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Treatment Patterns and Adherence according To the ADA's 2021 Treatment Guidelines in Patients with Type 2 Diabetes Mellitus: A Prospective Cross-Sectional Study

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Abstract

Aims: To study prescription pattern of anti-diabetic drugs and adherence to the American Diabetes Association (ADA)'s 2021 treatment guidelines in patients with Type 2 Diabetes Mellitus in a tertiary care hospital.

Methods: A prospective cross-sectional study was undertaken to investigate the prescription patterns and management practices of inpatients diagnosed with type 2 diabetes mellitus at Shri Mahant Indiresh Hospital, Dehradun, Uttarakhand. Utilizing a specifically designed patient profile document, patient prescriptions were systematically collected and relevant data was meticulously recorded and analyzed, subsequent to obtaining approval from the ethical committee. This study aimed to provide a comprehensive examination of the prevailing practices in the management of type 2 diabetes mellitus within a hospitalized setting.

Results: A prospective analysis of 100 diabetic patient prescriptions revealed a notable male preponderance, with 65% of patients being male compared to 35% female. The majority of patients (37%) fell within the age range of 51-60 years. Hypertension was the most common comorbid condition, affecting 65% of patients, followed by hyperthyroidism (15%). In terms of pharmacological management, metformin was the most frequently prescribed medication with a prescription rate of 29.62%, while Lantus Gold was the most commonly used parenteral preparation. Notably, 81% of prescriptions adhered to the 2021

American Diabetes Association (ADA) treatment guidelines, while 19% did not, highlighting the need for continued education and awareness among healthcare providers to ensure optimal management of diabetes and its comorbidities.

Conclusions: The prescription pattern of T2DM is complex and influenced by various factors, including guidelines, patient characteristics and regional healthcare systems. By understanding these patterns, healthcare providers can optimise treatment approaches, improve patient outcomes, and reduce the burden of T2DM.
Keywords: Prescription pattern, Adherence, ADA' s 2021 treatment guidelines.

Introduction

The prevalence of diabetes mellitus has increased by almost 50% since 1980, impacting 8.5% of the adult population globally (around 463 million cases, half of which are thought to be undiagnosed) [1]. The International Diabetes Federation (IDF) projects that the cost of diabetes to the US would reach $845 billion by 2045, affecting around 700 million people worldwide. Of the IDF areas, Europe has the second-lowest percentage of adult diabetes patients (6.8%). The intracontinental variations are wide, ranging from 2.1% in Greenland to 11.1% in Turkey. More than 600,000 (6.6%) of Austrians have diabetes mellitus, with 85%–90% of those cases being type 2 [2,3].

The diabetes pandemic has sped up the development of treatments and medications to control the condition, resulting in frequent modifications to national and international recommendations. The 2012 policy statement was revised in 2015 by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). The European Society of Cardiology (ESC) and EASD made a new update to the position statement in 2019, following another modification in 2018. When licensing new anti-diabetic medications in 2008, the US Food and Drug Administration (FDA) modified its standards for cardiovascular (CV) safety [4-8]. Since novel therapies, such as sodium/glucose cotransporter 2 inhibitors (SGLT-2i), gliptins, and glucagon-like peptide-1 agonists (GLP-1a), have entered the market, the FDA's requirements have resulted in the publishing of multiple large CV outcome studies (CVOT) [9,10]. When SGLT-2i was initially approved in 2011, it demonstrated cardiovascular safety, possible advantages for the kidneys, decreased cardiovascular events, decreased all-cause mortality, and decreased the risk of heart failure-related death and deterioration. GLP-1a, which was first authorized in 2005, demonstrated prospective benefits for the kidneys during this time and proved to be CV safe. Gliptins have demonstrated cardiovascular safety since 2013, and from 2015 to 2019, additional evidence supported renal safety. The guidelines were significantly altered as a result of this new research [9-12].

The goal of the 2018–2019 guidelines is to offer an algorithmic method for making decisions regarding the treatment of diabetes. The 2015 guidelines provided ambiguous advice for increasing medication if haemoglobin A1c (HbA1c) objectives were not met. Diabetes recommendations were more precisely defined thanks to mounting evidence from big CVOTs. A five-column step plan tailored to the demands of individuals,

related comorbidities, treatment objectives, and even expenses is offered by the 2018/2019 ADA and EASD guidelines [5,7]. Giving instructions is merely a first step toward altering treatment plans. The degree to which guidelines are followed varies, and understanding these issues and how to apply them is essential for improving treatments across all fields. Registries offer a strong instrument for evaluating treatment modifications. Many long-term repeated measurements are produced after years of closely monitoring a large number of patients with comprehensive demographic data [13].

