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PRESCRIPTION AUDIT AND PRESCRIBING PATTERNS OF ANTIDIABETIC DRUGS OF THE OUT-PATIENT DEPARTMENT OF MEDICINE IN A TERTIARY CARE TEACHING HOSPITAL IN SOUTH DELHI, INDIA.

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Abstract

Objective: Diabetes has gradually emerged as one of the most serious public health problems in our country. This underlines the need for timely disease detection and decisive therapeutic intervention. This prospective cross-sectional observational study aims to analyze the utilization pattern of antidiabetic agents in a North Indian tertiary care teaching hospital From the perspective of current standard treatment guidelines.

Materials and Methods: Diabetic patients receiving antidiabetic medication, both as outpatients and inpatients in our hospital over a period of 12 months (May 2021–May 2022), were included in this study. The data obtained was sorted and analyzed based on gender, type of therapy, and the hospital setting.

Results: A total of 310 patients were included in the present study. Metformin was the single most frequently prescribed antidiabetic agent (39.8%) followed by the Dipeptidyl peptidase-4 (DPP-4) inhibitors in 21.92% patients. Insulin was prescribed in 7.6% of the patients. The combination antidiabetic drug therapy (85.15%) was used much more frequently than the antidiabetic monotherapy (14.85%). The use of DPP-4 inhibitors and sulfonylureas in combination was significant as compared to their use as monotherapy. A total of 24.6% (n = 93) of all antidiabetic fixed drug combinations (FDCs), comprised DPP-4 inhibitors and metformin. The utilization of drugs from the National List of Essential Medicines (NLEM) was 56%. Only 5.16% of the total antidiabetic medications were prescribed by their generic names.

Conclusion: The pattern of utilization largely conforms to the current standard treatment guidelines. Increased use of generic drugs is an area with scope for improvement.

Introduction

Diabetes mellitus is a chronic metabolic disease characterized by elevated levels of blood glucose which may have consequences in various macro-vascular and micro-vascular systems, involving the heart, blood vessels, eyes, kidneys, and nerves besides other organ systems. At present an estimated

537 million people are suffering from diabetes worldwide of whom 101 million people are estimated to reside in India alone [1].

The overall prevalence of diabetes is expected to exceed about 800 million people by 2045. The global diabetes prevalence was estimated to be 10.5% in 2021 which is expected to rise to 10.2% by 2030 and 10.9% by 2045. An estimated 1 in every 11 adults worldwide is suffering from diabetes mellitus, 90% of whom have type 2 diabetes mellitus (T2DM) [2].

As per some surveys, 1 in every 12 people in India is affected by diabetes & an overall prevalence was estimated to be over 72 million cases which is more than entire UK population [3].

These data estimates highlight the burden that diabetes poses globally as well as on the country. Glycemic control by using rational & safe use of antidiabetic drugs remains the most key objective in preventing long term complications of diabetes [4].

Although the antidiabetic agents used in practice are safe and effective, junk food based lifestyle, poor patient compliance to therapy and Insulin resistance lead to poor glycemic control. The drug utilization studies or prescription pattern studies provide an insight into the rational drug consumption patterns which is important for improved glycemic control in diabetes management.

Hence, the present study was designed to assess the prescription pattern of standard antidiabetic drugs in a diabetic OPD of a tertiary care teaching Hospital in South Delhi.

AIM

To identify the prescription patterns in patients of T2DM with respect to the duration of the disease in the Department of Medicine in a tertiary care teaching hospital in South Delhi, Delhi, India.

Objectives

- 1. To evaluate the completeness and appropriateness of patients' and prescribers' information.
- 2. To analyze the drug-related information in prescriptions.
- 3. To evaluate World Health Organization (WHO) core prescribing indicators for each prescription [5].

Materials and methods

This study titled "Prescription audit and prescribing patterns of antidiabetic drugs of the out-patient Department of Medicine at a tertiary care teaching hospital in South Delhi" was carried out under the Department of Pharmacology in association with the Department of Medicine, Hamdard Institute of Medical Sciences and Research (HIMSR) and associated Hakim Abdul Hamid Centenary Hospital (HAHCH) in South Delhi, Delhi, India after receiving approval from the institutional ethics committee.

Using the formula, n= Z2*P*(1-P)/d2, sample size was calculated to be 310 at 95% confidence level And a prevalence of 28.3%. Convenience sampling was used As the sampling technique. The study data was collected over a period of 12 months i.e. May 2021- May 2022.

