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A STUDY TO COMPARE EFFICACY OF METFORMIN-GLIMEPIRIDE VERSUS METFORMIN-TENELIGLIPTIN IN TYPE II DIABETIC PATIENTS

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ABSTRACT: Diabetes mellitus relates a metabolic disorder of collective aetiology which is characterized by chronic hyperglycaemia caused due to disturbances of carbohydrate, lipid and protein metabolism due to impaired β cell function of pancreas or insulin resistance or both. Biguanides and Sulphonylureas are the most commonly prescribed drugs due to their efficacy and safety. A total of 60 patients were enclosed in the present study who met the inclusion criteria. They were divided into two groups based on their treatment plan-Group A and Group B. The Group B (P = 0.001) exhibited a significantly greater reduction in HbA1c as compared to Group A (P = 0.002). The reductions in FPG and PPG were also found to be significantly more in the Group B. In the present study, we observed that patients on Metformin-Teneligliptin exhibited better control over glycemic profile as well as lipid profile when compared to patients who are on Metformin-Glimepiride combination. Since, this study was conducted in less number of patients, to make consecutive remarks about the superiority of either of the treatment regimen, furthermore analysis of clinical trials is required for appropriate selection of best combination of anti-diabetic medication.

INTRODUCTION: Diabetes mellitus is the most common non-communicable diseases in the recent era and has reached to epidemic stages in various part of the world [1]. According to ADA redefined publication in 2017 [2] and of WHO in 2006 [3], DM is classified under four categories: type 1 DM (DM1), type 2 (DM2), other types and gestational diabetes.

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Diabetes mellitus is usually caused due to increase in age, urbanization, changes in diet and lifestyle and reduced physical activity [4]. Chance of developing type 2 diabetes depends on combination of risk factors such as genes and lifestyle.

Even though risk factors for DM such as family history, age, or ethnicity can't be reworked, lifestyle risk factors around eating, physical activity, and weight can be improved [5]. Diagnostic criteria for Diabetes mellitus include classical symptoms of diabetes (*i.e.*, Polyuria, polydipsia and unexplained weight loss) plus plasma glucose concentration ≥ 200 mg/dl (11.1 mmol/L) or fasting

blood glucose ≥ 126 mg/dL (7.0 mmol/l) or 2 h post prandial glucose levels of ≥ 200 mg/dL (11.1 mmol/L) [6]. HbA1c targets levels of less than 6.5 to 7% have been proposed by various organizations to define good control of diabetes mellitus. Treatment of diabetes mellitus patients include advice on nutrition, physical activity, weight loss and smoking cessation and anti diabetic medications. Oral hypoglycemic drugs used include Biguanides, Sulphonylureas, Dipeptidyl peptidase inhibitors [7, 8].

Metformin - Glimepiride and Metformin-Teneligliptin was selected for the study because Metformin-Glimepiride is the most commonly used combination whereas Teneligliptin is a newer drug with longer half-life, dual mode of elimination, superadded it has low cost when compared to other DPP's. Ultimately, Teneligliptin when added with Metformin when used in early treatment of Diabetes would be a good approach in treatment.

METHODS:

Study Population and Design: The study was carried out at in and out-patient department of General Medicine at SVS medical college and hospital, Mahabubanagar, Telangana, India. The study was a prospective, parallel-group, open-label comparative study conducted from August, 2017 to January, 2018 (06 months). The study was approved by Institutional Ethics Committee of SVS Medical College and Hospital and is in accordance with Declaration of Helsinki and Good Clinical Practice. The patients who were >18 years of age and diagnosed with type II diabetes of either sex confirmed with postprandial hyperglycemia were eligible to be included in the study design. Patients who are not willing to give the consent, pregnant and lactating women, drug addicted patients, patients with severe intestinal and pancreatic complications were excluded. Enrolled patients gave informed consent and were divided into two groups. Group A was taking dual therapy of Glimepiride 1 mg and Metformin 500 mg OD. Group B was taking Teneligliptin 20 mg and Metformin 500 mg OD. Total 60 patients were included for the study *i.e.,* 30 subjects in each group.

