Pattern of Disease and Therapy for Diabetes along with Impact of Generic Prescribing on Cost of Treatment among Outpatients at a Tertiary Care Facility

Shubham Atal1, Rajnish Joshi2, Sadasivam Balakrishnan1, Pooja Singh1, Zeenat Fatima1, Nidhi Jain3

1Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Bhopal, 2Department of General Medicine, All India Institute of Medical Sciences (AIIMS), Bhopal, 3Department of Pharmacology, Gandhi Medical College, Bhopal, Madhya Pradesh, India

Background: India has become the diabetes capital of the world. Analyzing trends in drug prescribing helps in judging rationality of prescriptions in different settings. This study aimed to assess disease and prescribing trends with a special emphasis on evaluating use of metformin, insulin, fixed dose combinations (FDCs), concomitant medications, pill burden, and costs of drug therapy in diabetes.

Materials and Methods: This was a cross-sectional study in which patients of either sex who attended the diabetes clinic at a tertiary care center over 9 months were included consecutively. Basic demographic profile, clinical, and treatment details on the day of visit were collected from the prescription charts. Drug costs for prescriptions were calculated using generic and median brand prices of formulations using a recognized commercial drug directory and generic price list of the government, respectively. Data were analyzed by using Microsoft Excel and Open Epi online software to compare results with published studies.

Results: Average age of diabetics was 53.9 ± 11.8 years and disease duration was 8.13 ± 7.78 years in 336 prescriptions analyzed. Dual drug regimens were seen in 32.7% prescriptions, most commonly metformin and sulfonylureas, followed by triple drug regimens (25%) with inhibition of dipeptidyl peptidase IV (DPP IV) inhibitor. Metformin was prescribed in 95% prescriptions (mean dose 1511 ± 559.87 mg) and insulin in 22.6% prescriptions. Angiotensin receptor blocker (ARBs) and statins were the most commonly prescribed concomitant drugs. One FDC per prescription (median) each for diabetes and comorbidities were prescribed. Daily pill burden was 4.59 ± 2.65 pills. The median monthly cost of drug therapy with branded prescribing was INR 870.43 and INR 393.72 with the use of generics. Inferences drawn by comparison with published data showed variable results for different parameters analyzed.

Conclusion: Disease pattern was as expected for the region and trends of therapy showed concurrence with rational prescribing. Pill burden and cost of therapy remain high with a significant contribution of comorbidities.

Keywords: Cost, diabetes, FDC, generics, prescription, regimens

INTRODUCTION

India has unceremoniously been tagged as the “diabetes capital” of the world with approximately 77 million adults with diabetes estimated to be living in the country, expected to reach 134.2 million by 2045.[1]
More than half remain undiagnosed, annual incidence rate is as high as 20%, and prevalence estimated to range from 7.3% to 8.8% or even higher. The “Asian Indian phenotype” signals an earlier age of onset, characteristic dyslipidemia, higher insulin resistance, lower body mass index (BMI) threshold for disease in the thin fat Indians. Insulin generally remains one of the last resorts in type 2 diabetes; however, timely institution and recognizing early indications are critical. Variability in response and intolerance makes optimization of metformin important. Economic considerations, patient convenience, pill burden also come into the picture in choosing formulations to prescribe.

This study aimed at addressing all these aspects of drug use in a concerted effort to analyze disease and treatment pattern for diabetes at an apex tertiary care center of central India with a special focus on use of metformin, insulin, fixed dose combinations (FDCs), drugs for comorbidities, pill burden, and the impact of generic prescribing on treatment costs.

**Subject and Methods**

A prospective cross-sectional observational study was conducted in the department of medicine, an apex tertiary care teaching hospital in central India for 9 months. Individuals with diabetes of either sex who attended the diabetes specialty clinic were included consecutively. Repeat or refill prescriptions were excluded. Permission to conduct this outpatient therapeutic audit as part of a broader diabetes project was obtained from the institutional human ethics committee.

