Original Article

Drug Prescription Patterns and Cost Analysis of Diabetes Therapy in India: Audit of an Endocrine Practice

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Abstract

Drug therapy in diabetes care along the duration of diabetes has been documented scarcely in literature, especially from Indian subcontinent. An audit of an endocrine practice from New Delhi was conducted to understand the current diabetes practice and its direct cost to the patient. **Aims:** The aim of this study was to analyze the current trend in the use of antidiabetes as well as other drugs for comorbidities along the duration of diabetes. The study also aimed to analyze the direct drug cost to patients. **Settings and Design:** Retrospective cross-sectional study. **Subjects and Methods:** Data captured in clinic electronic medical records of an endocrine practice was analyzed. **Statistical Analysis Used:** Data was analyzed descriptively using machine learning codes on python platform. **Results:** Records of 489 people who attended the clinic during the 6-month period were retrieved. Data of 403 people with diabetes were analyzed after exclusion of incomplete data. Use of antidiabetic drug increased from 1.44 (0.78) [mean (standard deviation)] in people with a duration of diabetes <5 years to 3.18 (1.05) in people with 20+ years of diabetes. The mean number of antidiabetic drug usage seems to plateau at 15 years of diabetes. About 46% of people with 20+ years of diabetes required insulin therapy. Prescription patterns involving a combination of different drug classes in patients were also analyzed. The cost of diabetes therapy increases linearly along the duration of diabetes. **Conclusion:** This study provides valuable insights on temporal prescription patterns of antidiabetic drugs from an endocrine practice. Metformin remains the most preferred drug across the entire duration of diabetes. Dipeptidyl peptidase-4 inhibitors seem to be fast catching up with sulfonylureas as a second-line treatment after metformin. After 20 years or more of diabetes duration, 46% people would require insulin for glycemic control.

Keywords: Cost analysis, diabetes mellitus type 2, diabetes therapy, drug prescription patterns, India, practice audit

Introduction

India is a complex country with its own unique sets of problems. Diabetes is one of these problems and is catching us unaware in huge proportions and at unexpected times (at much earlier age than worldwide).[1,2] The solution to these problems should be molded according to Indian conditions. An audit of current practices would help us in defining and subsequently tackling these problems more effectively. This study looks at prescription pattern of use of antidiabetic drugs in relation to the duration of diabetes. We also provide insights into health economics involved with the given prescription pattern.

Methodology

Electronic medical record data of patients attending clinic were extracted from the software "Healthvriksh EMR, version 1 (Kalpavriksh Healthcare, Delhi, India)." A total of 489 records were extracted for patients having complete documentation of their demographic profiles who attended the clinic during the 6-month period between February 2018 and July 2018. Out of these 489 records, 86 records with incomplete data were excluded. Complete records were assessed for the duration of diabetes, age, sex, body mass index (BMI), and medicines prescribed. The duration of diabetes was categorized as 5-year interval. The overall therapy was divided into six major classes, namely, antidiabetic therapy, antihypertensives, lipid-lowering medications, anticoagulants, vitamins, and others. Others included thyroxine, testosterone, antithyroid medications, laxatives, antacids, and so on. None

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of the prescribed medications including vitamins and thyroid medications (though their cost cannot be attributed to diabetes care directly) was excluded from final analysis as to analyze a real-world cost in selected population. For each 5-year interval, descriptive analysis was done to ascertain class of medication prescribed as well as total monthly cost that can be attributed to drug cost.

Statistical analysis was done using Python 3.7.0 and Jupyter 5.5.0 platforms with the help of various open source tools and libraries including Pandas, NumPy, collections.Counter, matplotlib, sklearn.cross_validation, sklearn.preprocessing, PolynomialFeatures, and sklearn.linear_mode. Descriptive analysis and graph preparation were done using Google analysis tools.

Results

Data extracted from our EMR allowed us to formulate a likely progression of a person with diabetes vis-a-vis medical therapy. Demographic characters of population studied are shown in Table 1. People attending practice are largely from middle to upper income groups. Detailed demographics and glycemic control status of wider population (that includes the current subset of population) attending the practice have been discussed previously.[2]

All the participants were divided into five different groups according to their duration of diabetes, and drugs prescribed in each group were analyzed. The mean number of antidiabetic drugs and total drugs prescribed to this population, segregated according to their duration of diabetes, is outlined in Figure 1.

