

Use of Antidiabetic Drugs and Glycemic Control with Life Style Management in Type II DM-A Cross: Sectional Study General Practice in Odisha

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ABSTRACT

Aim/Background: Our objective is to describe the patterns of prescribing drug combinations and lifestyle modification in which therapy focuses on SGLT2 and DPP4 inhibitors and dose variation according to the blood glucose level and the effective therapy in patients with T2DM. **Materials and Methods:** Using both prescription and questionnaire analysis, a cross-sectional study conducted in Odisha, including 100 diabetic subjects, is considered to evaluate effective combination therapy by comparing different glycemic indexes with Lifestyle modification. **Results and Discussion:** Age and duration of detection of diabetes are the factors through which the gender basis comparison is made and comparing the glycemic index according to different consultations, the drug therapy is considered so as to achieve safe and no or less hypoglycemia. Males (52%) constituted more than female (48%) respondents. The presence of T2DM was responded by 57%, whereas 68% suggest there is no permanent cure for T2DM. The lifestyle changes with medicine, in control of T2DM has been reported by 59% of respondents. There is a significant change ($p \leq 0.005$) in FBS and PPBS levels as compared from 1st visit to 5th visit with the effective combination of Metformin and teneligliptin. **Conclusion:** DPP4 inhibitor and SGLT 2 inhibitor are the newer antidiabetic drugs used as add-on therapy to minimize different risk factors and enhance the quality of life. It is essential to consider diabetes education to improve knowledge of the risk factors associated with type 2 diabetes.

Keywords: Diabetes, Drug, Drug Utilisation Pattern, DPP4i, SGLT2i.

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INTRODUCTION

A drug utilisation pattern is required in order to enable proper utilisation of prescription drugs in populations and for specific patients, as well as to improve the prescribing practices of medical professionals. This information should be provided regarding the pattern of medications prescribed, patient signs and symptoms, lab tests and how they relate to treatment, as well as issues with Adverse Drug Reactions (ADRs), drug interactions, etc.¹

Currently, Non-Communicable Diseases (NCDs) are responsible for over 36 million deaths annually and the burden is only growing in low- and middle-income nations. The World Health Organisation (WHO) has listed diabetes mellitus as a

non-communicable epidemic because it is one of the chronic diseases with the highest rate of increase worldwide.²

Diabetes mellitus is a significant public health issue for the entire world, but especially for India. According to the International Diabetes Federation (IDF), there are an estimated 451 million diabetics worldwide as of 2017; by 2045, that number is projected to rise to 693 million.³

The most prevalent clinical case of diabetes in the world is Type 2 Diabetes (T2D), whose long-term consequences raises healthcare costs and degrades patients' quality of life.⁴

Although lifestyle change is still the fundamental principle of type 2 diabetes management, the majority of these individuals eventually need oral anti-diabetic drugs target to maintain glucose control, blood pressure and lipid levels control.^{5,6}

With an expanding selection of Glucose-Lowering Medications (GLD) now available, questions have been raised concerning their safety and new issues regarding careful control of glucose



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levels. Glycemic treatment in type 2 diabetes has also become more difficult and contentious.⁵

Large number of people need combination therapy less than a few years of diagnosis to normalize glycemic objectives though T2DM is increasing. Metformin and sulfonylureas remain the preferred first-line therapy for Type 2 Diabetes Mellitus (T2DM) otherwise it contraindicated. Now newer classes of anti-diabetes agents are available to achieve the required therapeutic glycemic index, including Sodium-Glucose co-Transporter (SGLT)-2 inhibitors and Dipeptidyl Peptidase IV (DPP IV) inhibitors, has transformed the therapeutic landscape.⁷

DPP4 inhibitor enhances glycemic control by increasing insulin secretion from pancreatic β -cells and decreasing glucagon secretion from pancreatic α -cells, thereby reducing Endogenous Glucose Production (EGP). SGLT2 inhibitor lowers plasma glucose concentrations by preventing renal glucose reabsorption and encouraging urinary glucose excretion. The current recommendations for the therapy of T2DM include the use of SGLT2 inhibitors in individuals who have established or warning signs of a risky for Atherosclerotic Cardiovascular Disease (ASCVD), Chronic Kidney Disease (CKD), or Heart Failure (HF).⁸

An essential step in enhancing outcomes for T2DM patients is to prescribe the treatments suggested in evidence-based guidelines, obtaining focused glycemic control.^{7,9}

The present study described the patterns of prescribing drug combination therapy focusing on SGLT2 inhibitor and DPP4 inhibitor and dose variation according to the blood glucose level and the effective therapy in patients with T2DM along with their lifestyle management.