The basic demographic profile, clinical, and treatment details on the day of visit were collected from the patients’ prescription charts or diaries. The collected data was anonymized, linked through hospital ID numbers for retrieval and authenticity. All data was stored confidentially with limited access only to study investigators. Demographic and disease characteristics, prescribing pattern, pill burden for diabetes as well as comorbidities and complications were analyzed. Drug acquisition costs for the prescriptions were calculated using median prices obtained from listing of all brands for the prescribed drug formulations using a recognized commercial drug directory for the year of prescription (CIMS, October–December 2019) and generic drug prices from the latest price list of the government’s generic drug scheme in India. Statistical analysis was done using Microsoft Excel and IBM SPSS v. 23. Statistical tests of significance as appropriate (independent sample t test and chi-square test) were applied to analyze the study results in light of previously published studies, using the portal—Open Source Epidemiologic Statistics for Public Health (OpenEpi).

**Results**

A total of 336 prescriptions written for diabetes were analyzed. The mean age of the diabetic individuals was 53.9 ± 11.8 years, a predominance of males (57%) as shown in Table 1. Type 2 diabetes mellitus (T2DM) was predominant (> 95% cases) with a mean duration of diagnosed diabetes of 8.13 ± 7.78 years. More than 40% of individuals had duration of disease of more than 5 years. Hypertension was the most common comorbidity, seen in more than half of the prescriptions, followed by dyslipidemia and hypothyroidism.

**Glycemic Control Pattern**

Figure 1 shows glycemic control status seen in the prescriptions using different glycemic parameters—glycated hemoglobin (HbA1c), or fasting/random/post prandial blood sugars (FBS/RBS/PPBS). Mean HbA1c was found to be 8.3 ± 1.7% (n = 165), whereas

| Table 1: Demographic and Disease Profile |
|-----------------------------------------|
| **Characteristic** | **Frequency (proportion)** |
| Age (in years) | (N = 336) |
| < 20 | 5 (1.5) |
| 21–40 | 47 (14) |
| 41–60 | 181 (53.9) |
| >60 | 103 (30.6) |
| Gender | |
| Males | 191 (56.8) |
| Females | 145 (53.2) |
| Type of diabetes | |
| Type 1 | 14 (4.2) |
| Type 2 | 320 (95.2) |
| GDM | 2 (0.6) |
| Mean body weight (kg) | |
| Overall | 68.14 ± 12.02 |
| Males | 69.63 ± 11.56 |
| Females | 65.92 ± 12.30 |
| Duration of diabetes (years) | (N = 252) |
| 0–1 | 45 (17.9) |
| 1–5 | 100 (39.7) |
| 6–10 | 38 (15.1) |
| 11–15 | 35 (13.9) |
| 16–20 | 19 (7.5) |
| >20 | 15 (5.9) |
| Associated conditions* | |
| Hypertension | 171 (50.9) |
| Dyslipidemia | 116 (34.5) |
| Hypothyroidism | 39 (11.6) |
| Peripheral neuropathy | 18 (5.4) |

*On the basis of documented diagnosis and/or prescribed drugs
mean FBS, RBS, and PPBS were 168.74 ± 56.64 mg/dL (n = 55), 211 ± 85.9 mg/dL (n = 143), and 197.23 ± 80.05 (n = 39), respectively.

HbA1c was done in half of the patients of whom 79% were “not controlled” taking a cutoff of HbA1c <7%, whereas with a higher cutoff of 7.5% approximately 62% individuals were “not controlled.” Majority of the individuals (64%) had an HbA1c between 7% and 10%. Using FBS, 70% of the values were “not controlled” with standard cutoff value of ≥126 mg/dL, whereas control was better (> 50%) using the RBS and PPBS values available. No significant age-wise differences were observed in glycemic control status. However, the proportion of diabetic individuals having HbA1c >10% was double among females compared to males.

Glycemic control and pill burden
The glycemic control status was compared against the number of drugs prescribed for diabetes, and resulting pill burden [Table 2]. The highest glycemic control was seen in prescriptions containing a single drug, and prescriptions containing 2–5 or more drugs (including insulins) showed almost similar glycemic control pattern. Increasing pill burden generally showed lesser glycemic control except in cases with 5 or more pills where insulin was part of the regimens.

Drug prescribing pattern
Drugs for diabetes
A total of 687 formulations (58.37% of total) were prescribed for diabetes containing 874 drugs (including insulin), with a mean of 2.6 ± 1.19 drugs per prescription (median—2). Most of the drug formulations were prescribed as twice (50.1%) or once (45.6%) daily. The total pills prescribed per day for diabetes (daily pill burden) amounted to a mean of 3.19 ± 1.8 (median—3 pills per day). Table 3 shows the pattern of regimens for diabetes seen in the prescriptions; dual and triple drug regimens being most commonly prescribed.