Aim and Objectives

The primary objectives of this study are to conduct a comprehensive demographic analysis of patients diagnosed with Type 2 Diabetes Mellitus, examining factors such as age, gender, and other relevant characteristics. Additionally, this study aims to evaluate and analyze the prescribing patterns of antidiabetic medications in this patient population, including the types and combinations of medications utilized. Furthermore, the study seeks to assess the extent of adherence to the American Diabetes Association's (ADA) 2021 treatment guidelines for Type 2 Diabetes Mellitus, encompassing the appropriate use of medications, monitoring, and lifestyle modifications. By achieving these objectives, this study aims to provide valuable insights into the management of Type 2 Diabetes Mellitus and identify areas for improvement in clinical practice.

Need For the Study

The study on prescription patterns and adherence to the treatment guidelines for Type 2 Diabetes Mellitus (T2DM) is necessary due to the rising prevalence of the disease, variability in treatment approaches, and suboptimal adherence to guidelines. The research aims to identify gaps in care, optimize resource allocation, and improve health outcomes by understanding prescription patterns and adherence. With T2DM being a growing global health concern, standardized treatment protocols and consistent, evidence-based care are crucial. The study's findings will inform strategies to enhance patient education, provider training, and healthcare system improvements, ultimately contributing to better care and outcomes for T2DM patients.

Materials and Methods

This prospective cross-sectional study was undertaken over a six-month period at Shri Mahant Indiresh Hospital, Patel Nagar, Dehradun, with a participant population of 100 individuals. A structured data collection protocol was employed, utilizing a specifically designed patient profile document to garner prescription-related information. Following requisite ethical committee approval, the accrued data underwent recording and analysis. A comprehensive examination of prescription patterns was conducted, with particular emphasis on evaluating concordance with established treatment guidelines, as articulated in the 2021 American Diabetes Association (ADA) guidelines. Statistical analysis was performed utilizing Microsoft Excel software, with resultant data expressed as percentages to facilitate inferential statistical interpretation and analysis.

Selection of subjects:

Inclusion criteria:

- Patients of both sexes irrespective of age,
- Patients diagnosed with Diabetes Mellitus,
- Patients with Diabetes along with other comorbidities were selected,
- Patients with DM on treatment with oral hypoglycaemic agents and insulin therapy,
- Laboratory investigations

Exclusion criteria:

- Newly diagnosed,
- Gestational diabetics,
- Serious comorbid patients
- Subjects who had received anti-diabetic therapy for less than 6 months duration.

Results

Demographics: A total number of 100 prescriptions of diabetic patients were evaluated. Male preponderance of 65% was observed as compared to female. Most of the patients affected were of the age group of 51 to 60 years (37%), followed by the age group of 61 to 70 years (28%), age group above 70 years (15%), age group of 41-50 (12%), age group of 31-40(7%) and age group of 18-30 (1%) respectively (Table 1).

Table 1: Age Wise Distribution of Individual

S.no.	AGE GROUP (years)	No. of Individual(T2DM) (n=100)	Total No. of Individual (%) (n=100)
1	18-30	1	1%
2	31-40	7	7%
3	41-50	12	12%
4	51-60	37	37%
5	61-70	28	28%
6	>70	15	15%

A total of 65 male and 35 female diabetic patients were evaluated, where 69.23% of male individuals were found out to be with normal range of BMI and 62.85% of female individuals were found out to be with normal range of BMI respectively (Table 2).

Table 2: Gender Wise Distribution of BMI

S.no.	Variables	No. of Male Individual (%) (n = 65)	No. of Female Individual (%) (n = 35)
1.	BMI (Underweight <18.5)	9(13.85%)	9(25.71%)
2.	BMI (Normal range 18.5-24.9)	45(69.23%)	22(62.85%)
3.	BMI (Overweight 25.0-29.9)	11(16.92%)	4(11.42%)
4.	BMI (Obese ≥30.0)	0	0

Comorbidities: Various co-morbidities like hypertension, cerebrovascular accidents (CVA), chronic obstructive pulmonary disease (COPD), neuropathy, urinary tract infections, nephropathy, chronic kidney diseases (CKD), hyperthyroidism and polyneuropathy were observed among the studied patients. Hypertension (65%) was the most common co-morbid condition, followed by Hyperthyroidism (15%), COPD (12%), Nephropathy (12%), CKD (11%), Polyneuropathy (10%), UTI (8%) and CVA (8%) (Figure 1) (Table 3).