Efficacy and Safety Evaluation: The primary objective was glucose triad (HbA1c, fasting glucose and post-prandial glucose level) change from baseline to 3 months after treatment. Secondary objective was to measure lipid profile (TC, TGs, LDL and HDL) changes. Other demographic details like age, sex, height, weight, Body Mass Index (BMI), duration of disease and family history was also recorded. Then follow-up of all these parameters were carried out after successful completion of 3 months of treatment. The BMI was calculated by using metric imperial BMI formula. Estimation of blood glucose both fasting and postprandial was done by Glucometer Model-365702192102, lipid profile analysis was done by Enzymatic methods using Beckman Coulter instrument model: AU480, HbA1c was calculated by Borate affinity assay method using Biorad instrument model: D10 in clinical biochemistry laboratory of SVS medical college and hospital, Mahabubanagar, Telangana, India.

Statistical Methods: The analysis was carried out by using SPSS version 20.0 and MS-Excel. T- Test was applied for continuous data.

RESULTS: The demographic and clinical measurements in both the groups *i.e.,* group A and B of randomized patients are mentioned below.

Demographic Characteristics of the Study Subjects: During 6 months period a total of 60 participants were collected. Age distribution of patients is summarized in **Table 1**. In Group A, the mean average age was 53.7. In Group B, the mean average age was 52.66. Among 60 patients, out of 30 patients belonging to Group A, 15 were male, 15 were female. Out of 30 patients belonging to Group B, 20 were male, 10 were female. It has been shown in **Table 2**. **Table 3** shows the presence and absence of family history. In Group A out of 30 patients 13(43.3%) had a family history of DM whereas 17(56.7%) patients were found to have no family history of DM. In Group B out of 30 patients 16(53.3%) had a family history of DM whereas 14(46.7%) patients were found to have no family history of DM. **Table 4** shows duration of disease status. In Group A more number of patients (15) have greater than 5 yrs history of DM while less number of patients (4) belong to 1 - 2 and 3 - 4 yrs past history. In Group B more number of patients (12) have greater than 5yrs past history of DM while least number of patients (3) belong to group having less than 1 yr past history of DM.

Table 5 shows presence or absence of co-morbid conditions. In Group A 15 patients has other co-morbid conditions while 15 patients has no co morbidities. In Group B 16 patients has other co-morbid conditions while 14 patients has no co morbidities. **Table 6** shows the distribution of patients based on the type of co morbidities. Most of the patients has hypertension in both group A (13) and group B (9).

TABLE 1: DISTRIBUTION OF PATIENTS ACCORDING TO AGE

Age Category	Group A (No. of Patients)	Group B (No. of Patients)
<40	2(6.6%)	4(13.33%)
40-49	7(23.4%)	6(20%)
50-59	12(40%)	7(23.3%)
>60	9(30%)	13(43.4%)
Mean	53.7	52.66

TABLE 2: DISTRIBUTION OF PATIENTS ACCORDING TO GENDER

Gender	Group A (No. of Patients)	Group B (No. of Patients)
Male	15(50%)	16(53.3%)
Female	15(50%)	14(46.7%)
Total	30	30

TABLE 3: DISTRIBUTION AS PER FAMILY HISTORY

Family History	Group A	Group B
Present	13(43.3%)	16(53.3%)
Absent	17(56.7%)	14(46.7%)
Total	30	30

TABLE 4: DISTRIBUTION AS PER DURATION OF DISEASE

Duration of Disease (in Years)	Group A	Group B
<1	7(23.3%)	3(10%)
1-2	4(13.3%)	8(26.7%)
3-4	4(13.3%)	7(23.3%)
>5	15(50%)	12(40%)

TABLE 5: DISTRIBUTION AS PER PRESENCE OR ABSENCE COMORBIDITIES

Comorbidities	Group A (No. of patients)	Group B (No. of patients)
Present	15(50%)	16(53.3%)
Absent	15(50%)	14(46.7%)

TABLE 6: DISTRIBUTION AS PER TYPE OF COMORBIDITIES

Comorbidities	Group A	Group B
Hypertension	13	9
Cardiovascular diseases	1	5
Hypothyroidism	1	1
ALD Hepatitis	0	1

Biochemical Measurements: The changes in all the clinical parameters evaluated are enlisted in **Table 7, 8, 9** and **10** for group A and B respectively. **Table 7** shows that before starting the treatment, there was no significant difference between two groups.