Among the single drug (monotherapy) prescriptions, metformin was most commonly prescribed (16.4% of prescriptions). Combination of metformin with glimepiride was the most commonly seen dual drug regimen (18.8% of prescriptions) followed by metformin given with various DPP IV inhibitors chiefly teneligliptin (5.4% of prescriptions). Among triple drug

| No. of drugs | 1 | 2 | 3 | 4 | 5 | >5 | Overall control (pill wise) |
|--------------|---|---|---|---|---|----|-----------------------------|
| No. of pills (% glycemic control) | 54.76% | 64.28% | – | – | – | – | 57.14% |
| 2 | 41.67% | 39.58% | 27.27% | 21.4% | – | – | 35% |
| 3 | – | 46.67% | 35.13% | 40% | 60% | 14.29% | 38.37% |
| 4 | – | – | 50% | 16.67% | 35.71% | 40% | 30.77% |
| ≥5 | – | – | – | 50% | 33% | 37.51% | 38.09% |
| Overall control (pill wise) | 50% | 45.45% | 32.73% | 26.53% | 44.44% | 33.33% |
regimens, combinations of metformin, glimepiride, and a DPP IV inhibitor (13.76% prescriptions) were most common followed by metformin and glimepiride and pioglitazone (3.9% prescriptions). Various combinations were seen in prescriptions containing 4 or more drugs including oral drugs with/out insulin preparations.

Figure 2 shows the frequency of prescription of various classes of drugs for diabetes. Injectable insulins comprised 12% of the total drugs prescribed. Metformin was the most commonly prescribed drug (35%), followed by sulphonylureas (24%)—most commonly glimepiride, and DPP IV inhibitors—most commonly teneligliptin.

**Pattern of use of metformin**
Metformin was prescribed in more than 95% prescriptions for T2DM. The mean total daily dose of metformin prescribed was 1511 ± 559.87 mg (median—2000 mg). Frequency of prescribing metformin was twice daily in majority of prescriptions (68.7%). In more than 50% prescriptions, it was given at a total daily dose of 2000 mg whereas the total daily dose was 1000 mg in 35.3% prescriptions.

**Pattern of use of insulin**
A total of 111 insulin preparations were prescribed in 75 prescriptions (22.3% of total), out of which 59 prescriptions (17.6%) were for T2DM. Insulin glargine was most commonly prescribed (45.9%) followed by regular human insulin (35.1%) and premixed insulin 70:30 (16.2%). The mean total daily dose of insulin prescribed (combining all types of insulins) was 39 ± 22.4 U per day for T2DM (Median 46 U); which increased to 45.4 ± 17 U per day among individuals with type 1 diabetes (Median 34 U).

**Drugs for comorbidities/complications**
A total of 490 drug formulations (41.63% of total) were prescribed for treatment or prophylaxis of comorbidities (chronic diseases) or diabetic complications, out of

---

**Table 3: Patterns of regimens for diabetes**

| Drug regimen | No. of prescriptions \( (n = 336) \) | Common drug/regimen prescribed \( (n) \) |
|--------------|-----------------------------------|----------------------------------|
| Single (1)   | 64 (19%)                          | Metformin (55)                  |
|              |                                   | Glimepiride (5)                 |
| Dual (2)     | 110 (32.7%)                       | Metformin + glimepiride (63)    |
|              |                                   | Metformin + teneligliptin (18)  |
|              |                                   | Metformin + vildagliptin (9)    |
| Triple (3)   | 84 (25%)                          | Metformin + glimepiride + teneligliptin (25) |
|              |                                   | Metformin + glimepiride + vildagliptin (14) |
|              |                                   | Metformin + glimepiride + pioglitazone (13) |
| Quadruple (4)| 56 (16.7%)                        | Metformin + glimepiride + teneligliptin + pioglitazone (21) |
| ≥ 5          | 22 (6.6%)                         | Different combinations of OAD’s + insulin |

---

**Figure 2: Drugs prescribed for diabetes**
which 267 formulations (54.5%) were FDCs. The mean number of such drugs per prescription was 1.96 ± 1.85 (median—2). The daily pill burden was relatively low (1.5 ± 1.58, Median—1) signifying the large proportion of FDCs and once-daily administration in most cases. Table 4 shows the pattern of use of common drugs prescribed for such indications. Maximum numbers of drug formulations were prescribed for hypertension (43.5%) and dyslipidemia (24.5%).