Based on the above data for antidiabetic drugs, there would be addition of an antidiabetic every 4–5 years, and the drug count for antidiabetic drugs seems to stabilize after 15 years of duration of diabetes and three antidiabetic drugs. This plateauing effect is most likely due to the addition of insulin at that stage of diabetes (and insulin as a medicine has been counted as one only irrespective of its use as basal, premix, or multiple subcutaneous insulin injections). On the other hand, requirement of nondiabetic drugs keeps on increasing implying increased need of medications for developing comorbidities.

Trends for prescription of individual medication class across the duration of diabetes were analyzed and are displayed in Figure 2. Insulin usage is seen to be increasing as the duration of diabetes decreases. At 20+ years of duration of diabetes, 46% of people would be requiring insulin for management of their diabetes [Figure 2].

Metformin is the maximally used drug across all groups of duration of diabetes. There was no demographic difference between people with or without metformin prescription. Sulfonylureas are the second most common prescribed drug class. The most common antidiabetic classes used considering a patient as single entity along the duration of diabetes are shown in Table 2.

The overall therapy was divided into six major classes, namely, antidiabetic therapy, antihypertensives, lipid-lowering medications, anticoagulants, vitamins, and others. Others included thyroxine, testosterone, antithyroid medications, laxatives, antacids, and so on. Distribution of these classes over the duration of diabetes is shown in Figure 3. Antidiabetes' drug use was further analyzed across BMI and age groups and is depicted in Figures 4 and 5, respectively.

Furthermore, from actual prescription data, drug cost was calculated for both antidiabetic therapy and the overall therapy prescribed. The cost of all the drugs, including multivitamins and drugs for other comorbidities such as hypothyroidism, was considered to have a real-world economic pattern. Price was fetched for each prescribed drug from various online pharmacies and cost of diabetes therapy calculated, as displayed in Table 3.

The lifetime cost of diabetes care was then explored by calculating direct drug cost from these data and assuming that direct drug cost would plateau after 20 years of diabetes. For the purpose of calculation of lifetime cost, the onset of diabetes was considered at 30 years and life expectancy has been assumed to be 80 years.[2] The lifetime cost for all drugs using mean is estimated to be approximately Indian National Rupee (INR) 1,945,135, while the estimated lifetime cost for all drugs using median is approximately INR 1,592,234. For antidiabetic drugs alone, lifetime cost using the mean comes out to be approximately INR 1,518,540 and the same using the median gives an estimate of INR 1,131,297.

Table 1: Demography of population in subgroups according to duration of diabetes

	Mean age (years) (SD)	BMI (kg/m²) (SD)	Women population (%)
Overall	52.27 (11.78)	27.90 (4.72)	173 (42.92)
<5 years	46.69 (11.04)	27.87 (4.93)	64 (40)
5-10 years	51.05 (10.90)	28.18 (3.86)	41 (40.20)
10-15 years	56.62 (8.43)	28.22 (5.01)	35 (54.68)
15-20 years	58.08 (9.41)	27.78 (5.86)	17 (44.73)
20+ years	65.49 (7.02)	26.80 (3.94)	16 (41.02)

