyperlipidaemia and ischaemic heart disease<sup>[3]</sup>.

### III. RESULTS:

According to results reveal that out of 177

S.NO	PARAMETERS	No.of patients (males)	Percentage %(males)	No.of patients (females)	Percentage %(females)	TOTAL	PERCENTAGE %(total)
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### II. MATERIALS AND METHODS

The study was conducted in private hospitals at Guntur. A prospective hospital based non-experimental (observational study) was carried out for a period of 6 months. Ethical clearance was obtained from the Institutional Review board & Hospital Ethics Committee. The study recruited 177 prescriptions of diabetic patients according to the inclusion criteria.

#### Inclusion Criteria:

- Patients with Type 2 diabetes mellitus were included .
- Age group above 18 years were included.
- Patients with co- morbidities were also included in the study.

#### Exclusion Criteria:

- Pregnant and lactating women are excluded.
- Patients who are not willing and un co-operative are excluded.

#### **Operational modality & Statistical analysis:**

Patients were enrolled in the study after getting a verbal informed consent. The details were entered in the structured patient profile form. The filled patient profile forms were analyzed for various parameters like gender of patients, duration of diabetes, concurrent illness, therapeutic category of drugs, class of anti-diabetics, types of insulin preparations used. Data were entered into Microsoft excel and analyses were performed accordingly. Descriptive statistics such as frequencies and percentages were calculated for categorical variables. Mean ( $\pm$ ) and standard deviation ( $\pm$ ) were computed for continuous variables. Graphic representations were used for visual interpretation of the analyzed data<sup>[4]</sup>.

patients for the study, 47.5% of the patients were males and 52.5% of the patients were females. The results revealed that, maximum number of patients were in the age group 61-70 (35.6%) of followed by 31.1% of the patients in the age group of 51-60 years and 22.6% of the patients in the age group 41-50years followed by 9.6 % and 7.9% in age groups of 30-40 years and 71-80 years and 0.6% of patients were in the age group of 81-90 years respectively. The mean age group of males and females were found to be as  $55.33 \pm 11.64$  and  $56.04 \pm 11.79$  years respectively. ( Table1)

This study reveals that, 26.5% (n=47) were found to be normal (18.5-24.9). 58.7% patients (n=77) are found to be over weight (25-29.9). 21.5% patients (n=50) are found to be obese class 1 (30-39.9). 7.9% patients (n=3) are found to be obese class 2 (>40). The demographic data reveals that overweight and obese class 1 patients are more in number. The mean BMI of males and females were found to be  $27.18 \pm 5.17$  and  $30.14 \pm 6.59$  respectively. The P-value of BMI was found to be 0.285 i.e there was a significant statistical difference between males and females.

The HbA1C distribution in diabetic patients, among 177 patients, 5.08% patients (n=9) Under good control (<5.7), 15.25% patients (n=27) under control (5.7-6.5), 29.94% Patients (n=53) under poor control (6.5-5.8), 49.7% patients (n=88) under very poor control (>8.0). Very poor control patients high in number due to various factors over the past 3 months. The mean HbA1C levels of males and females were found to be  $10.06 \pm 3.72$  and  $10.6 \pm 3.68$  respectively. The P-value of HbA1C was found to be as 0.016 i.e there was no significant difference between males and females. (Table 1)

<b>I.</b>	<b>AGE</b>						
	30-40	8	4.5	16	9	17	9.6
	41-50	22	12.4	18	10.2	40	22.6
	51-60	26	14.7	29	16.4	55	31.1
	61-70	20	11.3	43	24.3	63	35.6
	71-80	7	3.9	7	3.9	14	7.9
	81-90	1	0.6	0	0	1	0.6
<b>II.</b>	<b>GENDE R</b>	84	47.5	93	52.5		
<b>III.</b>	<b>BMI</b>						
	Normal (18.5-24.9)	30	16.9	17	9.6	47	26.6
	Over wt. (25-29.9)	35	19.8	42	23.7	77	58.7
	Obese Class-1 (30-39.9)	18	10.2	20	11.3	38	21.5
	obese Class -2 (>40)	1	0.6	13	7.3	14	7.9
<b>IV.</b>	<b>HBA1C</b>						
	<5.7 (Good control)	6	3.4	3	1.7	9	5.6
	5.7-6.5 (control)	12	6.8	14	7.9	26	14.7
	6.5-8 (poor control)	27	15.3	26	14.7	53	29.9
	>8.0(very poor control)	39	22.0	49	27.7	88	49.7

