e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(2); 928-933

Original Research Article

Determinants of Treatment Satisfaction among Patients with Diabetes: Importance of Patient-Reported Outcomes

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Received: 25-12-2023 / Revised: 20-01-2024 / Accepted: 19-02-2024

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Conflict of interest: Nil

Abstract:

Treatment satisfaction is a significant determinant for patients in terms of physical and mental satisfaction, well-being and quality of life. The efficacy and safety of diabetes treatment should also focus on patient-reported outcomes (PROs), This type of study is relevant for patients with chronic diseases such as diabetes. DTSQ is not only used for comparisons between different medications or treatment strategies, but also can be used to assess the quality of diabetes care in clinical settings. This is important as an improvement in treatment satisfaction may enhance patients' self-analysis and adherence to therapy, leading to the achievement of long-term stable glycemic control and reduced the adverse effect due to diabetic complications. In this review, we summarize the current topics in DTSQ, introducing our own experience, and discuss the role of PROs in diabetes treatment.

Keywords: Patient-reported outcome (PRO), Quality of life, The Diabetes Treatment Satisfaction Questionnaire (DTSQ), SGLT2 inhibitors, Patient satisfaction.

Introduction

Diabetes Treatment Satisfaction Questionnaire (DTSQ) was first developed by Clare Bradley, an English health psychologist, in the 1990s for the purpose of assessing patients' satisfaction with their diabetes treatment [1]. It is now widely used, particularly in clinical trials, but also for routine clinical monitoring. One of the best examples showing the efficacy of DTSQ is the assessment of insulin analogs. Rapid-acting insulin analogs have been shown to improve postprandial glycemic excursion and reduce hypoglycemia compared with regular insulin due to their rapid onset of action [2]. Patient's satisfaction and health status were measured using Diabetes Treatment Satisfaction Questionnaire Hindi version (DTSQ): It consists of six item scale assessing treatment satisfaction and two item scale for perceived hypoglycemia and hyperglycemia [3]. DTSQ has been used extensively to measure treatment satisfaction in many studies and is sensitive to changes in treatment [4-6]. Overall, it contains eight questions: (1) satisfaction with current treatment, (2) perceived change in frequency of hyperglycemia, (3) perceived change in frequency of hypoglycemia, (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 hyperglycemia) and item 3 (perceived frequency of hypoglycemia) are treated individually in data analysis. Here, lower score indicated optimal blood glucose level. The perceived frequency of hyperglycemia and hypoglycemia were assessed by asking about the symptoms of these conditions. The symptoms of hyperglycemia are increased thirst, frequent urination, fatigue, sweat odour to the breath, weight

loss and vision problems. Symptoms of hypoglycemia 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 hemoglobin (HbA1c) and standard deviation of 1. The sample size derived was 150 per group. Hence 150 patients per group were included for the study.

Material and Methods

A prospective, open label; randomized, parallel group study which was conducted in the Department of Endocrinology with the collaboration of Department of Pharmacology, North Delhi Municipal Corporation and Hindu Rao Hospital Delhi. The study had taken 6 months during a period of April 2021 to October 2021 for treatment study and 6 months from December 2021 to June 2022 for treatment satisfaction study. During that period, out patients was divided into two groups. The patient was selected for the study based on the following inclusion and exclusion criteria. Group A of those who had taken Metformin (500 mg) with Glimepiride 2 mg. whereas Group B was received Vildagliptin 50 mg in fixed dose combination with metformin 500 mg. The study was approved by the Institutional Ethics Committee. The follow up visits was done on monthly basis. The patients diagnosed with type 2 DM, attending outpatient clinic was recruited after obtaining clearance from Ethical Review Board and took written informed consent. A baseline demographic data (age, sex, weight, blood pressure, associated diseases, habits, and drug history) was collected at the time of recruitment. HbA1c, FBS and PPBS had done at the time of recruitment. Patients were randomly assigned in (1:1) ratio after randomization to either of two groups. One group was prescribed glimepiride(2mg) +metformin (500mg) twice daily half an hour before meals and other group vildagliptin(50mg) + metformin(500mg) twice half an hour before meals. HbA1c, FBS, PPBS was repeated again at the end of 3-3 month.

Participants: Eligible adult patients with diabetes were included in the study.

Main Outcome Measures: Treatment satisfaction was the main outcome and was measured using the Diabetes Treatment Satisfaction Questionnaire.