SD: Standard deviation; BMI: Body mass index

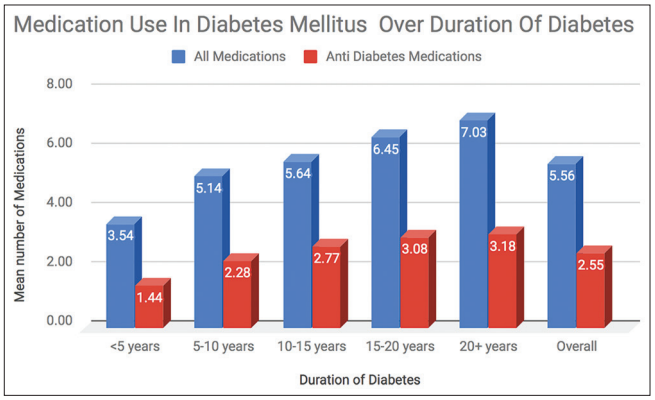
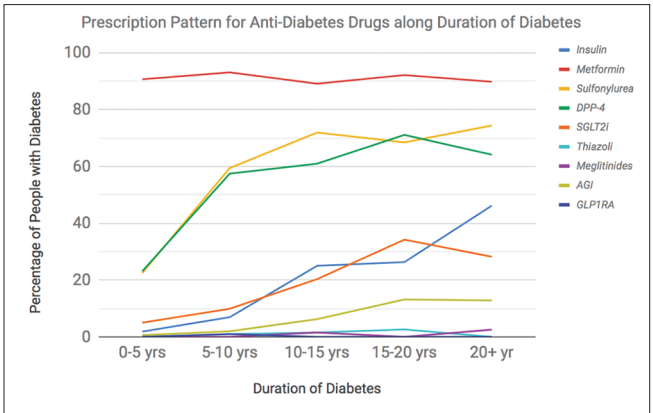


Figure 1: Medication use in people, segregated according to their duration of diabetes, with diabetes mellitus



Duration of Diabetes	0-5 years	5-10 years	10-15 years	15-20 years	20+ years	Total
Number of Patients (%)	160 (39.70)	102 (25.31)	64 (15.88)	38 (9.43)	39 (9.67)	403 (100)
Insulin	3 (1.87)	7 (6.86)	16 (25.00)	10 (26.31)	18 (46.15)	54 (13.39)
Metformin	145 (90.63)	94(92.16)	57 (89.06)	35 (92.10)	35 (89.74)	366 (90.82)
Sulfonylurea	36 (22.5)	60 (58.82)	46 (71.87)	26 (68.42)	29 (74.36)	197 (48.88)
DPP-4i	37 (23.13)	58 (56.86)	39 (60.94)	27 (71.05)	25 (64.10)	186 (46.15)
SGLT2i	8 (5.00)	10 (9.80)	13 (20.31)	13 (34.21)	11(28.20)	55 (13.65)
Pioglitazone	0 (0)	1 (0.98)	1 (1.56)	1 (2.63)	0 (0)	3 (0.74)
Meglitinides	0 (0)	0 (0)	1(1.56)	0 (0)	1 (2.56)	2 (0.50)
AGI	1 (0.63)	2 (1.96)	4 (6.25)	5 (13.16)	5 (12.82)	17 (4.22)
GLP1RA	0 (0)	1 (0.98)	0 (0)	0 (0)	0 (0)	1 (0.25)

Figure 2: Prescription pattern of antidiabetes drug classes over duration of diabetes

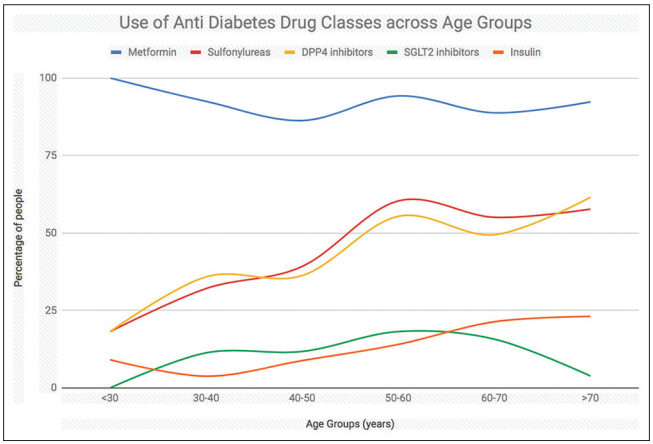
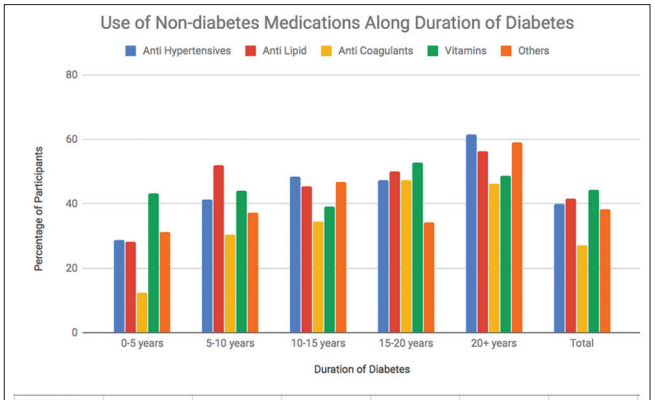