**Prescription of FDCs**

Table 5 gives a summary of commonly prescribed FDCs for diabetes and nondiabetes conditions (including oral and injectable).

**FDCs for diabetes**

A total of 222 FDCs were prescribed (32.2% of total formulation for diabetes). A mean of 0.6 ± 0.54 FDCs per prescription was seen for diabetes (median—1), with 58% of the prescriptions containing at least one FDC. Other than premixed insulin (n = 20), all the oral FDCs prescribed for diabetes contained metformin, of which the most common FDC was metformin + glimepiride (70.3%) in different dose combinations containing 1000/500 mg metformin with 2/1 mg glimepiride. Metformin FDCs with DPP IV inhibitors were seen mainly with vildagliptin 50 mg (13.86%), teneligliptin 20 mg (5.94%), sitagliptin 50 mg (3.96%). Some less frequently prescribed metformin FDCs were with linagliptin, voglibose, and glibenclamide. There were only five prescriptions with 3 drug FDCs containing metformin, glimepiride, and pioglitazone.

**FDCs for comorbidities/complications**

A total of 267 FDCs (22.68% of total formulations) were prescribed for nondiabetes conditions in 143 prescriptions (42.6%). The mean number of such FDCs per prescription was 0.8 ± 1.02 (median—1). A significant proportion of the prescribed nondiabetic FDCs were for hypertension, most commonly telmisartan 40 mg and amlodipine 5 mg [Table 5]. Very few prescriptions contained three drug FDCs such as telmisartan with amlodipine and hydrochlorthiazide.

**Pill burden on patients**

Figure 3 summarizes the total daily pill burden on the patients according to the afflicting conditions; overall pill burden being 4.59 ± 2.65 pills per day which reduced to 2.98 ± 1.7 in those with diabetes alone and increased to 7 ± 2.89 pills per day in those with both hypertension and dyslipidemia along with diabetes.

**Cost of drug therapy**

The average monthly acquisition cost of drug therapy was found to be INR 870.43 (median; IQR—1364.93)

---

### Table 4: Commonly prescribed drugs for comorbidities—complications

| Drug class (frequency) (N = 490) | Most common drug (frequency) |
|----------------------------------|-----------------------------|
| ARBs (131)                       | Telmisartan (116)           |
| Statins (120)                    | Atorvastatin (114)          |
| Antiplatelet drugs (105)         | Aspirin (97)                |
| CCBs (80)                        | Amlodipine (76)             |
| Thyroid hormone (39)             | Thyroxine (39)              |
| ACE inhibitors (30)              | Ramipril (26)               |
| Thiazide diuretics (21)          | Hydrochlorthiazide (14)     |
| Loop diuretics (11)              | Toresemide (7)              |
| Analgesics for neuropathic pain (14) | Pregabalin (8)            |