MATERIALS AND METHODS

The period from November 2022 to June 2023 was used for an independent cross-sectional study. This study used data from clinical practice by observing prescriptions and questionnaires. The respondents were chosen using a convenience sample technique. General practice conducted standardized questionnaires and interviews with participants. One hundred respondents (52 men and 48 women) came from Odisha to participate in this study. To prevent misunderstandings and confusion, a validated structured questionnaire was prepared in the local languages (Odia). All of the questionnaire's open-ended, non-suggested items were designed to minimize bias. In our study, 13 questions were split into two groups. Socio-demographic inquiries concerning the data provided by the respondent were found in Section A. Questions about the level of knowledge of type 2 diabetes were added in Section B. For inclusion in the study, diabetic patients had to arrive at the Out-Patient Department (OPD) with blood glucose levels that were managed or nearly controlled (as per the recommended standards) as determined by Fasting Blood Sugar

(FBS) and Postprandial Blood Sugar (PPBS). Only type 2 diabetes patients are the intended target population for the current report. If a patient was pregnant, under 25 years old, had chronic liver disease, or had psychiatric illnesses, they were excluded from the study. This study only considers a person's medical background, medication and glycemic control by observing their prescriptions.

Statistics analysis

The analysis was done using SPSSV20 statistical software. Paired *t* test was used to analyse the data and significance was found out by comparing the calculating *t* value at 95% confidence interval ($p \leq 0.005$). *p* value was considered to be significant.

Ethical Statement

The study had the approval of Institutional Ethics committee KIDS Hospital, Bhubaneswar, Odisha, India.

RESULTS

Table 1 represents the questionnaire Section A data, in which males (52%) constitute more than females (48%) respondents. The mean age (years) ranged from 25-39 years (36%), 40-54 years (44%), 55-69 years (19%) and more than 70 years (1%). When analysing the duration of diabetes, more (55%) are under 1-4 years and 36% are under 5-9 years. From the total respondents, 67% have family history, compared to 59% from rural areas and 41% from urban areas. Focusing on educational status, 84% are literate. 61% maintain a non-vegetarian dietary lifestyle, while 39% follow a vegetarian lifestyle.

Table 2 shows the level of knowledge among study subjects, which indicates that 57% of respondents have information about T2DM. Inclusive risk factors associated with T2DM include obesity, with 64% of individuals being overweight. Stress conditions significantly contribute, affecting 79% of the population surveyed. Smoking is another key factor, reported by 48% of individuals, while alcohol intake is noted among 85%. Additionally, a lack of regular physical activities or exercise affects 79% of people. 90% of individuals responded that an irregular diet is a risk factor. 68% of respondents suggest there is no permanent cure for T2DM, whereas 15% are not sure and 17% confirm that diabetes is permanently curable. When analyzing preferable treatment options, 83% of respondents chose only medicine, 29% chose herbal products, 96% chose dietary management, 100% preferred regular exercise and 69% agreed with all the preferable treatment options. 59% agree that lifestyle changes with medicine can control T2DM, whereas 36% disagree and 5% are not sure.

The result in Table 3 represents the male age group of 43.6 years out of 52 and the female of 47.17 years out of 48. At the same time, the duration of diabetes was 4.15 years and 5.42 years with respect to male and female diabetic subjects. However, the average age of the diabetic subject was observed as 45.31 years

Table 1: Demographic Details of the study subjects.

Categories	Variables	Frequency	Percent
Age (Years)	25-39	36	36
	40-54	44	44
	55-69	19	19
	More than 70	1	1
Gender	Male	52	52
	Female	48	48
Duration of Diabetes (Years)	1-4	55	55
	5-9	36	36
	10-14	8	8
	More than 15	1	1
Family History	Yes	67	67
	No	33	33
Residency	Urban	41	41
	Rural	59	59
Educational Status	Literate	84	84
	Illiterate	16	16
Diet	Vegetarian	39	39
	Non-vegetarian	61	61

and the duration of diabetes was 4.76 years out of 100 diabetic subjects considered in this study.