Figure 4: Pattern of use of individual antidiabetes drugs correlated with age groups

Table 2: Prescription pattern considering a patient as single entity along duration of diabetes

Duration of diabetes	Most common prescription patterns
<5 years	M (51.25%), M + D (11.87%), M + S (10.63%)
5-10 years	M + D + SU (36.27%), M (15.69%), M + D (13.72%)
10-15 years	M + D + SU (31.25%), M + D + SU + SG (9.37%), M + SU + I (9.37%)
15-20 years	M + D + SU + SG (21.05%), M + D + SU (15.79%), M + D + SU + I (10.53%)
>20 years	M + D + SU (20.51%), M + I + SU + SG (7.69%), M + I (7.69%)

M: Metformin; D: DPP4 inhibitors; SU: Sulfonylureas; I: Insulin; SG: SGLT2 inhibitors



Duration of Diabetes	0-5 years	5-10 years	10-15 years	15-20 years	20+ years	Total
Number of Patients	160	102	64	38	39	403
Anti Hypertensives	46 (28.75)	42 (41.18)	31 (48.44)	18 (47.37)	24 (61.54)	16 (39.95)
Anti Lipid	45 (28.13)	53 (51.96)	29 (45.31)	19 (50)	22 (56.41)	168 (41.69)
Anti Coagulants	20 (12.50)	31 (30.39)	22 (34.38)	18 (47.37)	18 (46.15)	109 (27.05)
Vitamins	69 (43.13)	45 (44.11)	25 (39.06)	20 (52.63)	19 (48.72)	178 (44.17)
Others	50 (31.25)	38 (37.25)	30 (46.88)	13 (34.21)	23 (58.97)	154 (38.21)

Figure 3: Use of nondiabetes medications along duration of diabetes

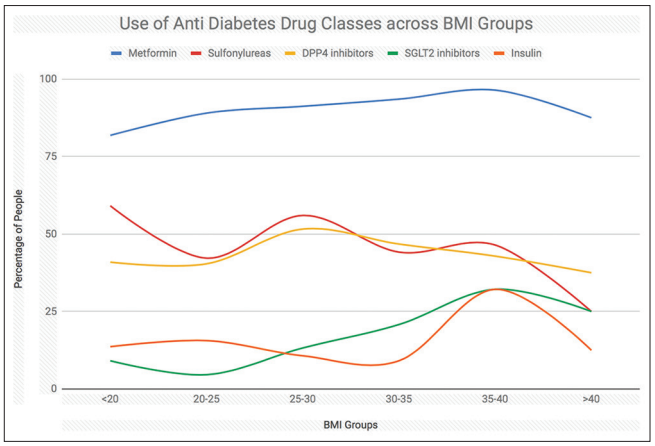


Figure 5: Pattern of use of individual antidiabetes drugs correlated with BMI groups

Discussion

India has a huge population living with type 2 DM with earlier onset of disease. It is a well established fact that Indians suffer from at least 10 years earlier onset of this lifestyle problem; even more disturbing is the emerging fact from recent studies that at least in urban India, new-onset diabetes peaks at 30–35 years of age.[2] A recent study from Delhi estimated that 27% of urban India's (Delhi) population already has diabetes and another 46% are suffering from prediabetes.[1] 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.

