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Original Article

Pharmacology Section

Efficacy, Safety and Treatment Satisfaction of Glimepiride vs Sitagliptin in Combination with Metformin in Type 2 Diabetes Mellitus

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ABSTRACT

Introduction: Metformin is a preferred drug for starting treatment in type 2 diabetes mellitus. But, eventually most of the patients need additional drug to control blood sugar level. The choice of drug depends upon several factors including patient specific criteria, economical factors and treatment satisfaction.

Aim: The aim of the present study is to investigate the effects of adding sitagliptin or glimepiride on efficacy, safety and treatment satisfaction in patients with type 2 diabetes mellitus.

Materials and Methods: It was a retrospective observational study on 50 patients each in sitagliptin and glimepiride group, who are receiving treatment for at least 12 weeks and are stable on respective treatment regimen. Glycated haemoglobin (HBA1c) was the primary measure of efficacy. Safety was assessed by checking weight gain/loss, hypoglycaemia episodes and other laboratory investigations. Patient satisfaction was assessed by Diabetes Treatment Satisfaction Questionnaire.

Results: The HbA1c level after 12-24 weeks of treatment was not found to be significant compared to each other or from baseline. Compared to baseline fasting plasma glucose & postprandial plasma glucose were lower in glimepiride group. Sitagliptin was associated with less episodes of hypoglycaemia. Weight gain was associated with glimepiride but it was non-significant (p=0.08). Overall treatment satisfaction score were better for sitagliptin but were not statistically significant.

Conclusion: The efficacy of sitagliptin was comparable. Sitagliptin had superior adverse effect profile with less chances of hypoglycaemia and weight gain. Questionnaire scores were higher for sitagliptin indicating better treatment satisfaction compared to glimepiride.

Keywords: Hypoglycaemia, Hyperglycaemia, Treatment satisfaction questionnaire, Weight gain

INTRODUCTION

The American Diabetes Association & European Association for the study of diabetes algorithm for treating type 2 diabetes mellitus (DM) recommends metformin as initial monotherapy [1]. The progressive deterioration of diabetes control leads to almost half of patient to start a second drug as an add-on therapy [2]. Sulphonylureas such as glimepiride are frequently used to control blood sugar in these patients. A prescription study in eastern India found that glimepiride was most common drug to be given with metformin as oral hypoglycaemic agent [3]. Sulphonylureas are associated with side effects such as frequent hypoglycaemia and weight gain [4,5]. In the past few years Dipeptidyl Peptidase-4 (DPP-4) inhibitor, an incretin-based therapy has emerged as important adjunctive drug in type 2 DM. It is effective and well tolerated when used in addition to metformin therapy [6-8]. Four different DPP-4 inhibitors are available in India: sitagliptin, vildagliptin, saxagliptin and linagliptin. Sitagliptin is the most widely used because it was the first DPP-4 inhibitor available in India and its efficacy and safety are proved. Sitagliptin is also not known to cause hypoglycaemia when used alone or when added to metformin [9]. The risk of hypoglycaemia with sitagliptin has been found similar to that observed when placebo is added to metformin [7,10]. Further, studies have found that sitagliptin does not cause weight gain which is beneficial as insulin sensitivity decreases with increase in weight [11,12]. But, despite all these findings there is no decisive evidence, that any specific combination is more effective in lowering blood glucose levels or in preventing complications and thus improving quality of life [13-15]. Thus decision to start a specific combination depends upon patient specific criteria, economic status of the patient and patient satisfaction. As goal of diabetes treatment is ultimately to improve physical as well as psychological well being, treatment satisfaction becomes the key issue to consider while treating a patient. This study attempts to assess efficacy, safety and overall treatment satisfaction in patients receiving glimepiride or sitagliptin in combination with metformin in patients of type 2 DM.

MATERIALS AND METHODS

It was a retrospective observational study. The study was conducted in outpatient department of medicine in a tertiary care teaching hospital, SRMSIMS, Bareilly, India. Patients more than 18 years of age, with type 2 DM while on a stable dose of metformin (≥1500 mg/day) and sitagliptin (100-200mg/day) or glimepiride (1-6 mg/day) for at least 12 weeks prior to the visit, but not more than 24 weeks, were eligible for this study. Fifty patients each were recruited in sitagliptin and glimepiride group. Patient were excluded from the study if they did not meet screening criteria which includes having records of patient about HbA1c, weight, BMI, blood glucose (fasting & post prandial) in last 3-4 months. Those patients were also excluded from the study who had a history of type 1 diabetes mellitus, used any other hypoglycaemic agent besides metformin and sitagliptin or glimepiride within 12 weeks of the screening visit or had impaired renal function. Concurrent medications such as anti-dyslipidaemic, anti-hypertensive medications, anti-thyroid medications and birth control medication were allowed, if they have been used at stable doses during study period. Patients continue to receive counselling on exercise and diet consistent with American Diabetes Association recommendations throughout the study.