### Table 5: Commonly prescribed FDCs

| Composition                                      | Frequency (proportion) | M.C. strength of combination (frequency) |
|--------------------------------------------------|------------------------|-----------------------------------------|
| Diabetes FDCs (18.86% of formulations)           |                         |                                         |
| Metformin + glimepiride                          | 142 (64%)              | 1000 + 2 mg (74)                       |
| Metformin + vildagliptin                         | 28 (12.6%)             | 1000 + 50 mg (24)                      |
| Metformin + teneligliptin                        | 13 (6.4%)              | 1000 + 20 mg (11)                      |
| Metformin + sitagliptin                          | 8 (3.6%)               | 1000 + 50 mg (8)                       |
| Premixed insulin (NPH + regular)                 | 20 (9%)                | 70:30 (18)                             |
| Metformin + glimepiride + Pioglitazone           | 5 (2.25%)              | 1000 + 1 + 15 mg (3)                   |
| Nondiabetes FDCs (22.68% of formulations)       |                         |                                         |
| Aspirin + atorvastatin                          | 74 (27.7%)             | 75 + 20 mg (55)                        |
| Telmisartan + amlodipine                         | 47 (17.6%)             | 40 + 5 mg                              |
| Aspirin + clopidogrel                            | 8 (3%)                 | 150 + 75 mg                            |
| Telmisartan + amlodipine + hydrochlorthiazide   | 5 (1.9%)               | 40 + 5 + 12.5 mg                       |
per prescription when calculated using median brand prices calculated for all the formulations of drugs prescribed for diabetes and nondiabetes indications. When brand prices were substituted with generic prices of formulations available in the government’s generic drug scheme (Jan Aushadhi scheme), the median drug acquisition cost for the prescription reduced to INR 393.72 (IQR—774.09). Figure 4 shows that in 24.1% of prescriptions, the median branded monthly cost of drug therapy was more than three times compared to costs calculated by substituting generic prices wherever possible. The monthly median branded cost of prescription was 6–10 times costlier in 8.6% prescriptions.

**Discussion**

A detailed analysis of the 336 prescriptions written for diabetes at this tertiary care center showed an overall picture of disease and drug therapy reflective of what is expected at tertiary care level in India, and the prescribing pattern was congruent to existing treatment guidelines as well as local drug availabilities.

The mean age of the persons with diabetes was around 54 years with majority of individuals in the 40–65 age groups, which is comparable to earlier similar studies in different parts of India [13,14,16,17] and significantly lower ($P < 0.0000001$) than a study conducted in the northeastern state of Sikkim [15]. This age is also significantly lower than that seen in the U.S. and other countries [18-20] indicating an earlier age of onset of T2DM in our setting. Around 15% of persons with T2DM were less than 40 years of age; Asian Indians have a significantly earlier onset of diabetes compared to white populations [7]. The mean duration of diagnosed diabetes was more than 8 years, which is statistically similar to earlier reported data [14,15]. Patients are likely to come to a tertiary care center later in their diabetes progression; almost half the patients had a duration of diabetes of >5 years which is a significantly higher proportion compared to a recently published from a private center in New Delhi [13] and one fourth had duration >10 years.

The average values of HbA1c and FBS were significantly higher compared to some of the previously reported studies, whereas PPBS value was comparable [7,16]. Approximately three-fourths of the individuals were in the category of glycemic status “not controlled.” However, the RBS values, which were done in significantly more number of individuals than FBS or PPBS, were within glycemic “control” in approximately 50%. This is reflective of the real-world situation where routinely individuals tend to provide RBS samples more commonly than FBS and PPBS, indicating difficulty in maintaining fasting status when coming for clinic appointments and practical issues of staying for 2 hours for PPBS. HbA1c is relied upon as the preferred glycemic marker, and was done whenever possible to reflect longer term glycemic status. The “inadequate glycemic control” has to be seen in the light of the characteristics of individuals and disease

![Figure 3: Daily pill burden](image-url)
in this government tertiary care set up—longer disease duration, complications/comorbidities, age, possibly lack of adherence to diet lifestyle and medications, and affordability issues. Guidelines also recommend relatively higher target values for “adequate control” as practical and beneficial taking into account age and status of complications/comorbidities. Using those criteria, an increased number of individuals in this analysis can actually be considered as “controlled.” Hypertension was the most common comorbidity seen which is consistent with published literature, albeit in higher or lower proportions. Association of diabetes with thyroid dysfunction is established; low levels of thyroid hormones increase risk of diabetes. Hypothyroidism seen in over 10% of cases in the study corroborates this.

The average of 4.56 drugs per day prescribed per patient varies in comparison to studies conducted in different parts of India; it is significantly lower than in a few studies \((P < 0.05)\). This variability could be due to many factors. The mean number of drugs for diabetes per prescription is significantly higher than some recent Indian studies \((P < 0.05)\) signifying perhaps the more advanced disease presentation to this apex center. Importantly, we were able to calculate the daily pill burden (4.59) which matters more to a patient—the number of pills he/she has to take; this is a unique finding not reported in most of the earlier studies. Because of the frequent use of FDCs for diabetes and hypertension along with statins—aspirin combinations, the pill burden was interestingly almost the same as the average number of drugs per prescription. This highlights the advantage of FDCs (if rational) in providing patient convenience and possibly improving adherence.