Prescription patterns

Diabetes is a problem where cure is still a work in progress. With current armamentarium, it is a disease that affects us for lifetime. Now, starting at 30 years of age and with a life expectancy going into 90s, it is a huge financial, social,

Table 3: Direct cost of antidiabetes drugs used in diabetes care per day (INR=Indian National Rupees)

Duration of diabetes	Direct cost of all drugs (INR)		Direct cost of antidiabetes drugs (INR)	
	Mean (SD)	Median	Mean (SD)	Median
<5 years	31.167 (29.36)	21.844	16.42 (23.34)	7.249
5-10 years	56.117 (49.75)	42.26	38.034 (47.06)	24.36
10-15 years	79.95 (58.085)	67.737	62.34 (54.36)	53.882
15-20 years	101.13 (67.75)	83.26	77.183 (60.37)	64.717
>20 years	132.90 (86.55)	109.558	106.34 (84.58)	78.28

SD: Standard deviation

and emotional burden on individuals. Previous studies in the literature show the prescription patterns in primary and tertiary care units, but none of these studies demonstrates the dynamic changes in the pattern of antidiabetic drugs in relation to the duration of diabetes. This study fills this lacuna in the literature. This study, though cross-sectional in nature, may still be representative of prescription pattern as data have been derived from a single practice catering to uniform population.

Metformin should be overwhelmingly the first choice among oral antidiabetic drugs at the onset of diabetes, according to all current guidelines. However, review of literature across the world reveals the heterogeneous use of metformin in early years of diabetes. Sharma *et al.* demonstrated the changing trend from 55% of patients being treated with metformin as first agent in 2003 to 83.6% in 2013 in the United Kingdom.[3] On the other hand, in a similar study from the United States, data collected over 2009–2013 revealed that only 57.8% of people were started on metformin as initial drug for new-onset diabetes.[4] In this study, metformin, at 90.62%, is the drug of choice during early years of diabetes.

The percentage of patients on metformin remains steady over the duration of diabetes from 0 to 20+ years. The percentage of sulfonylurea and dipeptidyl peptidase-4 inhibitors (DPP4i) increases from 23.12% and 22.5%, respectively, in 0–5 years of duration of diabetes to 70.77% and 60%, respectively, in 10–15 years of diabetes. Thereafter, the percentage of sulfonylurea and DPP4i becomes steady. And as prescription of sulfonylureas and DPP4i starts plateauing, prescription of insulin and sodium/glucose cotransporter 2 inhibitors starts rising. The percentage of alpha glucosidase inhibitors has a slight growth from 5 to 10 years of duration of diabetes to 20+ years of duration of diabetes. In the current practice and in the given set of patients, thiazolidinediones and glucagon-like peptide-1 receptors agonists share negligible percentage [Figure 2]. Insulin requirement at 46% after 20 years may seem lower than previous estimates, but may be explained by the availability of much wider choice of oral antidiabetic drugs today.

There are few studies that let us know that glycemic control can be maintained on either metformin or thiazolidinediones for 3–4 years, but real-world data on the requirement of antidiabetic drugs over years of diabetes are lacking. Sulfonylureas and DPP4i are the most likely add-on medications to metformin in this study. In a cross-sectional study from Mumbai, India, sulfonylureas were the most common drugs prescribed overall, whereas DPP4i were used only in 2.63% of people.[5] This is much lower than the usage in this study. Patel *et al.* revealed the use of metformin at 87.7%, sulfonylureas at 68%, and DPP4i at 10.5% among 114 people from Ahmedabad, India.[6] Another study from Catalonia, Spain, had metformin usage at much lower levels of 68%, and sulfonyureas were the second most common drugs to be used at 25.6%.[7] Current study establishes that sulfonylureas are still widely used, although DPP4i are catching up fast as second-line medication after metformin.

As the duration of diabetes increases, variation in prescriptions also increases, presumably due to consideration of individual factors. This is demonstrated in Table 2 which lists the three most common prescription patterns in each group according to their duration of diabetes. While in a group with less than 5 years of duration of diabetes the three most common prescription patterns accounted for 75.65% of people, with a duration of more than 20 years the same accounted for only 36% of population.

Analysis of antidiabetes drug classes in people with diabetes according to their age and BMI, as shown in Figures 4 and 5, revealed a decrease in the usage of SGLT2 inhibitors in older age group, whereas the remaining of the drugs had no correlation with age. As BMI increases, there is a decrease in the usage of sulfonylureas, whereas there is an increase in the usage of SGLT2 inhibitors consistent with international guidelines.