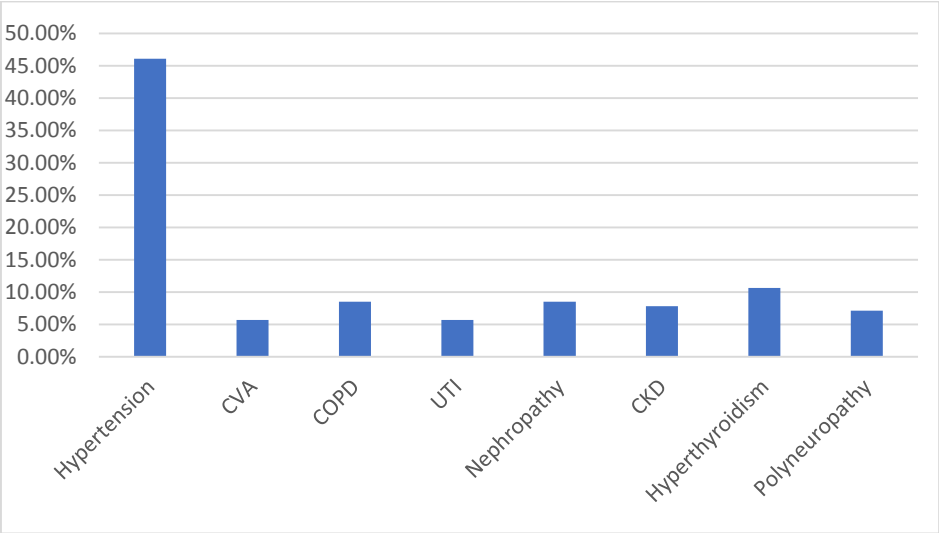

Figure 1: Comorbidities

Table 3: Comorbidities

S.no.	Comorbidity	No. of patient	%
1	Hypertension	65	46.09%
2	CVA	8	5.67%
3	COPD	12	8.51%
4	UTI	8	5.67%
5	Nephropathy	12	8.51%
6	CKD	11	7.80%
7	Hyperthyroidism	15	10.63%
8	Polyneuropathy	10	7.09%

Prescription Pattern of Anti-diabetic drugs: Table 4 shows various Anti-diabetic drugs prescribed, with Metformin as the most commonly used with prescription rate of 29.62%, followed by combination of Vildagliptin & Metformin (17.28%), and Amaryl (14.81%).

Table 4: Prescription Pattern of Anti-diabetic drugs

S.no.	Class of drug	No. of prescription	Prescription rate (%)
1	Vildagliptin & Metformin	28	17.28%
2	Sitagliptin	6	3.70%
3	Actos	5	3.08%
4	Metformin	48	29.62%
5	Amaryl	24	14.81%
6	Glimepiride & Metformin	15	9.25%
7	Inj. Insulin	12	7.40%
8	Dapagliflozin	4	2.46%
9	Glimepiride + Metformin + Pioglitazone	10	6.17%
10	Sulfonylurea	10	6.17%

Prescription Pattern of Insulin preparations: Table 5 shows various insulin preparations prescribed, with Lantus Gold as the most commonly used preparation (41.66%), followed by Basalog (33.33%) and Human Mixtard (25%).

Table 5: Prescription Pattern of Insulin preparations

S. No.	Insulin preparations	Frequency	(%)
1	Lantus Gold	5	41.66%
2	Basalog	4	33.33%
3	Human Mixtard	3	25%

HbA1c (Glycated haemoglobin levels):
Table 6 shows classification of individual patients on the basis of HbA1c (by automated CE HPLC). 79% patients were found out to be diabetic with higher levels of HbA1c (6.5 and above) followed by 13% were found out to be prediabetic (5.7-6.4%) and 8% with normal range of HbA1c levels (4.5-6%).