Proportion of single and dual drug regimen prescriptions was significantly lower \((P < 0.05)\) than some studies from India and Bangladesh, whereas proportion of prescriptions containing triple drug regimen was significantly higher \((P < 0.05)\). Most of the prescriptions at our center contained 2 or 3 drugs for diabetes which is consistent with earlier findings in tertiary care. The drugs in the regimens however varied from these studies. Prescriptions with metformin and glimepiride as dual drug regimens were significantly higher \((P = 0.00003)\) than a study done in Tamil Nadu; similarly prescriptions with metformin, glimepiride, and DPP IV inhibitor (teneligliptin/vildagliptin) among triple regimens were significantly higher too \((P = 0.00012)\) at this center. In other studies, metformin and DPP IV inhibitor or metformin and glibenclamide were commonly prescribed as dual regimens, and pioglitazone or voglibose commonly prescribed as part of triple drug regimens. This underlines the increased use of DPP IV inhibitors especially teneligliptin as add on drug, and glimepiride as the preferred Sulfonylurea (SU) here. It mirrors the recent national diabetes treatment guidelines as well as availability in the local pharmacy (Jan Aushadhi store).

Also consistent with treatment guidelines and recent studies was the use of metformin as the most commonly prescribed drug which reflects the recommended practice of prescribing metformin to every individual with T2DM unless contraindicated or not tolerated. Similar results have been reported in previous studies too. Metformin was optimally used at the center as indicated by its presence in almost all the T2DM prescriptions and a high mean total daily dose. SUs (predominantly glimepiride) were the second most commonly prescribed showing that the popularity of SUs is being maintained due to good efficacy and low cost, despite concerns of weight gain and hypoglycemia. DPP IV inhibitors came behind the SU’s, although being strongly recommended by guidelines as a preferable add-on drug. This is most probably due to their higher costs; yet their use is increasing. Teneligliptin was the molecule most prescribed, unlike in previously reported results, which indicates its growing popularity due to significantly lower cost and availability as the only DPP IV inhibitor in the generic drug scheme. It highlights patients’ affordability as a major consideration in prescribing. Pioglitazone was significantly less used compared to other centers which is again in line with latest guidelines, as this drug is not a preferable choice among add on drugs due to both safety and efficacy concerns. SGLT-2 inhibitors and voglibose were sparingly used mainly due to issues of high cost among patients and low efficacy, respectively.

Very few studies have described FDCs used in diabetes. After metformin and glimepiride combination which was the most frequently prescribed FDC, the DPP IV inhibitor FDCs (with vildagliptin and teneligliptin) in combination with metformin were prescribed in increasing numbers. These combinations are rational, the drugs being complimentary to each other, beneficial in increasing adherence and decreasing pill burden on patients. There was no tendency for prescribing metformin combinations in unapproved doses, or using three-drug FDCs which are largely banned in the country. Use of insulin in T2DM remains a contentious issue, with delay in institution or intensification recognized as common and counterproductive. It was encouraging to find that insulin was prescribed in 20% of T2DM individuals, similar to a study done...
in Gujarat,[16] which can be considered appropriate for tertiary care especially looking at the “inadequate glycemic control” status of individuals coming here, and considering previous evidence where significantly lower usage has been reported in similar setups.[13,14]

Not many studies from India have provided a detailed analysis of concomitant drug use in diabetes, prescribed for comorbidities and complications. We recorded a total daily drug and pill burden of approximately 2 and 1.5, respectively, for nondiabetes indications which make up a significantly high proportion (40%) of the total daily burden. The daily pill burden rose significantly among patients having diabetes along with hypertension and dyslipidemia. This highlights the burden that management of diabetes places on an individual due to accompanying problems. This is in congruence with previous national and international evidence.[13,14,16,20,23,24] We also described the pattern of usage of these drugs, revealing that angiotensin receptor blocker (ARBs) and ACE inhibitors were the predominant class of antihypertensives used which is rational considering their beneficial effects on nephropathy. Use of telmisartan as the most common molecule prescribed alone and in combination reflects upon the preference and availability of this drug locally. Aspirin, as expected, was the most common antiplatelet agent prescribed, mostly in combination with atorvastatin. The cardioprotective benefits provided by these drugs provide a rationale for their use in high-risk patients in tertiary care.