After obtaining due permission from concerned authority of the hospital, dated 19/03/2021, IEC number HIMSR/IEC/018/2021 the prescriptions from the Department of Medicine were accessed by logging in to the hospital information software (HIS) and the relevant information like demographic details, diagnosis, drug information and the completeness of the prescription were collected on a preset prescription audit form and were entered in the Excel sheets manually on a regular basis.

The collected data was screened, analyzed and evaluated for appropriateness and rationality using the WHO core prescription indicators.

Study design

Type of study: - Prospective observational cross-sectional study.

Sample size: - A total of 310 printed diabetes prescriptions were randomly sampled and analyzed using the HIS system, irrespective of the patient characteristics, diagnosis and treatment.

Manual ingress of the appropriate data in the MS excel spreadsheets was done on a daily basis.

The prescription pattern was used to collect information on the following:

- 1. Patients' and prescriber's information
- 2. Drug related information
- 3. WHO core prescribing indicators

Descriptive parameters were then used to combine the results for statistical analysis.

Data analysis was performed using MS-office excel software continuous variables were reported as means \pm standard deviation. Categorical variables were reported as proportions (%).

The following WHO core drug use indicators were used to analyze the obtained data [5]:

- (i) Percentage of antidiabetic drugs prescribed by generic name was calculated to measure the tendency of prescribing drugs by their nonproprietary name. It was calculated by dividing the total number of antidiabetic drugs prescribed by generic name by total number of antidiabetic drugs prescribed, multiplied by 100.
- (ii) Average number of antidiabetic drugs per prescription was calculated by dividing the number of antidiabetic drugs prescribed divided by total number of patients.
- (iii) Percentage of drugs prescribed from the NLEM was calculated to measure the degree to which practices conform to a national drug policy. Percentage was calculated by dividing number of products prescribed which were in essential drug list by the total number of drugs prescribed, multiplied by 100.
- (iv) Percentage of antidiabetic FDC prescribed = total number of antidiabetic FDC / Total antidiabetic drugs *100

Results

A total of 310 printed diabetes prescriptions from the OPD of the Department of Medicine of a teaching tertiary care hospital in New Delhi, India were randomly collected and evaluated irrespective of their diabetic status, age, religion, and other comorbid conditions. The standard prescription template was in a print format with the name of the hospital, complete name of the patient, prescriber's details, OPD registration number and the date of consultation. Common errors of omission in the prescriptions included the precautionary instructions to the patients regarding the treatment, details about subsequent follow-up visits, weight of the patient (pediatric age group) and the allergic history of the patient. The findings of our study from patient and prescriber data are listed in **Table 1**.

Out of the total sample 55 patients (17.74%) had a history of smoking, 84 (27.09%) patients had a history of alcohol consumption. Family history of chronic illnesses was present in 105 (33.87%) patients. Out of the total number of patients, 91 (29.30%) patients had a history of hypertension. Other parameters including the mean age of the patient, mean BMI, history of coexisting illnesses, patients' characteristics and other clinical parameters are listed in **Table 2**.

Prescription Analysis

The drug data findings are depicted in accordance with the WHO core prescribing indicators. In the present study the total number of drugs prescribed were 1880, The average number of medications per prescription was 6.06 ± 1.5 and the average number of antidiabetic agents per prescription was 2.27. [Table 2]

A total of 310 printed prescriptions were analyzed and a total of 705 antidiabetic agents were prescribed. The average number of antidiabetic agents per prescription was found to be 2.27. [**Table 2**]

As per the drug-utilization indicators, drug monotherapy was prescribed in only 46 (14.85%) prescriptions; remaining 264 patients (85.15%) received antidiabetic drugs as a part of combination therapy. Dual antidiabetic therapy was prescribed in 102 i.e. 32.90% patients whereas, 162 (52.25%) patients received three or more drugs at a time, suggesting inadequate control of blood glucose levels on monotherapy. A total of 7.6% of the patients were on insulin therapy suggesting inadequate control of blood sugar levels on oral antidiabetic agents.