**Table 1: Distrubution of diabetic patients based on different variables**

Among the study population, 83 patients (62.4%) had a diabetic history of less than 5 year, followed by 6-10 years in 38 patients (28.57%), 11-15 years in 6 patients (4.51%), 16-20 years in 5

patients (3.75%) and more than 20 years in one patient (0.75%). In the present study, nearly two-third of the patients had a diabetic history of less than 5 years. (Table2)

**Table2: Details of duration of Diabetes in the study population.**

DURATION	NO OF PATIENTS
< 5 Years	57 (32.2%)
6-10 years	84 (47.5%)
>10 years	36 (20.3%)
Total	177

Among all diabetic patients with other co-morbidities 34.4 % (n=61) were effected with other diseases like AKI, anaemia, UTI, COPD, etc.... 29.9% (n= 53) were effected with peripheral neuropathy along with Hypertension, 14.1% (n=25) were effected with HTN, 10.1% (n=18) were effected with hypothyroidism, 7.9% (n=14) were effected

with coronary artery disease (CAD). Among the various complications, cardiovascular complications pose a major treat. In this study, Dm with others (AKI, anaemia, UTI, COPD, etc) are accounted for 34.4% of the total complications seen in the diabetes patients. (Table 3)

**Table 3: Diabetes associated with co-morbid conditions**

S.NO	DM ASSOCIATED WITH CO-MORBID CONDITIONS	NO. OF PATIENTS	PERCENTAGE (%)
1.	DM WITH OTHERS	61	34.4
2.	DM, HTN WITH PN	53	29.9
3.	DM WITH HTN	25	14.1
4.	DM WITH HYPOTHYROIDISM	18	10.1
5.	DM WITH CAD	14	7.9
6.	DM	6	3.3

**Prescribing patterns**

Altogether 645 drugs were prescribed in the study population. The average number of drugs per prescription was 3.64. Antidiabetics were the commonest class of drugs accounting for 382 (59.22%) of the total drugs. In general, due to multiple diseases, diabetes patients are at a greater risk of polypharmacy. In this study, Antidiabetics drugs accounted for 382 (59.22%) of the total drugs prescribed.

Rosuvastatin accounted for 48 (22.5%) followed by Atorvastatin accounted for 44 (20.7%),

Telmisartan accounted for 40 (18.8%), Olmesartan accounted for 27 (12.7%), levothyroxine accounted for 20 (9.4%), chlorthalidone accounted for 15 (7.04%), multivitamin accounted for 9 (4.2%), Amlodipine accounted for 6 (2.8%), Hydrochlorthalidone accounted for 4 (1.9%), and other drugs accounted for less than one percent.

The results revealed that, maximum number of patients 93 (52.54%) underwent triple therapy, followed by 80 (45.19%) patients underwent dual therapy, 4 (2.250%) patients underwent

monotherapy, 2 (1.50%) patients were prescribed with more than 3 drugs.(Table 4)

Table 4 :prescribing pattern of anti-diabetic drugs

S.NO	PRESCRIPTION	NO.OF PATIENTS	PERCENTAGE(%)
1.	TRIPLE THERAPY	93	52.54%
2.	DUAL THERAPY	80	45.19%
3.	MONOTHERAPY	4	2.250%

Among all 177 diabetic patients, 4 patients were prescribed with mono therapy, and that includes the anti-diabetic drugs like TENELIGLIPTIN (1.1%,n=2), GLIMEPIRIDE (0.6%,n=1), GLIPIZIDE (0.6%,n=1).

Among all 177 diabetic patients, some patients were treated with dual therapy and that includes the anti-diabetic drugs like Teneligliptin +metformin (30.5%,n=54), Sitagliptin + metformin(5.6%,n=10), Linagliptin +

metformin(1.7%,n=3), Vildagliptin + metformin(1.7%,n=3), Dapagliflozin + metformin(3.9%,n=7), Empagliflozin + metformin(0.6%,n=1), Glimepiride + metformin(0.6%,n=1), Glipizide+ metformin(0.6%,n=1).The demographic data reveals that, in dual therapy TENELIGLIPTIN + METFORMIN combination was mostly prescribed.(figure 1)