STUDY EVALUATION

The patient's baseline characteristics were noted from prescriptions and other case records. The primary efficacy end point was HbA1c level. Change from baseline in fasting plasma glucose (FPG) post-prandial plasma glucose (PPG) was also assessed. Other laboratory investigation which were compared are fasting lipid parameters i.e. total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG) and serum creatinine was compared depending upon availability. The data of drug-related adverse experiences about hypoglycaemia events, weight gain or loss and other laboratory tests in last three months were collected by asking

patients and checking prescriptions. Patients were asked about the symptoms of hypoglycaemia i.e. sweating, palpitation, confusion, weakness or dizziness, which required some assistance (medical or non medical) in previous three months whether or not checked by blood glucose measurement was considered as an adverse event.

Patients' satisfaction and health status were measured using questionnaire: Diabetes Treatment Satisfaction Questionnaire Hindi version (DTSQ). It consists of six item scale assessing treatment satisfaction and two item scale for perceived hypoglycaemia and hyperglycaemia [16]. DTSQ has been used extensively to measure treatment satisfaction in many studies and is sensitive to changes in treatment [17-19]. Overall it contains eight questions: (1) satisfaction with current treatment, (2) perceived change in frequency of hyperglycaemia, (3) perceived change in frequency of hypoglycaemia, (4) convenience of the treatment, (5) flexibility of the treatment, (6) understanding of diabetes mellitus, (7) willingness to recommend the treatment to others, and (8) satisfaction to continue the treatment.

Scoring: The DTSQ has been scored on a scale of 6 to 0. The scale total is computed by adding six items i.e. 1, 4, 5, 6, 7 & 8 to produce total treatment satisfaction score. Thus a high score indicates greater treatment satisfaction. Item 2 (perceived frequency of hyperglycaemia) and item 3 (perceived frequency of hypoglycaemia) are treated individually in data analysis. Here, lower score indicated optimal blood glucose level. The perceived frequency of hyperglycaemia and hypoglycaemia were assessed by asking about the symptoms of these conditions. The symptoms of hyperglycaemia are increased thirst, frequent urination, fatigue, sweat odour to the breath, weight loss and vision problems. Symptoms of hypoglycaemia are cold, clammy skin, trembling or feelings of nervousness, lack of motor coordination, fatigue, irritability or confusion, headache or dizziness, nausea, fainting or unconsciousness.

Permission to use the questionnaire had been taken prior to the study. Institutional ethics committee approval and informed patient consent were taken.

Sample size calculation was done on the basis of non-inferiority margin of 0.5 for glycated haemoglobin (HbA1c) and standard deviation of 1. The sample size derived was 49 per group. Hence 50 patients per group were included for the study.

STATISTICAL ANALYSIS

The data were analysed using the Statistical Package for the Social Sciences, version 15 for Windows (SPSS, Chicago, Illinois, USA). The comparison of qualitative data was done by using Student's t-test. Within-group pre and post-treatment comparisons were performed by applying a paired t-test separately in each group. The data were expressed as mean± SD. A p-value <0.05 was considered statistically significant.

RESULT

Base line parameter

As shown in [Table/Fig-1], the baseline parameters of both groups are almost similar and there is no statistically significant difference among them. Weight and BMI in sitagliptin group was lower compared to glimepiride group and it was close to being significantly different. It might be due to some patients were already on respective treatment before baseline parameters were extracted. Efficacy related parameters were similar in both groups.

Efficacy and safety

As shown in [Table/Fig-2], there is no statistically significant difference in between the groups as far as efficacy parameters i.e. HbA1c, FPG & PPG are concerned. But, compared to baseline glimepiride group showed significant reduction in FPG & PPG (p <0.05) [Table/Fig-3]. Rest of the parameters are not significant in either sitagliptin or glimepiride group. There were 15 episodes of symptomatic hypoglycaemia in glimepiride group compared to five episodes in sitagliptin group. Three patients had more than one episodes of hypoglycaemia. Ten episodes of hypoglycaemia in glimepiride group and one episode in sitagliptin group were confirmed by blood glucose measurement (finger-prick method). Further, the glimepiride group was associated with weight gain (mean weight gain 1.58 kg) whereas the sitagliptin group was associated with weight loss (0.52 kg) {p>0.05, [Table/Fig-2]}. This resulted in a statistically meaningful differencebetween-groups after at least 16 weeks of treatment {p<0.01, [Table/Fig-3]}.