Table 8 shows that after the treatment follow up for 3 months there was significant difference found between two groups. Coming to the glucose triad, in group A, HbA1c before treatment was found to be 8.28 ± .13 and after treatment it was found to be 7.44 ± .12. FBS levels before and after treatments were found to be 165.93 ± 3.46 and 132.63 ± 4.96 respectively. PPBS before and after treatment are 271.00 ± 7.58 and 191.06 ± 8.63. There was significant difference between the group before and after treatment.

In group B, HbA1c before treatment was found to be 8.26 ± .15 and after treatment was found to be 7.07 ± .12. FBS levels before and after treatments were found to be 169.76 ± 3.49 and 125.60 ± 4.04 respectively. PPBS before and after treatment are 283.03 ± 8.37 and 208.66 ± 8.20. There was significant difference between the group before and after treatment.

Coming to the lipid profile, in group A, the mean triglycerides levels before and after treatment were found to be 157.33 ± 7.85 and 157.03 ± 6.79 respectively. Mean HDL levels before and after treatment were found to be 37.70 ± 1.25 and 41.26 ± 1.44 respectively. Mean LDL values before treatment is 97.00 ± 3.80 and after treatment is 87.00 ± 3.10. Whereas the mean VLDL values before and after treatment are 38.83 ± 2.61 and 36.30 ± 1.46 respectively. In group B, the mean triglycerides levels before and after treatment were found to be 151.36 ± 6.67 and 140.06 ± 5.68 respectively. Mean HDL levels before and after treatment were found to be 38.96 ± 1.32 and 42.63 ± 1.34 respectively. Mean LDL values before treatment is 111.84 ± 5.95 and after treatment is 94.26 ± 5.91. Whereas, the mean VLDL values before and after treatment are 38.26 ± 2.30 and 31.40 ± 1.93 respectively.

Table 9 and **10** shows significant difference before and after treatment within the group for group A and B. By using the independent t-test, changes of

biochemical baseline parameters were evaluated before and after treatment within the group. In group A, the P-values for biochemical parameters are HbA1c (0.002), FBS (0.00), PPBS (0.002), Triglycerides (0.01), HDL (0.002), LDL (0.013), VLDL (0.04). In group B, the P-values for biochemical parameters are HbA1c (0.001), FBS (0.000), PPBS (0.002), Triglycerides (0.013), HDL (0.002), LDL (0.005), VLDL (0.02).

TABLE 7: COMPARISON OF DIFFERENCES IN BIOCHEMICAL PARAMETERS BETWEEN METFORMIN-GLIMEPIRIDE (GROUP-A) AND METFORMIN-TENELIGLIPTIN (GROUP-B) BEFORE TREATMENT

Independent t test, t (.05, 95 CI, df-85)

Parameters	Group	Mean ± Std. Error Mean	P - value
HbA1C	A	8.28 ± 0.13	.922
	B	8.26 ± 0.17	
FBS	A	165.93 ± 3.46	.439
	B	169.77 ± 3.49	
PPBS	A	271.00 ± 7.58	.291
	B	283.03 ± 8.38	
Triglyceride	A	157.33 ± 7.85	.565
	B	151.37 ± 6.68	
HDL	A	37.70 ± 1.26	.491
	B	38.97 ± 1.33	
LDL	A	97.02 ± 3.80	.040*
	B	111.85 ± 5.97	
VLDL	A	38.83 ± 2.61	.871
	B	38.27 ± 2.30	

*P< 0.05: Significant, ** P< 0.01: more significant, *** P< 0.001: highly significant

TABLE 8: COMPARISON OF DIFFERENCES IN BIOCHEMICAL PARAMETERS BETWEEN METFORMIN-GLIMEPIRIDE (GROUP-A) AND METFORMIN-TENELIGLIPTIN (GROUP B) AFTER TREATMENT

Independent t test, t (.05, 95 CI, df-85)

Parameters	Group	Mean ± SEM	P - value
HbA1C	A	7.44 ± .13	.048*
	B	7.08 ± .16	
FBS	A	132.63 ± 4.97	.276
	B	125.60 ± 4.04	
PPBS	A	191.07 ± 8.64	.145
	B	208.67 ± 8.21	
Triglyceride	A	157.0333 ± 6.80	.060
	B	140.07 ± 5.69	
HDL	A	41.27 ± 1.44	.491
	B	42.63 ± 1.34	
LDL	A	87.00 ± 3.10	.281
	A	94.27 ± 5.918	
VLDL	A	36.30 ± 1.46	.049*
	B	34.40 ± 1.94	