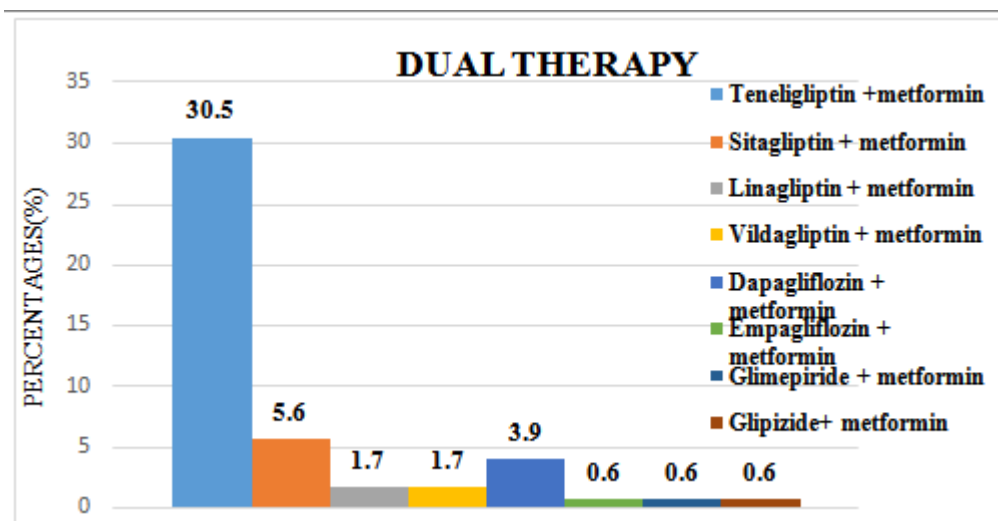


Figure 1:Distribution of different classes of anti-diabetic drugs used as dual therapy

Among all 177 diabetic patients, the prescriptions includes triple therapy and the drugs as follows Teneligliptin +metformin +glimepiride(14.6%,n=26), Teneligliptin +metformin

+glipizide(6.77%,n=12)Teneligliptin+metformin+voglibose(2.25%,n=4),Teneligliptin+metformin+Insulin(3.95%,n=7)Canagliflozin+teneligliptin+metformin(0.56%,n=1),Sitagliptin+metformin+voglibose(

3.38%,n=6),Insulin+sitagliptin+metformin(0.56%,n=1),Sitagliptin+metformin+glimepiride(3.38%,n=6),Sitagliptin+metformin+glipizide(0.56%,n=1),Sitagliptin+metformin+empagliflozin(0.56%,n=1),Dapagliflozin+metformin+glimepiride(2.25%,n=4),Dapagliflozin+metformin+glipizide(1.69%,n=3),Dapagliflozin+metformin+voglibose(1.12%,n=2),Dapagliflozin+metformin+Insulin(1.12%,n=2),Empagliflozin+metformin+glimepiride(2.25%,n=4),Empagliflo

zin+metformin+voglibose(0.56%,n=1),Vildagliptin+metformin+glimepiride(1.69%,n=3),Vildagliptin+metformin+glipizide(0.56%,n=1),Vildagliptin+Insulin+metformin(1.12%,n=2),Vildagliptin+metformin+voglibose(0.56%,n=1),Saxagliptin+metformin+Insulin(0.56%,n=1),Saxagliptin+metformin+glipizide

(0.56%,n=1),Saxagliptin+metformin+voglibose(0.56%,n=1),Linagliptin+metformin+Insulin(0.56%,n=1),Canagliflozin+metformin+glimepiride(0.56%,n=1).The demographic data reveals that in triple therapy Teneligliptin +metformin +glimepiride was mostly prescribed.(Table 5)

Table 5 : distribution of different classes of anti-diabetic drugs used as triple therapy

TREATMENT (TRIPLE THERAPY)	NO OF PATIENTS	PERCENTAGE(%)
Teneligliptin +metformin +glimepiride	26	14.6
Teneligliptin +metformin +glipizide	12	6.77
Teneligliptin + metformin + voglibose	4	2.25
Teneligliptin+ metformin +Insulin	7	3.95
Canagliflozin +teneligliptin +metformin	1	0.56
Sitagliptin +metformin +voglibose	6	3.38
Insulin +sitagliptin+ metformin	1	0.56
Sitagliptin +metformin +glimepiride	6	3.38
Sitagliptin + metformin +glipizide	1	0.56
Sitagliptin +metformin + empagliflozin	1	0.56
Dapagliflozin +metformin +glimepiride	4	2.25
Dapagliflozin +metformin +glipizide	3	1.69
Dapagliflozin +metformin + voglibose	2	1.12
Dapagliflozin +metformin +Insulin	2	1.12
Empagliflozin +metformin +glimepiride	4	2.25
Empagliflozin +metformin + voglibose	1	0.56
Vildagliptin + metformin +glimepiride	3	1.69
Vildagliptin + metformin + glipizide	1	0.56
Vildagliptin +Insulin + metformin	2	1.12
Vildagliptin+ metformin+ voglibose	1	0.56
Saxagliptin +metformin +Insulin	1	0.56
Saxagliptin +metformin + glipizide	1	0.56
Saxagliptin +metformin + voglibose	1	0.56
Linagliptin +metformin +Insulin	1	0.56
Canagliflozin +metformin + glimepiride	1	0.56