The result depicted in Table 4 found that patients with poor glycemic control of 100 subjected Type II Diabetics are considered to take different combination drugs to achieve normal glycemic index by analyzing Fasting Blood Glucose level (FBS) and Post Prandial Blood glucose Level (PPBS). In a day, the samples are considered for a specific combination. Either Combination 1 (Voglibose 0.2 mg + Glimpiride 1 mg +Metformin 500 mg +Teneligliptin 20 mg +Dapagliflozin 10 mg) or Combination 2 (Glimpiride 1 mg +Metformin 500 mg +Teneligliptin 20 mg +Dapagliflozin 10 mg) or Combination 3 (Teneligliptin 20 mg +Metformin 500mg) is used only in total duration of each day. When analyzing different visits, we compared visit 1 FBS and PPBS to other visits by using different drug combinations to normalize the FBS and PPBS and to check the effective therapy approach.

Considering visit 1, FBS is 198.32 ± 39.8 (mg/dL) and PPBS is 258.65 ± 66.4 (mg/dL) to control the glycemic index Combination 1 is given to 38% of patients and Combination 2 to 49% and Combination 3 is given to 13% respectively. Comparing visit 1 and visit 2, there is a significant (p -value is .000) change in FBS (160.65 ± 33.1 mg/dL) and PPBS (195.98 ± 42.8 mg/dL) then the therapy is considered to Combination 1 to 24%, Combination 2 to 40%, Combination 3 to 36%. Visit 3 also showed a significant (p -value is .000) change in FBS (127.39 ± 23.7 mg/dL) and PPBS (156.57 ± 33.5 mg/dL) when compared to Visit 1. Then, the drug

was considered in visit 3 as combination 1 to 13%, combination 2 to 46% and combination 3 to 41%. When comparing Visit 4 with Visit 1 shows Significant (p -value is .000) changes, i.e., FBS (151.14 ± 47.6 mg/dL) and PPBS (190.82 ± 68.7 mg/dL) so that Combination 1 given to 4%, Combination 2 to 38%, Combination 3 to 58%. Visit 5 shows a significant (p -value is .000) effect on the FBS (131.84 ± 27.7 mg/dL) and PPBS (159.12 ± 41.8 mg/dL) when compared to visit 1 and therapy continued as Combination 1 to 5%, Combination 2 to 36%, Combination 3 to 59%.

DISCUSSION

In the current study, participants' knowledge of type II diabetes treatment choices, including effective lifestyle change and selective medication therapy, was evaluated. A greater understanding of the risk factors for diabetes can aid in preventing and reducing the disease's rising prevalence. To prevent and minimize diabetes, it is crucial to know about the disease, how to treat it and be aware of these variables.

The outcomes are in correspondence with research done in eastern Saudi Arabia, Malaysia, Iraq, Bangladesh and Ethiopia, where respondents most commonly chose obesity as one of the risk factors for diabetes. One major risk factor for type 2 diabetes is widely recognised as obesity.¹⁰ In our study, more than half of the respondents (64%) agreed that obesity is an effective risk factor, with 85% choosing alcohol intake, followed by stress and a lack of regular exercise by 79% of respondents. The possibility of preventing type 2 diabetes through dietary restrictions,

Table 2: Level of Knowledge among Study Subjects.

Categories	Variables	Frequency	Percent
Information about T2DM.	Yes	57	57
	No	26	26
	Not Sure	17	17
Inclusive Risk Factors.	Obesity (Overweight).	64	64
	Stress Condition.	79	79
	Smoking	48	48
	Alcohol intake.	85	85
	Lack of Regular activities/exercise.	79	79
	Irregular Diet.	90	90
Permanent cure for T2DM.	Yes	17	17
	No	68	68
	Not Sure	15	15
Preferable Treatment Option.	Medicines	83	83
	Herbal Product.	29	29
	Dietary Management.	96	96
	Regular Exercise.	100	100
	All of the Above.	69	69
T2DM can be managed by Drugs.	Yes	35	35
	No	26	26
	Not Sure	39	39
Lifestyle changes can treat T2DM.	Yes	72	72
	No	13	13
	Not Sure	15	15
Lifestyle changes with medicine can control T2DM.	Yes	59	59
	No	36	36
	Not Sure	5	5

Table 3: Basic parameter of 100 sample size Type II Diabetic subjects according to Gender.

