Others Section

Prescription Pattern and Cost Analysis of Nutraceuticals among Type 2 Diabetes Mellitus Patients: A Cross-sectional Study

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is a disorder related to the relative lack of insulin secretion leading to abnormal metabolism. In addition to insulin, various micronutrients takes part in the metabolic processes. The imbalance between these vital micronutrients might be one reason for the progression of chronic diseases. There is a need to understand the utilisation pattern of these nutraceuticals in treating chronic conditions like DM.

Aim: To study the prescribing patterns of various types of nutraceuticals and the cost of nutraceuticals per prescription in T2DM patients.

Materials and Methods: This cross-sectional study was conducted in a tertiary care teaching hospital of Dakshin Karnataka, India, from September 2021 to April 2022. Total 150 T2DM patients, who were prescribed atleast one nutraceutical, were included in the study. Collected data was assessed by descriptive analysis

(quantitative data; age, height, weight, Body Mass Index (BMI), number of drug prescribed, number of prescriptions, cost of nutraceuticals) whereas qualitative data (gender, social classes, qualification, occupation, domiciliary status, marital status, duration of diseases, family history, social history, personal history) was documented using frequency/ percentage.

Results: Out of total 150 subjects, 92 (61.33%) were males, and 58 (38.67%) were females. At the same time, the mean age of the patients was found to be 58.1 years. Among all the prescribed nutraceuticals, vitamins were found to be the most frequently prescribed 97 (64.66%), followed by proteins 45 (30%) and vitamins+minerals 42 (28%). The average number of nutraceuticals per prescription was 1.57±0.76. The average cost of nutraceuticals was 440.55 (Indian rupee) INR per prescription.

Conclusion: The most commonly prescribed nutraceuticals were vitamins in 97 (64.66%) patients. The average additional cost for the nutraceuticals was found to be 440.55 INR.

INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disorder characterised by elevated blood glucose levels [1]. T2DM is the condition in which sufficient amount of insulin may be produced by the pancreas but there could be the resistance in the receptors site that will uptake it [2,3]. The human body's metabolic process is regulated by insulin and other micronutrients. The deficiency of mineral and trace elements may play a vital role in the pathophysiology and progression of metabolic diseases, including diabetes mellitus [4], and finally, benefits in dropping the glycated haemoglobin [1]. The term 'nutraceuticals' has been defined as any substance that may be considered a food or a part of food and provides medical and health benefits, including preventing and treating disease [5]. Nutraceuticals are dietary supplements that balance energy, improve mental concentration, and prevent nutritional deficiencies [5]. In today's health-conscious culture, nutraceuticals are steadily becoming an essential part of the prescription, especially in chronic diseases; these agents widely gain importance for annexation in the diet. Patients' attitudes towards the consumption of nutraceuticals are due to increased risks of various lifestyle diseases. Nutraceuticals established the role of improving physical and mental well-being. Nutraceuticals include vitamins, herbal products, minerals, metabolites, and functional foods like bran, oats, and antioxidants [6,7]. The poor clinical outcomes and long-term complications of diabetes can be due to the poor balance between the free radicals generated and their scavenging by the physiological process of the human body. Thus, the micronutrients might have a crucial role in preventing complications of chronic diseases and arresting the disease progression [5,7]. Nutraceuticals will play a vital therapeutic function, and their effectiveness will estimate

their success with minimum or no adverse effects [8]. According to the World Health Organisation (WHO), 50% of hospitalised patients have malnutrition, increasing morbidity and death risk [9]. Prescription pattern study insights into the trends of pharmaceutical products prescribed by the physician. Analysis of utilisation patterns may help identify commonly prescribed drugs for managing particular conditions [10]. Thus, there is a need to understand the utilisation pattern of these nutraceuticals in treating chronic conditions like DM. Rajasekaran A et al., in a review, found that using nutraceuticals has benefited cardiovascular diseases, obesity, DM, malignancies, osteoporosis, and neurological disorders. Nutraceuticals play an essential role in several biological progressions and have protective action against various illnesses [11]. Nutraceuticals are one of the majorly prescribed classes of drugs for treating chronic diseases [12].