Table 6: Classification of individual patients on the basis of HbA1c

S.no.	HbA1c levels	No. of Individual (n=100)	Total No. of Individual (%) (n=100)
1.	>10%	12	12%
2.	6.5-10	67	67%
3.	5.7-6.4%	13	13%
4.	4.5-6%	8	8%

Adherence to the American Diabetes Association (ADA)'s 2021 treatment guidelines:
Figure 2 demonstrated that 81% of prescriptions adhered to the 2021 ADA treatment guidelines, and 19% of prescriptions did not adhere to the guidelines. The main reasons for non-adherence were as follows: 12 patients were on insulin therapy of which 16.67% had HbA1c <10, and there was no need for insulin therapy as no weight loss

noted. 2% of patients with a HbA1c >10 declined to begin insulin therapy, which is also a sign of non-compliance with ADA standards. 8% of patients had HbA1c <6.5 but were receiving combination therapy with dipeptidyl peptidase 4 inhibitors (DPP4I); 7% of patients had experienced multiple hypoglycemic episodes in the past, but they were receiving combination therapy with metformin and sulfonylurea which shows non-adherence to the ADA guideline.

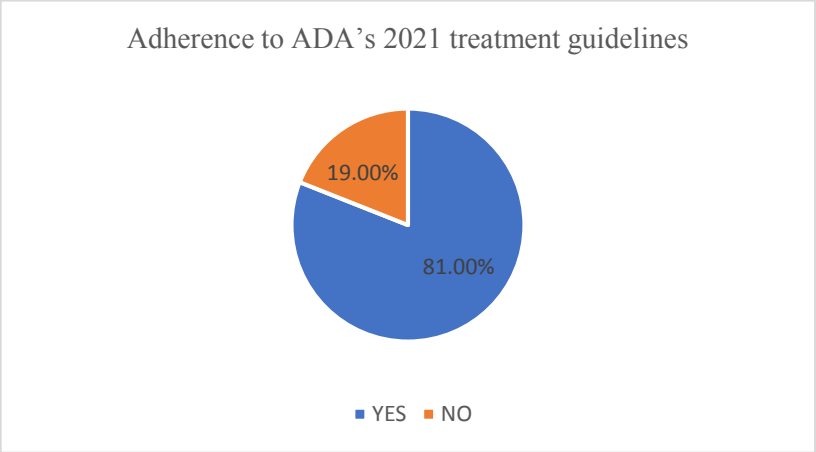

Figure 2: Adherence to ADA's 2021 treatment guidelines

Discussion

Clinical Characteristics:

A total of 100 subjects of type 2 DM participants were evaluated, it was found that there were more men (65%) than women (35%), and this pattern was consistent with previous research [5]. The distribution of body fat differed by gender, with a greater percentage of male visceral and hepatic fat compartments associated with insulin resistance. Women are more likely to have larger levels of peripheral and subcutaneous fat, which are protective against type 2 diabetes and associated with insulin sensitivity. Females are therefore less likely to acquire type 2 diabetes [14].

According to our study, 77% of the patients were between the ages of 41 and 70. This is consistent with previously published material, which found that 75% of patients were between the ages of 41 and 60. This could be the result of an increasingly sedentary lifestyle, elevated stress levels, and aging, which raises the risk of diabetes mellitus in this age range. Additionally, there is a greater likelihood that these patients would experience other chronic issues related to type 2 diabetes [15,16]. Age distribution of patients with diabetes mellitus with or without associated co-morbidities: cases in the age group 51–60 made up 37%, followed by 21% in the 61–70 age group and the lowest in the 18–40 age group (8%). This is consistent with findings by Mohd Mahmood et al., who found that the majority of patients were in the 41–60 age group (45.53%) and the lowest percentage were in the 20–40 age group (6.38%) [17]. The majority of patients (45% males, 22% females) had BMIs within the normal range. Patients who were overweight (11% males, 4% females) had BMIs that were somewhat higher than those of Patel B et al.'s study (19.3%) [16].

Associated Comorbidities:
Diabetes mellitus is a long-term metabolic illness that frequently coexists with other conditions. The most prevalent comorbidity in our study was hypertension, which was followed by hyperthyroidism. Large artery stiffness is linked to hypertension and frequently occurs before macrovascular events. Similar findings were noted in a number of studies, with 49.09% of patients reporting hypertension as the most prevalent comorbidity [17, 18]. Similar findings were found in another study [19], which found that dyslipidaemia was the second most prevalent comorbidity, behind cardiovascular disease, hypothyroidism, and urinary tract infections, and that hypertension was the most common comorbidity, reported in 51% of patients with diabetes mellitus. In terms of other co-morbidities, hypertension was the most common co-morbid condition (46.09%), followed by hyperthyroidism (10.63%). This is significantly less than the study conducted by Alex et al. [20], who showed hypertension in 68.5% of cases. Regarding the comorbidity in people with diabetes, various research from India and other nations have revealed comparable findings. Nonetheless, there has been a 31–70% range in the prevalence of hypertension [21].