Statistical Analysis: Quantitative data was summarized in terms of descriptive statistics like mean and standard deviation for patients who are treated for both the therapies. The data were analyzed using the Statistical Package for the Social Sciences, version 29 for Windows (SPSS USA). The comparison of qualitative data was done by using Student's t-test within-group pre- 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. Base line parameter of both groups is almost similar and there is no statistically significant difference among them. Weight and BMI in Vildagliptin 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.

Results and Discussion

It was observed that mean age among Group A and Group B subjects were 30.00 ±28.61 and 30.02 ±22.01 years respectively and does not show any statistical difference (P>0.05). The number of subjects in age group 50-60 years were maximum i.e.71 (47.34%) and 58 (38.67%) in Group A and Group B respectively. In the study among 300 subjects,154(51.34%) were male and 146 (48.72%) were females. The distribution of males and females in both the study groups were nearly similar with no statistical difference.

Table 1: Distribution of subjects according to age

Age Group	Group A (%)	Group B (%)	Total (%)
30-40	08 (05.34)	07 (04.67)	**15(5)**
41-50	58(38.67)	52(34.67)	**110(36.67)**
51-60	71(47.34)	58(38.67)	**129(43)**
61-70	11(7.3)	28(18.67)	**39(13)**
71-80	2(1.34)	5(3.34)	**7(2.34)**
Total	150(50)	150 (50)	**300(100)**
Mean age	**30.00**	**30.02**	
Standard Deviation	**28.61**	**22.01**	**P= 0.94***

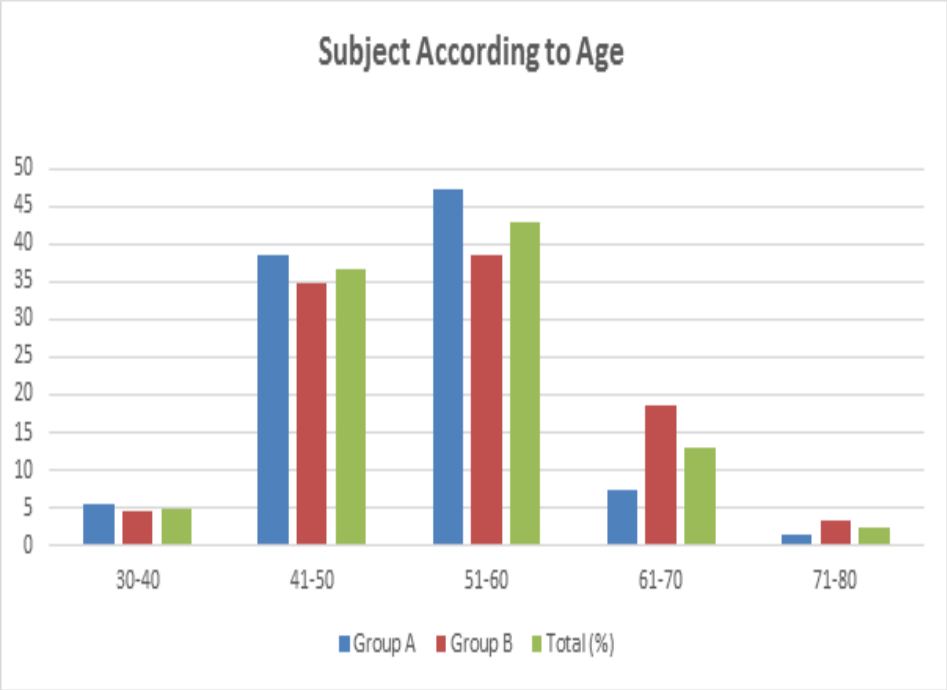

Figure 1: Distribution of subjects according to age

Table 2: Effect of treatment on HbA1c levels in study

Time	Group A	Group B	P value*
0 week	8.80 ±0.62	8.99 ±0.37	0.12
12 weeks	6.47±0.44	6.42±0.42	0.92
Change frombaseline to 24 weeks	-26.06±7.47	-27.86±5.96	0.26

The mean HbA1c levels at baseline (0 weeks) were Group A - 8.80 ±0.62 and Group B - 8.99 ±0.37. Similarly, at 12 weeks mean HbA1c levels were Group A - 6.47±0.44 and Group B - 6.42±0.42. The change in percentage of HbA1c at 24 weeks was Group A = -26.06% and Group B = -27.86% but nil statistical significance difference. (P=0.26).