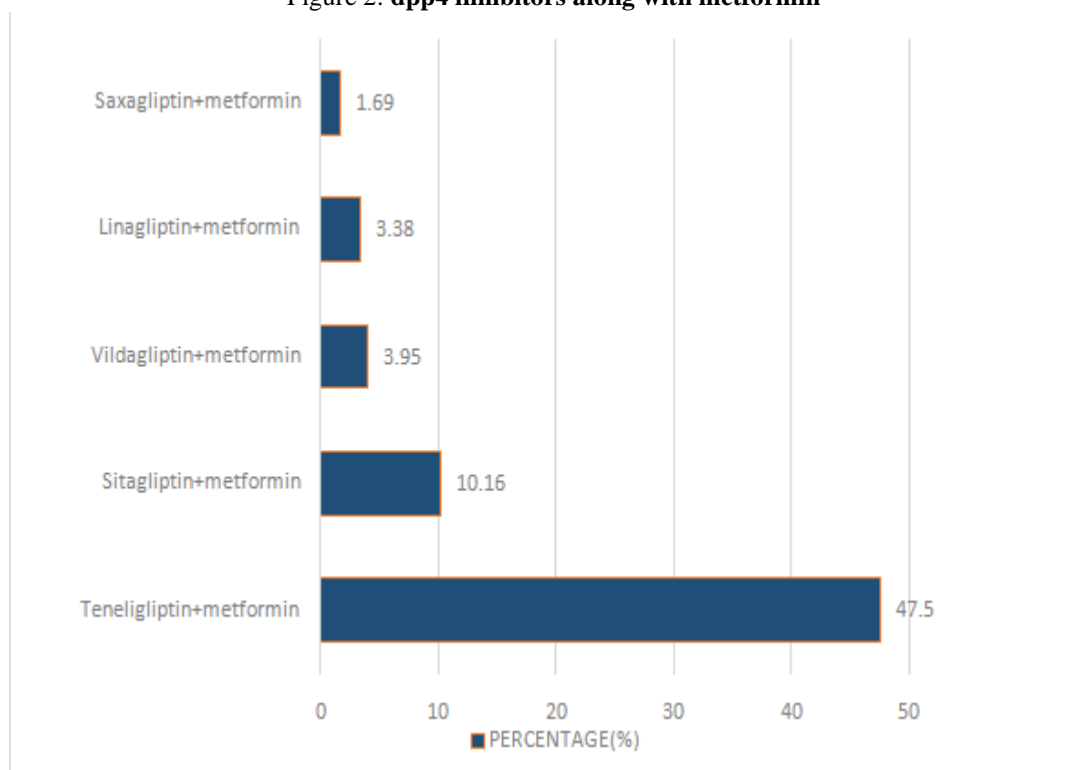
**Distribution of classes of newer anti diabetic drugs used in the treatment:**

**DPP4 INHIBITORS ALONG WITH METFORMIN:**

The study shows that prescription patterns of newer anti-diabetic drugs in diabetic patients, among 177 patients, 81(47.5%) patients were prescribed with teneligliptin with metformin combination, 18(10.16%) patients were prescribed

with sitagliptin with metformin combination, 7(3.95%) patients were prescribed with vildagliptin with metformin combination, 6(3.38%) patients were prescribed with linagliptin with metformin combination, 3(1.69%) patients were prescribed with saxagliptin with metformin combination. The demographic data reveals that patients were mostly using teneligliptin with metformin combination(81)(figure 2)

Figure 2: dpp4 inhibitors along with metformin



Study shows that prescription patterns of newer anti-diabetic drugs in diabetic patients, among 177 patients, 14(7.9%) patients were prescribed with dapagliflozin with metformin combination, 2 patients were prescribed with empagliflozin with metformin combination. the

demographic data reveals that patients were mostly using dapagliflozin with metformin combination as compared to other drugs of same class (sglt2 inhibitors). (Table 6)

Table 6 : sgl2 inhibitors along with metformin:

<b>SGLT2 INHIBITOR ALONG WITH METFORMIN COMBINATION</b>	<b>NO. OF PATIENTS</b>	<b>PERCENTAGE(%)</b>
<u>Dapagliflozin+ metformin</u>	14	7.9
<u>Empagliflozin+ metformin</u>	2	1.12

#### IV. DISCUSSION:

Our study provides the information on prescribing patterns and treatment outcomes with trend of anti-diabetic drug therapy. The study was also considered to be one of the most effective method to assess and to promote the rational use of drugs in hospital settings.