All the prescriptions were in the printed format. Among all the antidiabetic drugs prescribed less than 6% of the total antidiabetic drugs were prescribed by their generic names. Presumptive / definitive diagnosis was missing in 53 i.e. 17.09 % prescriptions. About 42% and 23% of the prescriptions, lacked the total duration of the treatment prescribed and the complete drug schedule respectively. About 31% of all the prescriptions included some form of a multi-vitamin and/ or a multi-mineral supplement. Over 60% of the prescribed medications were available at the hospital dispensary. Findings are mentioned in **Figure 1**.

About 56 % of all the prescribed drugs were prescribed from the NLEM. Around 53.7% of the antidiabetic drugs were used as FDCs in our study. A comparison of WHO core prescribing indicators in our study vs. the WHO standards have been depicted in **Table 3.**

All the participants were divided into three different groups according to their duration of diabetes and the drugs prescribed in each group were analyzed. Metformin belonging to a class of antidiabetic drugs known as biguanides was the most prescribed antidiabetic drug in all the sub-groups of patients irrespective of the duration of T2DM.

Metformin either alone or in combination as FDCs was the most frequently prescribed drug to 265 patients (37.5%) followed by DPP-4 inhibitors to 125 (21.92%), sulfonylureas to 89 patients (15.6%) and sodium-glucose transport protein 2 (SGLT-2) inhibitors to 81 (14.2%). The DPP-4 inhibitors were the most prescribed antidiabetic agents in the sub-group of patients with more than 10 years history of T2DM. The usage of insulin as an adjuvant agent or single therapy has been seen to be increasing with about 7.6% of the diabetic patients requiring insulin for diabetes management especially in the sub-group of patients with more than 10+ years of duration of the disorder. The prescription pattern of various antidiabetic drug classes with the duration of T2DM has been summarized in **Table 4.**

In the present study an average of 6.06 ± 1.5 drugs were prescribed per patient suggesting an overall increase in drug usage besides those used in the management of diabetes, indicating an increase trend towards polypharmacy. The prescription of multiple drugs needs to be checked as it increases the chances of drug-drug and drug-food interactions. The various multi-vitamin and/ or multi-mineral drugs comprised the highest fraction of commonly coprescribed drugs, constituting 30.90% of all the coadministered drugs. The various groups of antibiotics constituted 6.8% of all the drugs prescribed. The percentage prescription of other coprescibed drugs is depicted in the **Table 5.**

The percentage of population prescribed antidiabetic drug mono-therapy, dual-therapy and triple therapy has been depicted in **Figure 2.**

The most common antidiabetic drugs used as single entity are shown in **Table 6.**

A total of 379 antidiabetic FDCs were prescribed to the patients. Among the several antidiabetic FDCs, the combination of DPP-4 inhibitors with metformin was the most commonly prescribed fixed drug combination in 93 i.e. 24.6% of the patients followed by FDCs of metformin, DPP-4 inhibitors and SGLT-2 inhibitors which was prescribed to 86 i.e. 22.7 % of the patients. **Figure 3.**

Table 1: Patients' and Prescriber's information

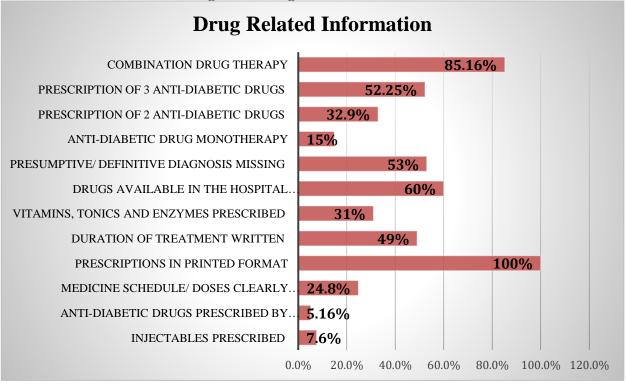
S. No.	Parameter	Percentage
1	OPD registration number mentioned	100%
2	Complete name of patient is written	100%
3	Age in years mentioned (months if <5 years)	89%
4	Weight in kg (only patients of pediatric age group)	16%
5	Gender of patient	100%
6	Date of consultation (day/month/year)	100%
7	Brief history written	72%
8	Salient features of clinical examination recorded	70%
9	Allergy status mentioned	<1%
10	Presumptive/definitive diagnosis written	47%
11	Investigations advised	57%
12	Follow up advice and precautions are recorded	42%

13	In case of referral, the relevant clinical details and reason for referral given	55%
14	Date of next visit written	41%
15	Prescriber's name	100%
16	Prescription duly signed	100%