*P< 0.05: Significant, ** P< 0.01: more significant, *** P< 0.001: highly significant

TABLE 9: COMPARISON OF CHANGES IN BIOCHEMICAL PARAMETERS FOR GROUP A

Dependent t test, t (.05, 95 CI, df-29)

Parameters	Before Treatment	After Treatment	P Value
	Mean ± SEM	Mean ± SEM	
HBA1C (%)	8.28 ± .13	7.44 ± .13	0.002***
FBS (mg/dl)	165.93 ± 3.46	132.63 ± 4.97	0.000***
PPBS (mg/dl)	271.00 ± 7.58	191.07 ± 8.64	0.002**
Triglyceride (mg/dl)	157.33 ± 7.85	157.033 ± 6.80	0.013*
HDL (mg/dl)	37.7000 ± 1.25867	41.27 ± 1.44	0.002**
LDL (mg/dl)	97.02 ± 3.80	87.00 ± 3.10	0.013*
VLDL (mg/dl)	38.83 ± 2.61	36.30 ± 1.46	0.04*

*P< 0.05: Significant, ** P< 0.01: more significant, *** P< 0.001: highly significant

TABLE 10: COMPARISON OF CHANGES IN BIOCHEMICAL PARAMETERS FOR GROUP B

Dependent t test, t (.05, 95 CI, df-29)			
Parameters	**Before Treatment**	**After Treatment**	**P Value**
	Mean ± SEM	**Mean ± SEM**	
HbA1c (%)	8.26 ± .17	7.08 ± .16	0.001**
FBS	169.77 ± 3.49	125.60 ± 4.04	0.000***
PPBS	283.03 ± 8.38	208.67 ± 8.21	0.002**
Triglyceride	151.37 ± 6.68	140.07 ± 5.69	0.013*
HDL	38.97 ± 1.33	42.63 ± 1.34	0.002**
LDL	111.85 ± 5.97	94.27 ± 5.918	0.005**
VLDL	38.27 ± 2.30	34.40 ± 1.94	0.02*

*P< 0.05: Significant, ** P< 0.01: more significant, *** P< 0.001: highly significant

DISCUSSION: American Diabetic Association guidelines have recommended Metformin as first line drug to be used in type II Diabetes mellitus patients. If there is glycemic variability with Metformin, add-on drugs like Sulphonylureas, DPP-4 Inhibitors or other OHA's or insulin to be considered depending on the clinical scenario.

Sulphonylureas are one of the most potent oral anti-diabetic agents. Due to good efficacy, safety, and cost-effectiveness, Sulphonylureas, especially modern ones like Glimepiride, are the most preferred first add-on to Metformin in Indian clinical settings [9]. It has dual mode of action – reduces insulin resistance and improves glucose utilization through glucose transporter -4 resulting in potent glycemic reduction with minimal risk of hypoglycemia or weight gain [10].

Dipeptidyl peptidase inhibitors are a well-established class of oral agents having moderate efficacy with a good overall safety profile including low risk of hypoglycemia and weight neutrality. Teneligliptin has dual mode of excretion *i.e.,* hepatic (35%) and renal (65%) routes [11]. Metformin belongs to the class-Biguanides remains as a first line drug for type II diabetes mellitus because of its long term safety profile, weight neutral or helps people lose weight.

In the present study, satisfactory results were obtained for estimation of glucose triad. Between the groups in group A, HbA1c before treatment was found to be 8.28 ± .13 and for group B HbA1c before treatment was found to be 8.26 ± .15 there were no significant difference found between treatment groups. After treatment for group A HbA1c was found to be 7.44 ± .12 where as in group B, It was found to be 7.07 ± .12 and P value was 0.048.