Health economics of type 2 diabetes

In India, the amount spent by the government on health is relatively less when compared to Western and European countries. Few notable points regarding health economics of diabetes in India are first, private healthcare is the predominant provider of diabetes care in India with government setups providing only around 20% of care; second, expenditure done on diabetes care is largely out-of-pocket expense and contributes to catastrophic health expenditure (defined as household health spending exceeding 10% of household consumption expenditure) in 45% of patients; third, 23% meet this expenditure by borrowing from banks and money lenders, also known as distress financing.[8] Situation is little better in higher socioeconomic strata.

Diabetes is a progressive disease and the cost of therapy keeps on increasing as the duration of diabetes increases and more medications are required to keep glycemic control in optimal range [Table 3]. Cost of Diabetes in India (CODI) study outlined that antidiabetic drug cost accounts only for 17% of direct medical expenses on diabetes care.[9] Although a few other studies estimate it at much higher proportion to 30%–50% of direct costs.[10,11] A large proportion is spent on hospitalization (35%), followed by investigations (22%), consultations (12%), and other drugs (11%).[9] Moreover,

indirect costs corresponding to man-days lost and the loss of personal as well as family income contribute to even larger burden than direct cost *per se*.

This study, when compared with a study published in 2007 from the same geographical area, reveals a sharp increase in the cost of diabetes care. The mean cost of antidiabetes therapy increased from INR 5.44 to 7.25 per day in people with less than 5 years of diabetes, from INR 9.5 per day to 24.23 with the duration of diabetes between 5 and 10 years, from INR 12.69 to 52.12 with 10–15 years' duration of diabetes, and from INR 17.50 to 63–78 among people with more than 15 years of diabetes.[12]

The cost of therapy increased with complications, use of insulin, hospitalization, and availing private healthcare.[13-16] In 2014, a meta-analysis by Yesudian *et al.* reviewed the literature on cost of illness studies of diabetes and its complications in India.[17] The authors concluded that literature on the costs of diabetes and its complications in India provides a fragmented picture.[17]

Ramachandran *et al.* compared the cost incurred on diabetes care between years 1998 and 2005. Direct expenditure on medication increased by 39% over 7 years after adjustment of inflation. Their population had a mean duration of diabetes of 10.4 ± 7.1 years. On comparing similar population (vis-a-vis duration of diabetes) from this study, direct medical cost has increased by 266% after inflation adjustment.[18] The cost of therapy seems to be almost similar to that incurred in the United Kingdom considering purchasing power parity between two countries.[19]

This must be acknowledged here that these cost estimates are likely to be an underestimation as complication rate is likely to be higher in future and upper estimates are likely to be more near to reality especially in people with earlier onset of diabetes and increased life expectancy.

Strengths and limitations of study

The strength of this study lies in the accuracy of data used for analysis. Most of the previous studies have relied on recall by patients or availability of paper prescriptions with patient. Furthermore, price of drugs has been extrapolated to one particular brand of medicine while its well-known that there can be huge variations among brand.[20] Another strength of the study is demonstration of drug utilization data across the duration of diabetes revealing the current patterns.

The limitations of the study include nonassessment of prevalent complications and cross-sectional nature of study. Further studies with prospective follow-up are required to further validate the results. Use of vitamin B12 and vitamin D has been liberal in our clinic, but that is after internal assessment which revealed huge prevalence of deficiency of these vitamins (data not shown) in population that we serve and is also consistent with previously published studies from India.[21]

Conclusion

This study provides a valuable insight into temporal prescription patterns of antidiabetic drugs from an endocrine practice. Metformin remains the most preferred drug across all the duration of diabetes. DPP4i seems to be fast catching up with sulfonylureas as second-line treatment after metformin. SGLT2 inhibitors are being used as third- or fourth-line drug. After 20 years or more of diabetes duration, 46% people would require insulin for glycemic control. With earlier onset of diabetes and increasing life expectancy, the cost of diabetes is likely to escalate.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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