Table 2: - Patients' Characteristics and clinical parameters

S.No.	Parameters	Value
1.	Average age of the patients (Mean \pm SD)	48.9 ±11.33
2.	Percentage of patient > 50 yrs. (Percentage)	35.7
3.	BMI (Mean \pm SD)	27.88 ± 1.58
4.	History of smoking (Percentage)	17.74
5.	History of alcohol consumption (Percentage)	27.09
6.	Family history of chronic illnesses (Percentage)	33.87
7.	History of hypertension (Percentage)	29.30
8.	History of dyslipidemia (Percentage)	22.58
9.	History of hypothyroidism (Percentage)	3.2
10.	Systolic blood pressure (Mean \pm SD)	141.47±31.65
11.	Diastolic blood pressure (Mean \pm SD)	87.73±15.88
12.	$HbA1c (Mean \pm SD)$	8.46±1.8
13.	Fasting blood glucose (Mean \pm SD)	156.64±57.76
14.	Post prandial blood glucose (Mean \pm SD)	251.29±90.09
15.	Average number of drugs / prescription	6.06 ± 1.5
16.	Total number of antidiabetic drugs prescribed	705
17.	Average number of antidiabetic medications/ Prescription	2.27

Figure 1: Drug related information



Anti-diabetic drugs prescribed by generic name 5.16%

Table 3: WHO Core prescribing Indicators

S. No.	Parameter	Our Study	WHO Standard
1.	Average number of drugs per prescription	6.06 ± 1.5	
2.	Percentage of antidiabetic drugs prescribed by generic name	5.16%	100 %
3.	Percentage of encounters with an injection preparation prescribed	7.6%	13.4 – 24.1 %
4.	Percentage of drugs prescribed from NLEM/ essential drug list	56%	100 %
5.	Percentage of Antidiabetic drugs used as FDC	53.7%	

Table 4: Prescription pattern of antidiabetic drug classes over duration of diabetes

Duration of diabetes (Number of patients)	0-5 years (155)	5-10 years (82)	>10 years (73)
Biguanides	117 (59.6%)	76 (31.6%)	66 (26.7%)
DPP-4 inhibitors	45 (22.9%)	54 (22.5%)	60 (25.2%)
SGLT-2 inhibitors	39 (14.4%)	48 (20)	18 (11.7%)
Sulphonylureas	28 (14.2%)	40 (16.6)	16 (7.4%)
Insulin	3 (1.5%)	7 (2.9%)	39 (16.3%)
Pioglitazone	5 (2.5%)	12 (5%)	8
Meglitinides	0	0	2
Alpha-glucosidase inhibitors	1	2	14
GLP-1 Receptor antagonists	2	1	2
Total	240	240	225

Table 5: Therapeutic category of common co-prescribed drug

Therapeutic classification of Drugs	Number	Percentage (%)
Vitamins, minerals, and dietary supplements	405	30.90%
Drugs modifying GIT functions	276	21.06%
Analgesics and anti-inflammatory drugs	184	14.04%
CVS Drugs	143	10.90%
Antibiotics	90	6.8%
CNS Drugs	72	5.3%
Drugs used in dyslipidemia	70	5.4%
Antihistamine drugs	50	3.8%
Drugs acting on respiratory system	10	<1%
Antithyroid drugs	10	<1%

Percentage of Patients

15%

52%

33%

Mono-therapy

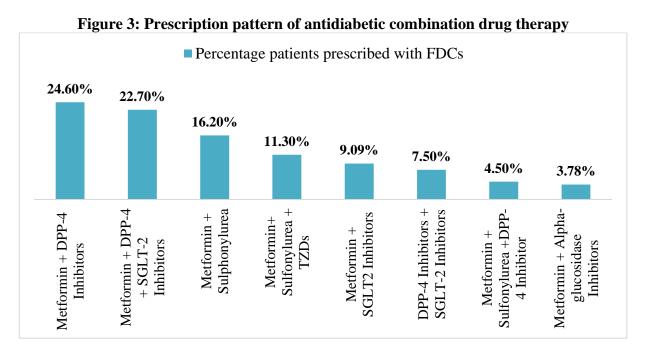
Dual-therapy

Triple-therapy

Figure 2: Percentage distribution antidiabetic drug/s combination therapy

Table 6: Prescription pattern of antidiabetic mono therapy

Drugs	No. of Patients (n=46)	Percentage (%)
Metformin	25	9.4%
Dapagliflozin	17	6.4%
Glimepiride	4	1.5%