Till date there are scarce of data from Karnataka (Southern part of India) that reports mainly on prescription as well as cost of nutraceuticals among diabetic patients. Thus, there is a need to understand the prescription pattern and cost of nutraceuticals per prescription among diabetic patients. Hence, present study was conducted to assess the prescription pattern and cost of nutraceuticals among T2DM patients.

MATERIALS AND METHODS

This cross-sectional study was conducted on Inpatient and Outpatients Department of General Medicine, Justice K.S Hegde Charitable Hospital, Deralakatte, Mangalore, Karnataka, India for a period of eight months, from September 2021 to April 2022. The study was approved by Institutional Ethical Committee (IEC) [REF. NO: NGSMIPS/IEC/12/2021], Clinical Trials Registry-India approval:

CTRI/2021/09/036684. The written informed consent was taken from the patients or their legal representative.

Inclusion criteria: Diagnosed cases with T2DM, aged above 18 years, who were prescribed atleast one nutraceutical in the outpatient and inpatient Department of General Medicine were included in the study.

Exclusion criteria: The pregnant mothers with gestational diabetes, Type 1 DM patients, patients who were unwilling to participate in the study, and with severe psychological disorders were excluded .

Sample size calculation: The sample size was calculated by using nMaster software 2.0, by using the following formula;

$$n = \frac{z^2 \frac{\alpha}{2}}{d^2} pq$$

p = proportion, q = 1-p, d = precision, z = 1.96 (at α = 5% level of sigma), n = sample size

The expected proportion of diabetes mellitus = 0.11 (from MRD record of K.S Hegde Hospital), Expected precision = 5%, At 95% confidence level [3], and the obtained sample size was 150.

Study Procedure
Data collection: The patients' data collection form was designed as per the study's needs. All relevant details were recorded, including patient socio-demographic parameters such as age, gender, weight, height, BMI [13], educational status, employment status, domiciliary status, co-morbid conditions, and social habits. Information regarding the antidiabetic drugs and nutraceuticals prescribed among the patients, including their dose, dosage form, frequency, route of administration, and duration, were recorded. The cost of nutraceuticals per prescription among diabetic patients was analysed considering parameters like brands with the generic name, frequency, and duration of treatment were collected from patient records, pharmacy bills, and interviewing the patients or patient parties.

Cost analysis of different types of nutraceutical drugs: The cost was analysed considering parameters like brands with each generic name used, collected from the patient records, medical invoice, hospital accounts section, and other relevant sources. Percentage price analysis was calculated for different nutraceuticals used in T2DM treatment by using the mean and standard deviation.

STATISTICAL ANALYSIS
The collected data was assessed by descriptive analysis whereas qualitative data was expressed into frequency/ percentage using the Statistical Package for the Social Sciences (SPSS) version 20.

RESULTS

Socio-demographic Distribution
A total of 150 patients were prescribed nutraceuticals. Out of them 92 (61.33%) were males and 58 (38.67%) were females. The 71 (47.33) patients belonged to the age group of 46-60 years old, and around one-third of the overall study patients were overweight. Only 36 (24.00%) of the enrolled patients had secondary-level educational degree qualifications, and 85 (56.67%) patients had low socio-economic status. The minimum duration of patients who had diabetes was found to be one year, the maximum was ≥10 years, and the median of 5 years. Around 121 (80.67%) of the patients had comorbidities; out of them, hypertension was the most common 73 (48.67%) patients. The 144 (96.00%) of the study population were found to take the mixed diet category [Table/Fig-1].

Out of 150 prescriptions, the most frequently prescribed antihypoglycaemic was Human insulin monotherapy for 53 (35.33%) patients, followed by Metformin for 39 (26.00%) patients. Empagliflozin and Dapagliflozin were found to be prescribed least frequently in 1 (0.66%) patient. Whereas around 60 (40.00%) of patients were prescribed the fixed-dose combination of antihypoglycaemic agents, among them, the

most commonly prescribed were 33 (22.00%) metformin+ glimepiride followed by the three drugs fixed-dose combinations 9 (6.00%) with metformin+ glimepiride+voglibose [Table/Fig-2].