Antidiabetic Therapy:
In our study, 21 patients (21%) had a HbA1c of less than 6.5. In our study, 48% of patients were receiving metformin monotherapy along with lifestyle change; this is somewhat similar to other studies that found that 69.42%–78.61% of patients were receiving metformin alone [21]. Compared to previous research, fewer study participants were receiving metformin monotherapy. We may have included patients who had been using anti-diabetic medication for longer than six months in our inclusion criteria, which may have contributed to the majority of them receiving combination therapy to reach their ideal glycaemic level [22]. In contrast to the prescription pattern found in other studies, where 53.3% of patients were on metformin + glimepiride and 22.4.02% of patients were on metformin + DPP4I, according to our analysis, DPP4I + metformin was the most often given dual medication therapy, with 28% of patients receiving this prescription. Metformin + glimepiride was the second most popular oral anti-diabetic combination, prescribed to 15% of patients. Both prescription trends are similar to those from a different study [23], in which metformin with DPP4I was the most often prescribed dual combination medication. Our analysis revealed that the most often prescribed triple combination was metformin + DPP4I + pioglitazone (10% of patients, 6.17% prescription rate), in contrast to a study where the triple combination was typically given as metformin + DPP4I + sulfonylureas [23]. 12 patients (12%) in our study were on insulin therapy; this was in line with the prescription pattern in other studies where 42.9% of patients were on long-acting insulin since it can lower blood sugar levels [24].

Adherence to ADA guidelines (2021):
In our study, 17% of patients on DPP4I + metformin had HbA1c of 6.5–8, and if no other risk factors are present, it is a second line medication for combination therapy to prevent hypoglycaemic shock, according to ADA guidelines.
Our study's findings indicate that DPP4I was the second most frequently prescribed

combination, which is similar to the prescription pattern of a different study where metformin + DPP4I was the most often given dual combination therapy [97]. Strict adherence to ADA treatment standards was not feasible in our study because the prescriber's biggest barrier was cost. When HbA1c is > 10%, insulin therapy should be taken into consideration, as per ADA guidelines. If HbA1c is < 10%, it may indicate a catabolic condition. In our analysis, we compared the patient's HbA1c number with all underlying circumstances and found that 81% of prescriptions met the ADA criteria, while only 19% did not. Previous research indicates that 78% to 83.6% of patients adhere to ADA treatment guidelines [24–26].

Conclusion

In conclusion, this study reaffirms metformin's central role in Type 2 Diabetes Mellitus (T2DM) treatment, with a high prescription rate. However, the increasing use of combination therapy underscores the progressive nature of the disease, necessitating multifaceted treatment approaches. Notably, newer classes of medications like SGLT-2 inhibitors and GLP-1 receptor agonists are gaining popularity due to their efficacy and cardiovascular benefits. Conversely, insulin therapy remains underutilized, potentially compromising optimal glucose control. Regional variations in prescription patterns emphasize the need for personalized treatment strategies. Moreover, adherence to treatment plans poses a significant challenge, with many patients struggling to maintain optimal glycemic control. These findings highlight opportunities for improvement in T2DM management, emphasizing the need for tailored treatment approaches, enhanced patient engagement, and ongoing research to optimize care.

Future Perspective

The future of prescription patterns and adherence in T2DM management holds promise for improvement through personalized medicine approaches, increased adoption of newer medication classes, and enhanced use of digital health technologies. Innovative insulin formulations and delivery systems may address underutilization, while precision medicine initiatives and multidisciplinary care teams can provide comprehensive support. Continuous monitoring of real-world evidence will inform treatment guidelines, and addressing regional disparities through education and policy initiatives can ensure equitable care. Furthermore, integrating artificial intelligence and machine learning algorithms can predict patient responses and optimize treatment plans. Ultimately, prioritizing patient-centered care through shared decision-making and individualized goal setting will enhance adherence and quality of life for individuals living with T2DM.

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