There was a significant reduction in both the groups. When analysis was done within the group HbA1c for group A was found to be 8.28 ± .13 before treatment and 7.44 ± .13 after treatment with P value 0.002 and for group B it was found to be 8.26 ± .17 before treatment and 7.08 ± .16 with P value 0.001. There was a high significant reduction in HbA1c levels in group B than in group A. These results are similar with the study conducted by Devarajan *et al.* [12]

When FBS levels were compared between the groups for group A before treatment it was found to be 165.93 ± 3.46 and for group B it was found to be be169.76 ± 3.49 with P value 0.439, there was no significant reduction between treatment groups, and after treatment for group A FBS levels were 132.63 ± 4.97 and for group B 125.60 ± 4.04 with P value 0.276 respectively and P value found to be significant. Within the group FBS for group A before and after treatment was 165.93 ± 3.46 and 132.63 ± 4.97 respectively. P value was 0.00. For group B FBS levels before and after treatment were 169.77 ± 3.49 and 125.60 ± 4.04 with P value 0.00 respectively. High Significant reduction was seen in both the groups and the study results are similar with the study conducted by Devarajan *et al.,* [12]

When PPBS levels were compared between the groups for group A before treatment it was 271.00 ± 7.58 and for group B 283.03 ± 8.38 with P value 0.29. There was no significant reduction between treatment groups and after treatment for group A PPBS was 191.07 ± 8.64 and for group B it was 208.67 ± 8.21 with P value 0.145. The results were highly significant. Within the group PPBS for group A before and after treatment was 271.00 ± 7.58 and 191.07 ± 8.64 with P value 0.002 and for group B the values are 283.03 ± 8.38 and 208.67 ± 8.21 with P value 0.002 respectively.

There was a significant reduction in levels of PPBS in both the groups and the study results are similar with the study conducted by Devarajan *et al.* [12]

Coming to the lipid profile, in both the groups there was a significant reduction in levels of triglycerides group A-157.0333 ± 6.80, group B -140.07 ± 5.69, LDL for group A-87.00 ± 3.10, group B -94.27 ± 5.918, VLDL group A-36.30 ± 1.46, group B-34.40 ± 1.94 and with increase in HDL levels *i.e.* group A- 41.27 ± 1.44, group-B 42.63 ± 1.34. When compared within the group for group A triglycerides before and after treatment were found to be 157.33 ± 7.85 and 157.033 ± 6.80 respectively and for group B 151.37 ± 6.68 and 140.07 ± 5.69 , while LDL values for group A are 97.02 ± 3.80 before treatment and 87.00 ± 3.10 after treatment and for group B the values of before and after treatment are 111.85 ± 5.97 and 94.27 ± 5.918 respectively, VLDL values group A are 38.83 ± 2.61 before treatment and 36.30 ±1.46 after treatment and for group B the values are 38.27 ± 2.30 and 34.40 ± 1.94, HDL levels for group A are 37.7000 ± 1.25867 before treatment and 41.27 ± 1.44 after treatment while in group B the values of before and after treatment are 38.97 ± 1.33 and 42.63 ±1.34. There was more significant reduction in LDL in Group B than in Group A, VLDL and Triglycerides Were significantly reduced in both the groups. HDL was significantly increased in Both Group A and B.

When the results were observed within the group Group B (P=0.001) exhibited a significantly greater reduction in HbA1c as compared to Group A (P = 0.002). The reductions in FPG and PPG were also found to be significantly more in the Group B. Similar conditions were found with lipid profile. Therefore, resultant data from group B was comparatively more significant than group A in terms of reduction in glucose triad levels and lipid levels.

CONCLUSION: In type 2 Diabetes Mellitus patients the more frequently used combination of oral hypoglycemic agents is Metformin-Glimepiride which exhibit significant reduction in glycemic parameters. Now-a-days, Teneligliptin is a newer drug of choice in DPP-4 inhibitor, cheaper and more efficacious when compared to other drugs of same class and used as on add on therapy to Metformin which also exhibit better control over glycemic parameters.

In the present study, both Glimepiride and Teneligliptin were well tolerated when added to Metformin. But patients on Metformin-Teneligliptin exhibited better control over glycemic profile as well as lipid profile when compared to patients who are on Metformin-Glimepiride combination. Hence, Teneligliptin is the better choice as a add on drug to Metformin in type 2 diabetes patients for its safety, efficacy and many other benefits. Modern DPP-4 inhibitors like Teneligliptin can be thus preferred as an important second line option for Metformin in this new era of newer anti-diabetic agents. The present study was conducted only on 30 patients in each group, so a larger cohort of patients and further follow up is required to access the safety, efficacy of the same.

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