Out of 150 antihyperglycaemic agents, the prescription majority were prescribed one drug for 85 (56.67%) patients, followed by two drugs

Categories	n (%)
Gender	
Male	92 (61.33)
Female	58 (38.67)
Age (years)	
18-30	1 (0.67)
31-45	14 (9.33)
46-60	71 (47.33)
>60	64 (42.67)
BMI (kg/m²)	
Underweight <18.5	6 (4.00)
Optimal 18.5-24.9	85 (56.67)
Overweight 25-29.9	53 (35.33)
Obese >30	6 (4.00)
Educational status	
No formal education	38 (25.33)
Primary level	29 (19.33)
Secondary level	47 (31.33)
Higher secondary and above	36 (24.00)
Employment status	
Unemployed	38 (25.33)
Daily wages	47 (31.33)
Self employed	43 (28.67)
Government sector	14 (9.33)
Retired	8 (5.33)
Domiciliary status	
Urban	36 (24)
Rural	114 (76)
Co-morbidities (n=121)	
Hypertension	73 (48.67)
Migraine	2 (1.33)
Ischaemic heart dsease	13 (8.67)
Rheumatoid arthritis	4 (2.67)
Bronchial asthma	4 (2.67)
Hypothyroidism	6 (4.00)
Hepatic failure	5 (3.33)
Renal failure	5 (3.33)
Tuberculosis	4 (2.67)
Dyslipidaemia	5 (3.33)
Social habits (n=44)	
Smoking	17 (11.33)
Alcohol	15 (10.00)
Both	12 (8.00)
Diet	
Vegetarian	6 (4.00)
Mixed	144 (96)
Duration of diabetes (n=150) (years)	
<1	36 (24.00)
1-3	20 (13.33)
4-6	34 (22.67)
7-9	10 (6.67)
≥10	50 (33.33)

Complications (n=18)	
Retinopathy	5 (3.33)
Neuropathy	3 (2.00)
Nephropathy	5 (3.33)
Diabetic foot ulcer	5 (3.33)

[Table/Fig-1]: Socio-demographic data of patients (n=150 patients).
*BMI: Body mass index

Monotherapy			
Class of drugs	Drug name	Frequency (n)	Percentage (%)
Injection (n=82)			
Insulin	Human Insulin	53	35.33
	Insulin Glargine	14	9.33
	Biphasic Isophane	15	10.00
Oral (n=74)			
Biguanides	Metformin	39	26.00
Sulphonylureas	Glimepiride	17	11.33
	Gliclazide	11	7.33
	Glipizide	02	1.33
Alpha glucosidase inhibitor	Voglibose	07	4.66
SGLT-2 inhibitor	Empagliflozin	01	0.66
	Dapagliflozin	01	0.66
DPP-4 inhibitors	Teneligliptin	16	10.66
Fixed dose combination (n=60)			
Class of drugs	Combination of OHA	Frequency (n)	Percentage (%)
Biguanides+ Sulphonylureas	Metformin+ Glimepiride	33	22.00
Biguanides+ DPP-4 inhibitor	Metformin+ Teneligliptin	04	2.66
Biguanides+ DPP-4 inhibitor	Metformin+ Vildagliptin	08	5.33
Biguanides+ Sulphonylureas	Metformin+ Glibenclamide	01	0.66
Biguanides+ Alpha glucosidase inhibitor	Metformin+ Voglibose	01	0.66
Biguanides+ Sulphonylureas+ Alpha glucosidase inhibitor	Metformin+ Glimepiride+ Voglibose	09	6.00
Biguanides+ Sulphonylureas+ Thiazolidinedione	Metformin+ Glimepiride+ Pioglitazone	03	2.00
Biguanides+ Thiazolidinedione	Metformin+ Glibenclamide+ Pioglitazone	01	0.66