	Total (n=100)	Male (n=52)	Female (n=48)
Age (Years)	45.31±10.5	43.60±10.4	47.17±10.5
Duration of Diabetes (Years)	4.76±3.4	4.15±3.0	5.42±3.7

Values are expressed in terms of Mean±SD.

Table 4: Clinical characteristics of 100 Type II Diabetic Subjects according to their Antidiabetic Treatment.

Visit	Determination of Glucose level (mg/dL)		p Value (2-tailed)		Percentage (%) of Drugs Used		
	FBS	PPBS	FBS	PPBS	Combination 1	Combination 2	Combination 3
V1	198.32±39.8	258.65±66.4			38	49	13
V2	160.65±33.1	195.98±42.8	0.000	0.000	24	40	36
V3	127.39±23.7	156.57±33.5	0.000	0.000	13	46	41
V4	151.14±47.6	190.82±68.7	0.000	0.000	4	38	58
V5	131.84±27.7	159.12±41.8	0.000	0.000	5	36	59

Values are expressed in terms of Mean±SD. Combination 1: Voglibose+Glimipride+Metformin+Teneligliptin+Dapagliflozin. Combination 2: Glimipride+Metformin+Teneligliptin+Dapagliflozin. Combination 3: Teneligliptin+Metformin.

medicines, exercises and herbal products has been accepted by 69% of respondents when it came to treatment choices. The claim that "modification of lifestyle is not effective in controlling type 2 diabetes" was rejected by responders from the Red River Delta area of Vietnam.¹¹

Male diabetic subjects are more prone in low age group while compared with female subjects. Male are exposed to more risk factors such as stress, life style changes including alcohol consumption and smoking, irregular diet habits as compared to female. Due to the production of oxidative free radicals in stress conditions diabetic conditions are affecting more to male as well as female. Diabetes is associated with an increase in the formation of Reactive Oxygen Species (ROS), according to cell culture experiments utilising pancreatic beta cells, aortic smooth muscle cells and endothelial cells. It has been demonstrated that exposing cell lines and isolated pancreatic islet cells to oxidative stress inhibits the promoter activity and mRNA expression of the insulin gene, lowering insulin gene expression. Chronic hyperglycemia-induced insulin resistance is also strongly suspected to be caused by oxidative damage.¹⁰ According to additional studies, men are more typically diagnosed with diabetes at younger ages due to sex differences in biological and psychological factors. But more investigation is required to determine why males often have worse glycemic control and whether the therapy recommendations should be gender-specific.¹²

If considering all the visit that only the prescribed drug pattern is useful to significant reducing of the FBS and PPBS value from Visit 1 to Visit 5. The combination of drug playing a crucial role to lowering the effect. Our analysis has added more details on the design of treatment protocols used by patients to attain normal glycemic index as compared to other national or regional surveys.⁶ According to a research of prescription frequency by combination therapy, the majority of patients were receiving metformin and glimipride. Our current study, metformin and sulfonylureas remained the most often prescribed drugs as add-on therapy, using compositions containing newer agents,

which are currently recommended.⁷ In our study the percentages of the total sample ($n=100$) obtaining a therapy regimen that combines newer therapies including DPP-4 inhibitor (Teneligliptin), α -Glucosidase inhibitor (Voglibose), SGLT2 inhibitor (Dapagliflozine).

In order to improve glycemic management, DPP4 inhibitor increases insulin secretion from pancreatic β -cells while lowering glucagon secretion from pancreatic α -cells, which reduces Endogenous Glucose Production (EGP).⁸ The Glucose-dependent Insulinotropic Polypeptide (GIP) and GLP-1 are deactivated by the enzyme DPP4. GLP-1 levels in the body are made more readily available when this enzyme is inhibited. DPP4 inhibitors are a class of medications that are an oral GLP-1-based therapy, although they are not as successful at lowering blood sugar or body weight, but they have a lower risk of hypoglycemia. Patients with chronic renal illness, people who are at a high risk of hypoglycemia, or individuals who are intolerant of or have complications to metformin, sulfonylureas, or thiazolidinediones may be followed for this class of medication.¹³

In our study Teneligliptin as a DPP4 inhibitor showing the result that normalise the glycemic index and used as an add-on therapy to achieve the glycemic goal. Which have less or negligible side effect as compared to others. In our study the DPP 4 inhibitor also used as a safer anti-diabetic agent.