Looking at the monthly cost of drug therapy for treating diabetes and related complications and/or comorbidities, it was found that prescription cost is significantly higher if branded drugs are prescribed as compared to generic prescribing. The median monthly cost with branded prescribing (INR 870.43) is almost 10% of the monthly per capita income of an Indian citizen,[27] and was found to be significantly higher ($P < 0.05$) than reported in previous studies.[15,16] This cost dropped down to less than half (INR 393.72) when generic formulations available in the government’s “Jan Aushadhi Scheme” were considered. Direct medical costs, especially monthly drug costs, have been earlier reported to range from INR 300 to 3000.[13]

As many as up to 65% prescriptions were more than twice as costly with only median branded prices of all formulations taken into consideration compared to generic prescribing, with more than five times higher cost variation seen in 16.4% prescriptions.

These costs and variations highlight two important things—firstly, the out of pocket expenditure on drug acquisition remains quite high among individuals with diabetes in tertiary care settings, and secondly, generic prescribing has a significant positive impact on this financial burden. Considering these costs in context of parameters like per capita income of Indians, and proportion of individuals under the poverty line, the magnitude of the economic burden of diabetes for simply the drug therapy required can be appreciated very well. The impact of generic prescribing on reducing cost of therapy is also clearly evident; however, skepticism remains regarding the quality and clinical effectiveness of these formulations. The physician community still remains incompletely convinced regarding use of generics exclusively despite the regulations ensuring that these drugs should have the requisite bioequivalence to standard innovator brands, and the government trying to ensure quality by procurement from only authorized listed manufacturers. Overall, there is a huge scope in

![Figure 4: Magnitude of cost variations with branded—generic formulations](image-url)
reducing the prescription cost by prescribing cheaper alternatives and reducing the number of medications per prescription.

**Limitations**
Sample size in this study could be considered insufficient, and being a single-center study our findings may not be generalizable. The design was cross-sectional not allowing us to evaluate trends in prescribing in patients along the course of their treatment. We also could not thoroughly evaluate factors like treatment adherence and adverse effects in the present analysis.

**Acknowledgement**
We would like to acknowledge the tutors in the department of pharmacology for their assistance in the study.