[Table/Fig-2]: Utilisation pattern of hypoglycaemic agents (n=150 patients).
*OHA; Oral hypoglycemic agent, SGLT2 inhibitor; Sodium-glucose co- transport-2, DPP4 Inhibitors; Dipeptidyl peptidase 4

for 47 (31.33%) patients and three drugs for 16 (10.66%) patients. Whereas, from the total of 150 prescriptions of nutraceuticals, the majority 85 (56.67%) patients were prescribed one drug, followed by two drugs for 50 (33.33%) patients and three drugs for 10 (6.67%) patients. The mean number of Nutraceuticals drugs per prescription was found to be 1.57±0.76 [Table/Fig-3].

Number of drugs	Frequency (n)	Percentage (%)
Antidiabetics		
1	85	56.67
2	47	31.33
3	16	10.66
4	01	0.67
5	01	0.67
Nutraceuticals		
1	85	56.67
2	50	33.33
3	10	6.67
4	05	3.33

[Table/Fig-3]: Number of drugs prescribed per prescription (n=150 patients)

Among the enrolled patients, the most commonly prescribed monotherapy nutraceutical were vitamins for 97 (64.66%) patients, followed by proteins for 45 (30.00%) patients. At the same time, minerals were prescribed to the least number of patients 2 (1.33%). Whereas in the case of the fixed-dose combination of nutraceuticals, the majority of the patients were prescribed vitamin+ minerals for 42 (28.00%) patients, followed by vitamins+ minerals+ herbs for 9 (6%) patients. Whereas vitamins+ minerals+ proteins 1 (0.66%) and vitamins + probiotics 1 (0.66%) were prescribed to the least number of patients [Table/Fig-4].

Monotherapy (n=150 patients)		
Nutraceuticals	Frequency (n)	Percentage (%)
Vitamins	97	64.66
Minerals	02	1.33
Proteins	45	30.00
Probiotics	12	8.00
Fibers	05	3.33
Enzymes	05	3.33
Fixed dose combination nutraceuticals (n=150 patients)		
Nutraceuticals	Frequency (n)	Percentage (%)
Vitamins+Minerals	42	28.00
Vitamins+Minerals+ Herbs	09	6.00
Vitamins+Minerals+ Proteins	01	0.66
Vitamins+Probiotics	01	0.66
Duration of nutraceutical therapy (*n= number of nutraceuticals)		
Number of days	Frequency (*n=222)	Percentage (%)
7	15	6.76
14	37	16.67
30	170	76.57

[Table/Fig-4]: Utilisation pattern of nutraceuticals.

The duration of a nutraceutical prescription ranged from 7-30 days. The majority, 170 (76.57%) of the nutraceuticals were prescribed for 30 days, followed by 14 days duration for 37 (16.67%), and seven days duration for 15 (6.76%) nutraceuticals [Table/Fig-4].

The minimum cost per nutraceutical was found to be 35 INR and maximum was 1363 INR, and the average cost per prescription was 440.55 INR. Enzymes were comparatively expensive 504.2±420.65 INR, followed by Proteins 426.63±95.79 INR, whereas vitamins and probiotics were the least cost 87±87 INR [Table/Fig-5].

Nutraceuticals	Mean (INR)	Std. deviation
Vitamins	249.77	178.22
Minerals	91	91.00
Proteins	426.63	95.79
Probiotics	170.36	77.48
Fibers	346	346.00
Enzymes	504.2	420.65
Vitamins+Minerals	360.4	224.24
Vitamins+Probiotics	87	87.00
Vitamins+Minerals+Proteins	181	181.00
Vitamins+Minerals+Herbs	111.12	2.47

[Table/Fig-5]: Cost of nutraceuticals per prescription.
*INR: Indian rupee

DISCUSSION

The combination of antidiabetics with nutraceuticals has shown a significant role in reducing the Glycated Haemoglobin (HbA1c), Fasting Blood Sugar (FBS), and Post Postprandial Blood Sugar (PPBS) compared to placebo [1]. Nutraceuticals are being increasingly perceived as beneficial to health and are being continuously used to treat various diseases. The safe and effective utilisation of nutraceuticals can help improve disease treatments, significantly hasten the prognosis of the patients condition, and mitigate the complications [4,6]. Research showed that the combination of nutraceuticals had a beneficial effect on insulin resistance associated with metabolic syndrome [14].