Diabetes mellitus is a major public-health problem over worldwide. Its prevalence was rising in many parts of the developing world and in India there is no exception to this. Individuals with Type 2 diabetes were considered on high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of many complications.

Type 2 diabetes is a chronic disease requiring lifelong treatment. Although life style modification plays an important role in managing diabetes, the usage of medication became unavoidable in many patients. A prescription based study was considered as one of the most effective method to assess and to evaluate the prescribing pattern of medications.

This study reveals that maximum numbers of patients were in the age group of 61-70 years and similar study was also published by the Quazi et al. In our study shows that, Diabetes is always being dominating in females as compare to males; similar study was reported by Agrawal et al..

In the present study, nearly two-third of the patients had a diabetic history of 6-10 years which observes equal study by Raheja BS et al . Patients with a long duration of diabetes are at a higher risk of developing complications. This study also revealed the common predominant co-morbidity with DM and others like Anemia, CVA, retinopathy etc., of 34.4 % . Similar study was observed by Nishanthini D et al.

Altogether 645 drugs were prescribed in the study population. The average number of drugs per prescription was 3.64. Antidiabetics were the commonest 177 class of drugs accounting for 382 (59.22%) of the total drugs. In general, due to multiple diseases, diabetes patients are at a greater risk of polypharmacy.

There are more class of anti-diabetic drugs are present the choice Antidiabetic depends on the type of patients, their concurrent illness, cost factors, as well as the availability of medicines. In general, Metformin is considered as a safer drug interms of hypoglycemia.

In this study, the patients were treated with monotherapy, dual therapy, and triple therapy where single ADDs, two ADDs and three ADDs respectively were used; this is due to the severity and condition of the diabetes along with other co morbidities or complications. The study revealed that, mostly acceptable treatment for older diabetic type 2 patients is done by single therapy only and that is insulin therapy & dpp4 Inhibitors. It includes Human Mixtard, Human Actrapid & Teneigliptin. A Study concluded that Metformin and Glimepiride is also most common drug of choice, Similarly results were correlated with Upadhyay DK et al .

According to this study finding, the most common and accepted dual therapy Antidiabetic drugs are in combination of Biguanides & DPP4 Inhibitors, by 69 (87.34%) patients. The dual combination prescription products are available with many other categories of drugs like Biguanides, such as Metformin with dpp4 inhibitors and sgl2 inhibitors. The preferred choices of drugs in combination are Teneigliptin & Metformin (68.3%), Metformin & sitagliptin (11.39%) and Metformin & ,linagliptin/vildagliptin (3.79%).



In this study triple therapy drugs are accounted to manage uncontrolled diabetes, these combinations were prescribed to 93 (53.1%) patients. The most preferred triple drug therapy combinations are Metformin, Teneeligiptin & glimepiride and Metformin, Glipizide and Teneeligiptin.

In conclusion study study showed the prescription pattern in practice for a large number of patients with type 2 diabetes. In conclusion, the antidiabetic prescribing trend has moved away from monotherapy with Sulphonylureas, metformin and toward combination therapies to achieve better glycemic control with increased use of Biguanides and DPP-4 inhibitors like metformin +Teneeligiptin.

#### V. CONCLUSION :

Diabetes mellitus is very common disorder in all population especially in adults. Type 2 diabetes is the most common clinical form of world wide . Type -2 diabetes is frequently associated with other cardiovascular and renal risk factors. Its chronic complications increasing cost of care and impacting negatively on quality of life of people with this disease. To improve the treatment outcomes of diabetes and reduce the risk of complications with other diseases , we are using anti diabetic agent Most of people are treated with oral hypoglycemic agents (65%) and followed by the combinations of these drugs with insulin and only insulin. A part from glycemic control cardiovascular outcome trails has shown benefit of these days in decreasing the onset and severity of cardiovascular events. It is also shown to decrease the albuminuria and halt the progression of nephropathy.

#### LIMITATIONS OF THE STUDY:

Our study has a few limitations ,the present study didn't include the all the diabetic patients visted to hospital during the study period because of logiclissues.there is no database or disease registry available. More over, our study was don for a short period of time and the no.of patients studied was low. Hence similar studies covering large no.of patients and need to conform our findings.

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#### CONFLICT OF INTEREST:

The author declares no conflict of interest.

#### ABBREVIATIONS USED:

**CVA** :Cerebro vascular accident, **BMI** : Body mass index, **DM** : Diabetes mellitus, **DPP4I** : Dipeptidyl peptidase-4 inhibitors , **HbA1c** : glycosylated hemoglobin type a1c, **IDF** : International diabetes federation

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