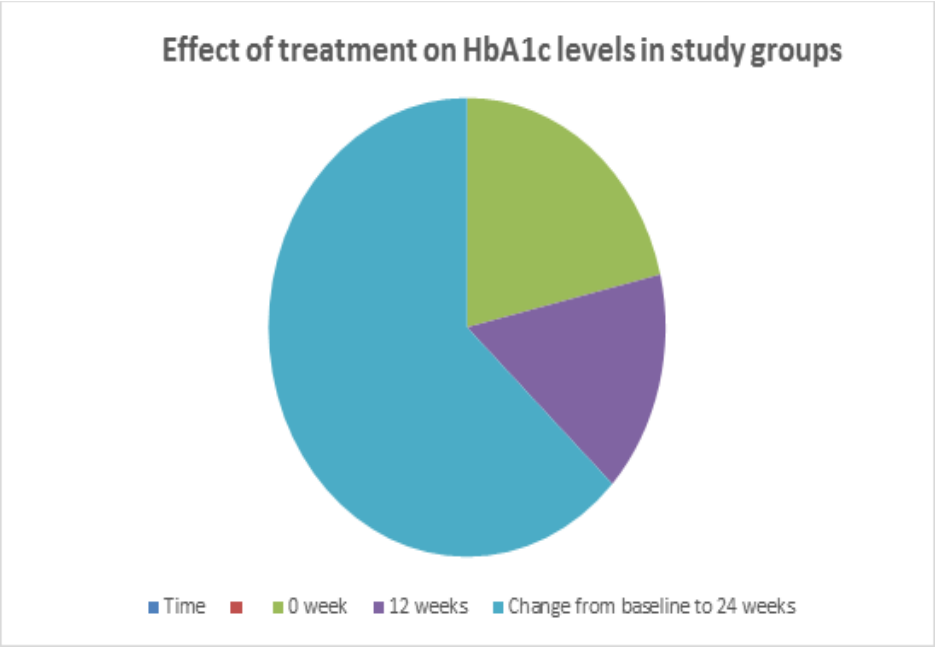

Figure 2: Effect of treatment on HbA1c levels in study groups

Table 3: Diabetic treatment satisfaction (DTSQ) results in study groups:

DTSQ Score Questions	Group A Metformin+ Glimepiride	Group B Metformin + Vildagliptin	P -Value
1	5.14±0.84	4.89±1.07	0.02
4	4.7±1.7	4.3±1.1	0.01
5	4.4±2.5	4.3±3.2	0.6
6	2.74±0.73	2.78±0.75	0.64
7	4.3±2.3	4.1±2.1	0.82
8	3.87±1.75	3.7±1.7	0.39
Overall	4.48±2.48	4.18±2.34	0.53
2	1.36±1.32	1.4±1.34	0.79

(*P <0.05 Statistically Significant)

Treatment with Vildagliptin was associated with less incidence of hypoglycemia compared to glimepiride and with weight loss whereas weight gain was observed in glimepiride group. The result of this study is consistent with prior studies where Vildagliptin was found to be equally efficacious to sulphonylureas such as glipizide and glimepiride [7,8,9,10]. DTSQ questionnaire results (Diabetes Treatment Satisfaction Questionnaire - as assessed by patients). Graph presents the percentage of patients that provided positive answers a series of questions.