Discussion

Diabetes mellitus is a chronic disorder of inadequate control of blood sugar levels. As per the WHO it is the 8th leading cause of mortality worldwide. The incidence and prevalence of T2DM are continuously increasing in developed as well as the developing countries. The mainstay of the management of diabetes requires strict lifestyle modifications including caloric restrictions, regular

exercise, and usually lifelong medications. In the early stages of the disease the glycemic control can be achieved by lifestyle modifications but as the disease progresses the use of the antidiabetic medications becomes unavoidable.

Poor patient adherence to the antidiabetic therapy & clinical inertia leads to uncontrolled glycemic control.

The present study was conducted to analyze the prescription patterns in T2DM patients who visited the OPD of the Department of Medicine in a tertiary care teaching hospital in South Delhi, Delhi, India.

This cross-sectional study involved analysis of 310 printed prescriptions of patients with T2DM accessed through the Hospital information system. The male to female patient ratio in our study was found to be 1.4:1 i.e. the occurrence of T2DM was slightly more in males compared to females. The study found a higher incidence of diabetes among the elderly.

Biguanides i.e., metformin are used as the drug of first choice among all the oral antidiabetic drugs at the onset of diabetes, as per existing guidelines. In a study done by Sharma et al, the changing trends in the usage of metformin as the first agent from 55% in 2003 to 83.6% in 2013 in the United Kingdom were observed [6].

In the present study, the use of metformin either as monotherapy or as FDC constituted about 37.5% of all the antidiabetic drugs may be because of its established safety profile in the patients of cardiovascular risks, reduction in the progression of chronic kidney disease and promotion of weight loss when combined with exercise. In a recent study, similar results with respect to the use of metformin were observed where over 50% of the patients received metformin therapy either alone or as a part of combination therapy [7].

The prescription patterns in the patients of diabetes mellitus on metformin in our study was observed to remain almost steady over the duration of diabetes, from 0 to 10+ years of antidiabetic drug treatment.

In the present study, the FDC of metformin & DPP-4 inhibitors constituted 24.6% of the FDCs prescribed in the patients with diabetes and was the most commonly prescribed FDC. In a similar study done in the patients of T2DM the FDC of metformin and DPP-4 inhibitors was the second most common FDC prescribed in 22.4 % of the patients with diabetes [8].

In a cross-sectional study DPP4-inhibitors were used only in 2.63% of diabetic patients whereas, the sulfonylureas were the most common prescribed drugs overall, which is in contrast with our study where DPP-4 inhibitors were used in 22.5% patients either alone or in combination therapy [8].

The prescription of the FDC of metformin & a DPP-4 inhibitor was followed by the dual drug FDC of metformin and sulphonylureas in 16.2 % of the diabetic patients. In a recent study done on the prescribing patterns in the OPD Medicine the metformin and sulphonylurea combination was prescribed in 11.40% of the patients which is almost like the pattern observed in our study [9].

In the present study, the most common triple drug FDC used in the management of T2DM was of metformin, DPP-4 inhibitors and SGLT-2 inhibitors which constituted 22.70% of the total number of FDCs prescribed. The prescription pattern to the use of this triple drug FDC contrasted with the triple drug FDC used in the past in a previous studies where the combination of metformin, DPP-4 inhibitors and sulphonylureas was the most used FDC may be because of an established safety and evidence of adequate control of hyperglycemia [10].

The percentage prescription of sulfonylurea decreased from 15.6% in 0-10 years of duration of diabetes to 7.4% in the patients with +10 years of diabetes. Whereas, the percentage prescription of DPP-4 inhibitors increased from 22.7% in 0-10 years of duration of diabetes to 25.2% in the patients with +10 years duration of diabetes.

In the current practice and in the given set of patients, thiazolidinediones (TZDs), alpha-glucosidase inhibitors (AGIs) and glucagon-like peptide-1 (GLP-1) receptor agonists given in 3.5%, 1.98% and 0.7% respectively. In our study these agents share a negligible percentage of the drugs used in the

management of T2DM [Figure 2]. The prescribing patterns of these agents are similar to the prescribing patterns observed in a recent study [9].