In present study, males patients consumed more nutraceuticals (61.33%) when compared to females (38.67%) which was in contrast to the studies conducted by Kulkarni M et al., which suggest that majority were females (51.92%) [15]. In this study, the majority of the patients were from the age group of 46-60 years (47.33%), which was in contrast to the study regulated by Dada AO et al., which showed that the majority of the patients were above 60 years (53.6%). The results of present study suggest that the risk of T2DM increases after the age of 40 years [3]. From present study, it can be seen that newly diagnosed, i.e., less than one-year diabetic patients were higher (24%) which was similar to the findings of the research conducted by Pushpa VH et al., in their study (56%) of the patients showed less than five years of duration of diabetes which was deviated from present study results of it could be due to they had included geriatric diabetic patients. In contrast, present study has included both adults and geriatric patients. Hence it can be seen that as age advances, the incidence of diabetes also increases [16].

In present study, authors have found that 35.33% of the patients were overweight, which was similar to the study performed by Dada AO et al., [3] which states that the majority of the patients had BMI in the range of 25-29.9 kg/m² (36.2%) suggesting that overweight is one of the significant risk factors for T2DM. In this study, the average age was found to be (58.1) years, where the co-morbidities (cardiovascular disorders, obesity, weight loss, constipation, diarrhoea, bone, and joint disorders) and complications (macrovascular and microvascular) significantly increase with age; additionally, contributing factors lifestyles and socio-behavioural activities, which are common risk factors for the complication and progression of diseases in India, which is supported by the review conducted by the Tamura Y et al., [7] around one third of our total study population found to have social habits of either smoking or consumption of alcohol or both. Hypertension was the most common co-morbidity (48.67) associated with T2DM among the patients in present study. This was similar to the study conducted by Das AK et al., [17]. This suggests that among patients with diabetes, cardiovascular (macrovascular) complications pose a significant threat.

In present study, authors have observed the following microvascular complications associated with patients diabetic retinopathy (5), diabetic nephropathy (5), diabetic foot ulcer (5), and diabetic neuropathy (3). This evidence shows similar to the study performed by Jyothi PD et al., [18] it was found that diabetic neuropathy (16 patients) followed by diabetic foot ulcer (15 patients), hypoglycemic episodes (7 patients), and diabetic nephropathy (5 patients) were the most common complications among the patients with T2DM. Among the 150 prescriptions of antidiabetics, in this study, authors observed that injectable dosage forms of antidiabetics were high in patients. In contrast, the oral dosage form of the antidiabetic was greater in the outpatients, and the reason could be that outpatients are more stable and can be managed with the oral. In contrast, the inpatients had uncontrollable blood sugar levels or severe conditions, so they needed to be managed with injectable antidiabetic therapy. The most commonly prescribed injectable

was human insulin (35.33%). However, the results of the studies conducted by Acharya KG et al., [19] and Anila AB et al., [5] showed that most patients received tablet metformin. This deviation may be because present study has enrolled both in and outpatients.

Among the total prescription, authors have analysed that frequently used oral antidiabetics drug was beguanides metformin (26%) followed by the sulfonylurea (glimepiride, gliclazide, glipizide (20%)). Among the fixed-dose combinations therapy, the most commonly prescribed drugs were metformin+ glimepiride (22%) which was in agreement with the study performed by Dada AO et al., [3] which states that metformin monotherapy and its fixed-dose combinations were most frequently prescribed medication (32.8%). They suggested that combining biguanides and sulfonylureas was the most commonly effective therapy. Most of the patients in present study were prescribed one antidiabetic drug (56.67%), which was in agreement with the study conducted by Abired A and Atia A, where most of the patients were prescribed with one antidiabetic drug (50%) [20].