**Financial support and sponsorship**
Nil.

**Conflicts of interest**
There are no conflicts of interest.

**REFERENCES**

1. International Diabetes Federation. IDF diabetes atlas. 9th ed. Brussels, Belgium: International Diabetes Federation; 2019.
2. Anjana RM, Shanthi Rani CS, Deepa M, Pradeepa R, Sudha V, Divya Nair H, *et al.* Incidence of diabetes and prediabetes and predictors of progression among Asian Indians: 10-year follow-up of the Chennai urban rural epidemiology study (CURES). Diabetes Care 2015;38:1441-8.
3. Anjana RM, Deepa M, Pradeepa R, Mahanta J, Narain K, Das HK, *et al.*; ICMR–INDIAB Collaborative Study Group. Prevalence of diabetes and prediabetes in 15 states of India: results from the ICMR–INDIAB population-based cross-sectional study. Lancet Diabetes Endocrinol 2017;5:585-96.
4. Sosale A, Prasanna Kumar KM, Sadikot SM, Nigam A, Bajaj S, Zargar AH, *et al.* Chronic complications in newly diagnosed patients with type 2 diabetes mellitus in India. Indian J Endocrinol Metab 2014;18:355-60.
5. Singh AK, Farag YM, Mittal BV, Subramanian KK, Reddy SR, Acharya VN, *et al.* Epidemiology and risk factors of chronic kidney disease in India—results from the SEEK (screening and early evaluation of kidney disease) study. BMC Nephrol 2013;14:114.
6. Indian Council of Medical Research. Guidelines for management of type 2 diabetes. Available from: https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_GuidelinesType2diabetes2018_0.pdf. [Last accessed on 2020 Jul 1].
7. Singla R, Garg A, Singla S, Gupta Y. Temporal change in profile of association between diabetes, obesity, and age of onset in urban India: a brief report and review of literature. Indian J Endocrinol Metab 2018;22:429-32.
8. American Diabetes Association. Pharmacologic approaches to glycemic treatment: standards of medical care in diabetes – 2019. Diabetes Care 2019;42:S90-S102.
9. Davies MJ, D’Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, *et al.* Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the study of diabetes (EASD). Diabetes Care 2018;41:2669-701.
10. Esposito K, Bellastella G, Giugliano D. When metformin fails in type 2 diabetes mellitus. Arch Intern Med 2011;171:365-6.
11. Bonnet F, Scheen A. Understanding and overcoming metformin gastrointestinal intolerance. Diabetes Obes Metab 2017;19:473-81.
12. Gama H. Drug utilization studies. Arq Med. 2008;22:69-74.
13. Singla R, Bindra J, Singla A, Gupta Y, Kadra S. Drug prescription patterns and cost analysis of diabetes therapy in India: audit of an endocrine practice. Indian J Endocrinol Metab 2019;23:40-5.
14. Dutta S, Beg M, Anjoom M, Varma A, Rawa S. Study on drug prescribing pattern in diabetes mellitus patients in a tertiary care teaching hospital at Dehradun, Uttarakhand. Int J Med Sci Public Health 2014;3:1351-4.
15. Satpathy SV, Datta S, Uperti B. Utilization study of antidiabetic agents in a teaching hospital of Sikkim and adherence to current standard treatment guidelines. J Pharm Bioallied Sci 2016;8:223-8.
16. Acharya KG, Shah KN, Solanki ND, Rana DA. Evaluation of antidiabetic prescriptions, cost and adherence to treatment guidelines: a prospective, cross-sectional study at a tertiary care teaching hospital. J Basic Clin Pharm 2013;4:82-7.
17. Thakur A, Ray TK, Goel MK. Expenditure pattern on diabetes care: a community based longitudinal study in resettlement colony of East Delhi. Indian J Comm Health. 2017;29:209-12.
18. Kalyani RR, Golden SH, Cefalu WT. Diabetes and aging: unique considerations and goals of care. Diabetes Care 2017;40:440-3.
19. de Pablos-Velasco PL, Martinez-Martin FJ, Molero R, Rodriguez-Perez F, Garcia-Puente I, Caballero A. Patterns of prescription of hypoglycaemic drugs in Gran Canaria (Canary Islands, Spain) and estimation of the prevalence of diabetes mellitus. Diabetes Metab 2005;31:457-62.
20. Mastura I, Chew BH, Lee PY, Cheong AT, Sazlina SG, Jamaiah H, *et al.* Control and treatment profiles of 70,889 adult type 2 diabetes mellitus patients in Malaysia: a cross sectional survey in 2009. Int J Collab Res Intern Med Public Health 2011;3:98-113.
21. Venkateswaramurthy N, Shajee MS, Sambathkumar R. Prescribing pattern of antidiabetic drugs in type-2 diabetic patients. Int J Pharm Sci Res. 2016;7:4550-5.
22. Wang C. The relationship between type 2 diabetes mellitus and related thyroid diseases. J Diabetes Res 2013;2013:390534.
23. Ahmed Z, Hafez MA, Bari MA, Akhter J. Pattern of antidiabetic drugs prescribed in a tertiary care hospital of Bangladesh. Int J Basic Clin Pharmacol 2016;5:6-12.
24. Jimoh AGO, Sabir AA, Chika A, Sani Z. Pattern of antidiabetic drugs use in a diabetic outpatient clinic of a tertiary health establishment in Sokoto, North-western Nigeria. J Med Sci 2011;11:241-5.
25. Perreault L, Vincent L, Neumiller JJ, Santos-Cavaia T. Initiation and titration of basal insulin in primary care: barriers and practical solutions. J Am Board Fam Med 2019;32:431-447.
26. Goodall G, Sarpong EM, Hayes C, Valentine WJ. The consequences of delaying insulin initiation in UK type 2 diabetes patients failing oral hyperglycaemic agents: a modelling study. BMC Endocr Disord 2009;9:19.
27. India’s per capita income grows by 8.6% to Rs 1.13 lakh in FY18. [Internet]. Available from: https://economictimes.indiatimes.com/news/economy/indicators/indias-per-capita-income-grows-by-8-6-to-rs-1-13-lakh-in-fy18/articleshow/64403623.cms. [Last accessed on 2019 Jul 15].