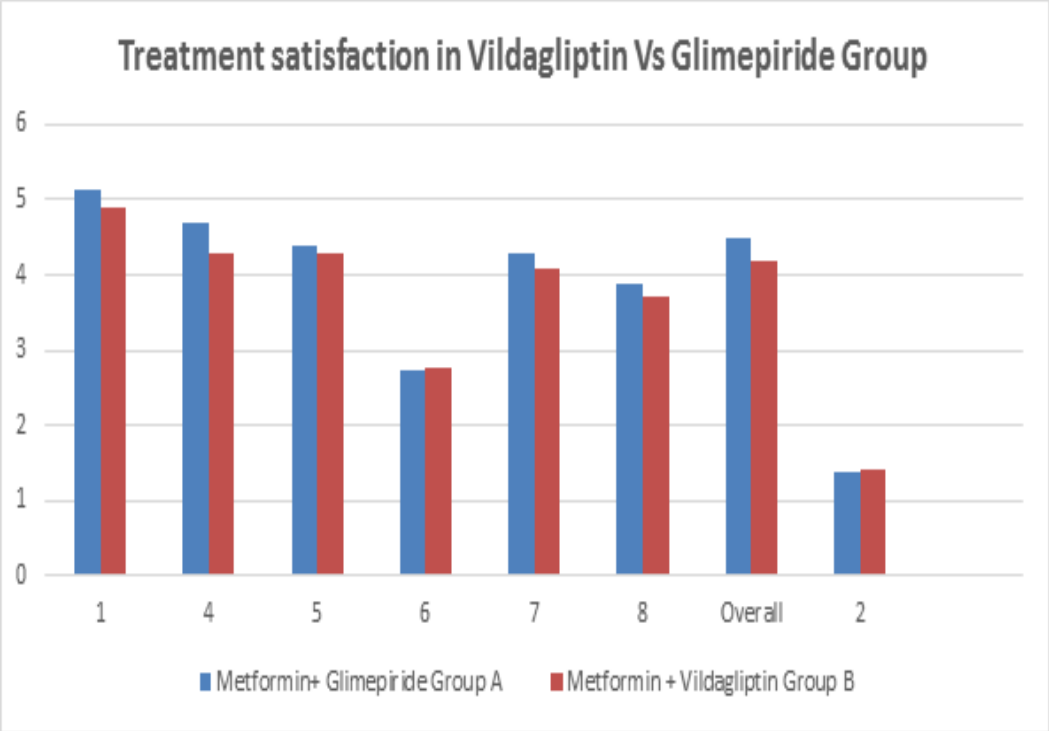

Figure 3: Treatment satisfaction in Vildagliptin Vs Glimepiride group

Table 4: Distribution according to adverse effects among study groups:

Adverse Effects	Group A (n=150)	Group B(n=150)	P Value
Edema	**14**	**10**	**0.50**
Headache	**16**	**11**	**0.35**
Elevated liver enzymes	**11**	**13**	**0.30**
Symptomatic hypoglycemia	**14**	**2**	**0.3**
Abdominal discomfort	**27**	**17**	**0.55**
Diarrhea	**32**	**8**	**Less than 0.001**
Chest discomfort & dyspnea	**13**	**8**	**0.2**
No side effect	**23**	**81**	**0.35**

(* P value calculated by Fisher Test and # P <0.05 significant)

The adverse effects in Group A subjects were maximum with related to hypoglycemia. 14 subjects suffered symptomatic hypoglycemia in Group A as contrasted to 2 subjects in Group B. Elevated liver enzymes was seen more in group B subjects along with diarrhea which shows statistical significance. The data of drug-related adverse experiences i.e. Hypoglycemia and weight gain the between-group differences in incidence were small. No significant differences were observed in laboratory safety assessments between two groups. The combination of Vildagliptin and Metformin in type 2 diabetes management has been shown in clinical trials to be effective in blood glucose lowering, with very low associated rates of hypoglycemia and no attenuation in the potential weight loss effects seen with Metformin monotherapy [11].

The main disadvantage of Glimepiride is the risk of hypoglycemia, and increase weight which rises with advanced age, poor nutrition, alcohol consumption, liver or kidney disease and polypharmacy 11 and is higher than with other oral medications [12].