Parameter	Metformin + Sitagliptin	Metformin + Glimepiride	p-value
Age	62.3±10.8	63.5±12.3	0.60
Male (%)	32(64)	35(70)	0.52*
Weight	72.6±11.2	76.7±12.8	0.09
BMI	30.2±5.5	32.5±6.7	0.06
HbA1C(%)	7.46±1.8	7.56±1.6	0.48
FPG	122.5±30.6	132.6±28.6	0.09
PPG	206.3±40.6	211.3±42.7	0.66

[Table/Fig-1]: Comparison of baseline parameter in siatgliptin and glimepiride group
- BMI- Body Mass Index, HbA1c- Glycated haemoglobin, FPG- fasting plasma glucose, PPG- post-prandial plasma glucose
- Values indicates Mean±SD
- Unpaired t test was used for statistical analysis. (*z test.)
- p<0.05 was considered significant

Parameter	Metformin + Sitagliptin	Metformin + Glimepiride	p-value
HbA1C (%)	7.21±1.7	7.12±1.2	0.15
FPG	121.3± 32.4	118.6±30.4	0.63
PPG	205.2±36.7	201.4±32.6	0.31
Weight	72.1±11.4	78.3±12.6	0.01

[Table/Fig-2]: Efficacy & safety parameters after 3-6 months of treatment
- HbA1c- Glycated haemoglobin, FPG- fasting plasma glucose, PPG- post-prandial plasma glucose
- Values indicates Mean±SD
- Unpaired t test was used for statistical analysis
- p<0.05 was considered significant

Treatment satisfaction

The overall mean treatment satisfaction score (1,4,5,6,7&8) for sitagliptin was significantly greater than glimepiride group. Mean score of each item was also better for sitagliptin group, but, it was statistically significant for item number 1 and is very close to being significant for item number 6. Similarly perceived hyperglycaemia and hypoglycaemia score were lower, indicating good adverse effect profile, in sitagliptin group compared to glimepiride group. But, score was significant only for perceived hypoglycaemia in glimepiride group compared to sitagliptin group. The detailed distributions of statistical difference of different component of questionnaire have been shown in [Table/Fig-4].

DISCUSSION

In this study, patients with type 2 diabetes mellitus on a stable dose of metformin in addition to treatment with the DPP-4 inhibitor, sitagliptin, or the sulfonylurea agent, glimepiride were included. The result shows that efficacy of lowering HbA1c is equivalent for sitagliptin and glimepiride group. The reduction in fasting and post prandial blood sugar level were also found to be similar, an additional indication of the non inferiority of two groups. However, the majority of patients in both groups did not have an HbA1c value at the glycaemic goal of ≤7.0%. Compared with sitagliptin, number of patients reaching the therapeutic target of HbA1c ≤7% was greater, reflected by the slightly greater reduction (0.44 vs. 0.25) in the HbA1c observed in the glimepiride group.

Parameter	Metformin + Sitagliptin		p-value	Metformin + Glimepiride		p-value
	Before	after		Before	after	
HbA1c(%)	7.46±1.84	7.21±1.73	0.38	7.56±1.63	7.12±1.25	0.06
FPG	122.52±30.63	121.35± 32.41	0.87	132.61±28.62	118.63±30.48	0.01
PPG	206.34±40.65	205.28±36.76	0.91	211.36±42.73	201.42±32.65	0.03
Weight(kg)	72.64±11.23	72.12±11.49	0.18	76.73±12.85	78.31±12.66	0.08
Lab values*						
TC	197.21±30.93	191.41±31.70	0.49	186.36±33.28	184±36.39	0.52
LDL	121.81±29.56	116.89±18.95	0.46	128.72±22.37	127.73±21.81	0.34
TG	134.56±37.48	132.13±38.87	0.87	141.68±42.76	140.36±41.39	0.67
HDL	42.92±5.80	44.47±6.57	0.35	43.76±6.53	42.86±6.53	0.25
Sr Creat	0.93±0.14	0.96±0.15	0.43	0.98±0.19	0.96±0.18	0.86

[Table/Fig-3]: Change in parameters before and after treatment for 12-24 weeks in sitagliptin and glimepiride group
* Data for lipid profile was available from 84 patients whereas for serum creatinine in 56 patients.
- HbA1c- Glycated haemoglobin, FPG- Fasting plasma glucose, PPG- Post-prandial plasma glucose, TC- Total cholesterol, LDL- low density lipoprotein, TG- Triglycerides, HDL- High density lipoprotein, Sr Creat.- Serum creatinine
- Values are Mean ± SD.
- Statistical analysis was done using paired t test. (p<0.05 considered significant)