Insulin requirement used was required in 2.2% of the diabetics with 0-10 year history of the disorder and in 16.2% of patients with more than 10 years history of diabetes suggesting comparatively lower usage than in previous similar studies, and the possibly due to availability and preference of a much wide spectrum of better and safer oral antidiabetic agents. In a recent similar study the prescription patterns of insulin were seen in contrast to our study, where about 44% of the total number of patients were on insulin therapy. Whereas, in another similar study, about 10% of the diabetic patients were on insulin therapy, which corresponds to the pattern of drug use observed in our study [11].

This pattern of drug use in our study suggests that the DPP4-inhibitors and the SGLT-2 inhibitors were the most common antidiabetic medications used as add on drugs to metformin in our study.

The SGLT-2 inhibitors have established themselves as effective agents in reducing the blood glucose levels, preventing the progression of end stage kidney disease and heart failure. In the present study, the SGLT-2 inhibitors were used in 15.6% the diabetic patients, highlighting a paradigm shift in the prescribing patterns of the SGLT-2 inhibitors as a single preferred agent or as a part of the combination with the other antidiabetic agents [12].

As the duration of diabetes increases, variation in prescriptions also increases, presumably due to consideration of individual factors and increasing resistance to the conventional first line antidiabetic agents.

Analysis of various antidiabetic drug classes in association with the duration of diabetes as shown in table 4, reveals a decline in the usage of metformin, sulphonylureas and SGLT-2 inhibitors in patients with more than 10 years duration of diabetes whereas, the usage of insulin individually or as an add on medication to the oral antidiabetic medications has increased in patients with more than 10 years duration of diabetes.

Several forms of insulin preparations were prescribed in our study in 7.6% of the patients, which contrasted with 27.6% usage of insulin preparations in a study done by Tiwari et.al. Insulin preparations are used if the Hba1c, fasting and post prandial blood glucose levels do not respond well to the oral antidiabetic drugs and hence insulin helps in decreasing the insulin resistance effectively, which may lead to a better glycemic control [11].

The average Body mass index (BMI) in the present study was 27.88 ± 1.58 in patients diabetes mellitus. An increase in the BMI is associated with a decrease in the tendency to prescribe insulin, sulfonylureas and thiazolidinediones which themselves are associated with weight gain. In the present study, there is an increase in the use of SGLT2 inhibitors in 15.6% patients, which besides acting as an antihyperglycemic medication can cause weight loss and has shown to prevent the progression of kidney and heart failure. Similar findings were seen reported in another study [13].

India has a huge population living with T2DM with earlier onset of disease. It is a well-established fact that Indians experience a 10 years earlier onset of this lifestyle disorders; even more disturbing is the emerging fact from recent studies which postulates, new onset diabetes in the 30–35 years age group of urban indian population. A recent study from Delhi estimated that 27% of urban Indian population already has diabetes and another 46% are suffering from pre-diabetes. With 10%–15% of conversion rate per annum from prediabetes to diabetes, there would be an ever increasing proportion of population suffering from this chronic problem [8].

Diabetes is a chronic disorder for which a cure is still being sought. Diabetes is a chronic disorder which affects the person for a lifetime. The present available treatment modalities aim at modulating the blood glucose levels and decreasing the disease progression. At present, the disordar are appearing in the early decades of life, diabetes management for almost a lifetime poses a huge financial, social and emotional burden on the individuals.

The existing literature shows the prescription patterns in primary and tertiary health care units, but there is a scarcity of literature on the prescription pattern of antidiabetic drugs in relation to the duration of diabetes. In the present study we have tried and highlighted the pattern of antidiabetic

drug/s usage and the altering patterns of antidiabetic medications use according to the duration of diabetes.

Conclusion

This study provides a valuable insight into temporal prescription patterns of antidiabetic drugs from a medicine practice point of view. Metformin remains the most preferred drug across all the age groups of people suffering from diabetes. The DPP-4 inhibitors seems to be fast catching up with sulfonylureas as the second-line preferred treatment after metformin. The SGLT2 inhibitors are still being used as third- or fourth-line drugs. After 20 years or more of diabetes duration, about 50% of the people experience an increased need of insulin for glycemic control. With earlier onset of diabetes and increasing life expectancy, the cost of diabetes is likely to escalate, and hence the focus in diabetes management should be laid at improving the lifestyle, controlling the blood glucose levels with a minimum number of medications, focusing on montherapy and prescription of generic medications wherever convenient.

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