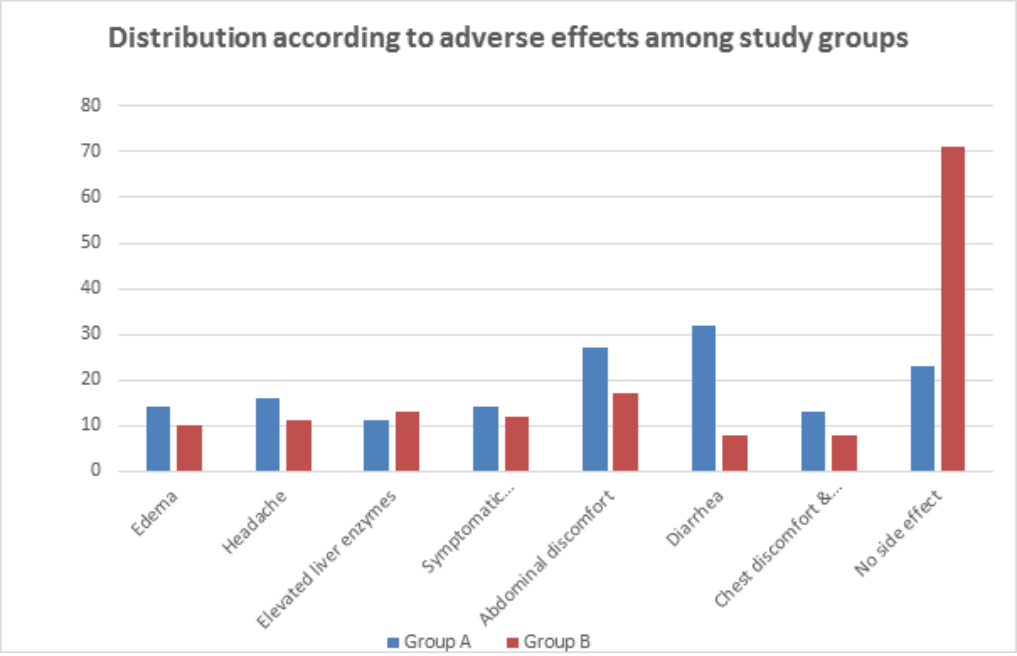

Figure 4: Distribution according to adverse effects among study groups

Conclusion

The present study we conclude that, the efficacy and tolerability of Vildagliptin, was similar, with no significant differences, when used to treat type 2 diabetic patients with inadequate blood glucose control by dual combination of metformin and another traditional oral hypoglycemic agent (glimepiride). Vildagliptin in combination with Metformin also had good safety with low risk of hypoglycemia and weight gain. In term of safety group B (Vildagliptin-Metformin) is a better combination than group A (Vildagliptin-Glimepiride).

Acknowledgement

We would like to thankHealth Psychology Research Limited, University of London, for their continuous support to use Drug Treatment Satisfaction Questionnaire (DTSQ- Hindi version) for India. The authors also thank to all the patients participating in the study.

References

1. Bradley C., Gamsu D.S. Guidelines for encouraging psychological well-being: Report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet. Med. 1994;11:510–516.
2. Ishii H., Bradley C., Riazi A., Barendse S., Yamamoto T. The Japanese version the diabetes treatment satisfaction questionnaire (DTSQ): Translation and clinical evaluation. J. Clin. Exp. Med. 2000;192: 809–814.
3. Simonson GD, Cuddihy RM, Reader D, Bergenstal RM. International Diabetes center Treatment of Type 2 Diabetes glucose algorithm. Diabet Manag. 2011;1(2):175-89.
4. Cobble M. Differentiating among Incretin-based therapies in the management of patients with Type 2 diabetes mellitus. Diabetol Metab Syndr. 2012;4(8):1-10.
5. Vishal G, Sanjay K. Choosing a Gliptin. Indian J Endocrinol Metab. 2011;15(4):298-308.

6. Drucker DJ, Nauck MA. The Incretin system: Glucose-Like Peptide 1 Receptor agonists and Dipeptidyl Peptidase-4 Inhibitors in Type 2 Diabetes. Lancet. 2006;368(9548):1696-705.
7. Janumet TM. (Sitagliptin/Metformin Hydrochloride) tablets [package insert] white house station. NJ: Merck pharmaceuticals, inc. 2012.
8. Juan J, Iciar M. Update on the treatment of Types 2 Diabetes Mellitus. World J Diabetes. 2016;7(17):354-95.
9. Bolli G, Dotta F, Rochotte E, Cohen SE. Efficacy and tolerability of vildagliptin vs. pioglitazone when added to metformin: a 24-week, randomized, double-blind study. Diabetes Obes Metab. 2008; 10:82–90.
10. Fonseca V, Baron M, Shao Q, Dejager S. Sustained efficacy and reduced hypoglycemi during one year of treatment with vildagliptin added to insulin in patients with type 2 diabetes mellitus. Horm Metab Res. 2008; 40:427–430.
11. Harrigan RA, Nathan MS, Beattie P, Oral agents for the treatment of type 2 diabetes mellitus pharmacology, toxicity and treatment, Ann Emerg Med. 2001; 38:68-78.
12. Bolen S, Feldman L, Vassy J, et al, Systematic review: comparative effectiveness and safety of oral medications for type 2 diabetes mellitus, Ann Intern Med 2007;147:38.