DTSQ	Metformin + Sitagliptin	Metformin + Glimepiride	p-value
1	5.1±1.8	4.3±1.9	0.02
4	4.7±1.7	4.1±1.8	0.24
5	4.4±2.5	4.3±3.2	0.60
6	4.4±2.4	4.1±2.6	0.55
7	4.3±2.3	4.1±2.1	0.82
8	4.8±1.9	4.1±1.8	0.06
Overall	4.48±2.48	4.18±2.34	0.53
2	2.8±2.4	3.6±2.3	0.06
3	2.7±1.7	3.5±2.1	0.03

[Table/Fig-4]: Treatment satisfaction in sitagliptin Vs glimepiride group
- Values indicates Mean±SD
- Unpaired t test was used for statistical analysis
- p<0.05 was considered significant

Treatment with sitagliptin was associated with less incidence of hypoglycaemia compared to glimepiride and with weight loss whereas weight gain was observed in glimepirde group. The result of this study is consistent with prior studies where sitagliptin was found to be equally efficacious to sulphonylureas such as glipizide and glimepiride [13,14,20,21].

The data of drug-related adverse experiences i.e. hypoglycaemic events, weight gain or loss and other laboratory tests in last three months were collected by asking patients and checking prescriptions. The adverse events were more frequently associated with glimepiride group. There was increased incidence of hypoglycaemia as well as weight gain. However, apart from the increased incidence of hypoglycaemia for patients treated with glimepiride, both sitagliptin and glimepiride were generally well tolerated and had no adverse effect on lipid profile and kidney function (as shown by normal laboratory parameters). During the study period 30% of the patients treated with glimepiride experienced at least one episode of hypoglycaemia, compared with 10% in the sitagliptin group. Patients in the glimepiride group compared with the sitagliptin group also experienced multiple episodes of hypoglycaemia. The increase in bodyweight associated with certain anti- hyperglycaemic agents is an undesired side effect in patients with type 2 DM [9], though glimepiride has been associated with less weight gain compared to other sulphonylureas [22]. In this study, the pattern of body weight change differed between treatment groups the addition of sitagliptin to ongoing metformin monotherapy was associated with weight loss, whereas the addition of glimepiride was associated with weight gain. For specific adverse experiences other than hypoglycaemia and weight gain the between-group differences in incidence were small. No significant differences were observed in laboratory safety assessments between two groups.

Few other Indian studies have also investigated this issue of clinical importance. A study by Srivastava S et al., had similar finding with glimepiride group showing better glycaemic control whereas sitagliptin has better adverse effect profile when added to metformin [23]. It showed that 12% patients in sitagliptin group and 36% patients in glimepiride group achieved target HbA1c. The weight gain (- 0.102 kg vs 0.493 kg) and incidence of hypoglycaemia (4% vs 8%) were more with glimepirde group.

Another study by Muthukrishnan J et al., slightly differed in the finding as it found that sitagliptin fared better than glimepiride in both efficacy and safety parameters in young newly diagnosed patients with diabetes mellitus [24]. It is reflected by the finding that 73.3% of the patients receiving sitagliptin achieved pre-specified glycaemic target as compared to 30% patients in glimepiride group (p<0.001). Sitagliptin group also had less weight gain (mean wt. change in kg. 1.9 vs 3.5, p<0.05) and chances of hyperglycaemia.

Treatment satisfaction as reflected in DTSQ was in favour of sitagliptin group. Though the DTSQ was not compared from the baseline the finding of result suggests that patient satisfaction was better for all six parameters [1,2,4-8] for sitagliptin group. Mean hyperglycaemia and hypoglycaemia scores at the final evaluation point were significantly lower for sitagliptin group compared to glimepiride group. The improvement in treatment satisfaction in sitagliptin group seems to be due to low frequency of hypoglycaemia and weight gain despite the fact that control of hyperglycaemia was slightly better in glimepiride group.

LIMITATIONS

Two baseline parameters (weight and BMI) were almost significantly different which may be expected to cause favourable outcome in sitagliptin group. The sample sizes were calculated for efficacy parameters. It is evident from the study, that for showing statistically significant difference in treatment satisfaction, sample size should have been larger. Our study finding were also limited by the fact that treatment satisfaction were assessed on the basis of memory of events for the past three months which may lead to some bias. Further, the result of the study should not be interpreted as a class effect of gliptins as like this study most of the studies compared sitagliptin with other sulphonylureas. So whether these favourable effects can be extrapolated to other gliptins is yet to be seen.

CONCLUSION

The addition of sitagliptin to ongoing metformin monotherapy provided non- significant HbA1c-lowering efficacy after at least 12 weeks of treatment compared with the addition of glimepiride. Patients treated with sitagliptin had a significantly lower rate of

hypoglycaemic events and higher degree of satisfaction to those treated with glimepiride.

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