Nutraceuticals are defined as dietary supplements that increase energy, improve mental concentration, and prevent nutritional deficiencies [21]. Now-a-days, the main reason for the increased use of nutraceuticals can be attributed to the swift urbanisation, increased prevalence of lifestyle disorders, and people knowingly taking preventive healthcare measures in the form of dietary supplements [21]. Vitamins, including fat-soluble and water-soluble, are vital for various physiological functions. Minerals are necessary for properly maintaining bones, heart muscles, and brain, followed by proteins for synthesising various hormones and enzymes. Enzymes are proteins that help speed up chemical reactions in the body. Probiotics help digestion, nutrient absorption, maintain gut health, and contribute to immune function. Although fibres usually maintain normal bowel health and cholesterol levels, the antioxidants are required to normalise the body's free radicals Nimesh S and Nimesh VD, [22].

In present study, it was found that vitamins (64.66%) were the most prescribed nutraceuticals. This result agrees with the study performed by Shrestha R et al., [23] where vitamins (40.7%) were the most commonly prescribed nutraceuticals among the patients. The most commonly prescribed fixed-dose combination nutraceutical in present study was found to be vitamins+ minerals (28%), followed by vitamins+ minerals+ herbs (6%). A similar result was found in the study performed by Anila AB et al., where most prescriptions (72.17%) contained water-soluble vitamins+ minerals [5].

Present study found the average number of nutraceuticals prescribed per prescription was 1.57±0.76. The minimum number of nutraceuticals per prescription has one drug, and the maximum number of nutraceuticals per prescription has four drugs. This was similar to the result of the study conducted by Shrestha R et al., which shows that the average number of nutraceuticals per prescription was 1.52 [23]. In present study, the duration of nutraceutical prescription was mainly from 7 days to 30 days, the maximum days (30 days) of nutraceutical prescription were vitamin (56.66%) followed by protein (24.66%) and vitamin+mineral (24%). The least duration of nutraceutical prescription was found for an enzyme (2%) among patients for seven days, which was parallel with the study result of Anila AB et al., where the duration of vitamins prescription was for 30 days, but diverged in the case of the prescription duration of vitamins and mineral were prescribed for the maximum of 90 days [5]. Even though nutraceuticals have pharmaceutical benefits, only (24%) of the study population had received a higher secondary and above education, and most of the patients were unemployed or daily wages workers from low-income sources backgrounds, which shows the prescribed nutraceuticals exerted an additional economic burden.

In this study, the average cost of each prescription due to the nutraceuticals was found to be 440.55 INR, whereas the maximum

cost per prescription was 1363 INR, and the minimum cost was found to be 35 INR. These results for the average cost per prescription of the nutraceuticals deviated from the study conducted by Shrestha R et al., [23] and Gosavi S et al., which showed that the average cost of each prescription in the Department of General Medicine was found to be NRs 575.78 [which is around 360 INR] and 219 INR for nutraceuticals respectively [6]. Compared to other types of nutraceuticals, the highest average cost per prescription was found to be with enzymes (504.2±420.65 INR), followed by proteins (426.63±95.79 INR), vitamins+ minerals (360.04±224.24 INR), and whereas the vitamins and probiotics cost found to be least (87±87 INR). The observed greater average cost of vitamins alone compared to the vitamin+ probiotics was that vitamin+ probiotics were prescribed for only one patient, whereas vitamin monotherapy was prescribed for more than (60%) of the patients.

Limitation(s)

This was part of an academic project, so the study period was only eight months. It could be better if the sample size were large. In addition, present study could be better if authors had observed nutraceuticals efficacy in blood sugar control.

CONCLUSION(S)

Present study observed that vitamins, proteins, and minerals were the most frequently prescribed nutraceuticals, whereas enzymes and fibers were the least. Even though nutraceuticals are an integral part of the management of chronic diseases like T2DM, at the same time, patients are facing additional economic burdens due to these nutraceuticals. In this study, the cost per prescription of nutraceuticals was 440 INR. So, more research needs to be focused on the cost analysis of nutraceuticals among T2DM to eliminate the undesirable economic burden on patients.

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