Facilitative glucose transporter, an active co-transporter and sodium glucose co-transporter, a passive transporter, work together to reabsorb glucose in the proximal convoluted tubule. SGLT2 inhibitors block the SGLT2 in proximal convoluted tubule, which limits glucose absorption and raises glucose excretion in urine. The blood glucose level and other glycaemic indicators are maintained while glucose is eliminated in urine.¹⁴ Dapagliflozin as a SGLT2 inhibitor controlled the glycemic index when used with combine with DPP4 inhibitor.

Alpha-Glucosidase Inhibitors (AGIs) are typically used to treat T2DM. By moving the undigested carbohydrates to the distal portions of the small intestine and colon, AGIs slow down the

process of carbohydrate absorption in the gastrointestinal system. Drugs in this class aid in lowering postprandial hyperglycemia. AGIs are saccharides that function as competitive inhibitors for the enzymes in the small intestine to slow down the digestion of carbohydrates which convert polysaccharides into monosaccharides and resulting in a decrease in postprandial hyperglycemia.^{13,14} Voglibose is considerably effective to decrease the PPBS and is slowly minimized the used when glycemic control is normalized.

Our present study was describing the patterns of prescribing drug combination therapy focusing on SGLT2 inhibitor and DPP4 inhibitor and dose variation according to the blood glucose level and the effective therapy in patients with T2DM. The combination resulted in greater reductions in FBS and PPBS as comparing from visit 1 to 5. The risk of hypoglycaemic events was low. There are several requirements that must be met for the best combination of glucose-lowering medications, such as complementing physiological pathways. Minimal risks of hypoglycemia, weight gain and cardiovascular problems, as well as favourable safety profiles.

CONCLUSION

There is currently inadequate information on the prescription practices of T2DM patients in medical clinics. The current study offers significant new insights in this field in this context. Additionally, this study supports the need for more research into the elements that influence providers' prescription choices, such as treatment costs, formulary inclusion and reimbursement standards, as well as patient-related elements like insurance coverage, socio-economic status and cultural influences. This information could help in the creation of educational programmes for physicians to support the application of suggested therapies from guidelines. Clinical inertia factors connected to providers, patients and systems may be addressed with the aid of more study, improving results for T2DM patients.

The participants in the questionnaire were aware of the essential role of food, exercise and medicines in the management of type 2 diabetes. They also understood that changing one's lifestyle may help control type 2 diabetes. Additionally, it is believed that diabetes could be cured.

Glycemic control can be achieved in the human body by a variety of processes, according to the analysis of the numerous anti-diabetic drugs' mechanisms of action that has been presented. Each medication class has a unique mechanism of action, glycemic control effectiveness and side effects.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

T2DM: Type II Diabetes Mellitus; **ADRs:** Adverse Drug Reactions; **NCDs:** Non-communicable diseases; **WHO:** World Health Organisation; **IDF:** International Diabetes Federation; **GLD:** Glucose-Lowering Medications; **SGLT2i:** Sodium-glucose co-transporter 2 inhibitors; **DPP4i:** Dipeptidyl Peptidase IV Inhibitors; **EGP:** Endogenous Glucose Production; **ASCVD:** Atherosclerotic Cardiovascular Disease; **CKD:** Chronic Kidney Disease; **HF:** Heart Failure; **OPD:** Out-Patient Department; **FBS:** Fasting Blood Sugar; **PPBS:** Postprandial Blood Sugar; **SPSS:** Statistical Package for Social Sciences; **AGIs:** Alpha-glucosidase inhibitors.

SUMMARY

Currently, only limited information is available about the prescribing strategies of T2DM patients in medical clinics. The current work provides important new insights into this topic in the current context. The patterns of prescription pharmacological combinations and lifestyle adjustments in which therapy emphasizes SGLT2 and DPP4 inhibitors, as well as dose adjustment based on blood glucose level and treatment success in T2DM patients. DPP4 and SGLT2 inhibitors are novel antidiabetic medications used as add-on treatments to reduce various risk factors and improve quality of life. This information may assist in developing teaching programs for clinicians to support the use of prescribed medicines from recommendations. The questionnaire respondents knew the importance of diet, exercise and medications in treating type 2 diabetes. Glycemic control may be achieved by several methods, according to an examination of the different anti-diabetic drugs' mechanisms of action.

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