



Cost Comparison of Different Brands of Anti-Diabetic Drugs With Drug Prices Control Order Price List

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ABSTRACT

Introduction: India, the “diabetes capital” of the world, 74 million diabetics with a prevalence of ~8.7% among the adult population. People require lifelong treatment for diabetes. Six of the top 10 drugs sold in India are anti-diabetes brands. For most multinational drug makers the diabetes market has been highly lucrative. **Objective:** This study was undertaken to compare the price of anti-diabetic branded drugs with the Drug Price Control Order (DPCO) price list. **Methods:** This is a cross-sectional, observational study. The price of different branded anti-diabetic drugs (included in NLEM) was obtained from drug compendia and different pharmacy stores situated in five zones of Ahmedabad. A comparison was done between the price of branded drugs in compendia, Pharmacy store, and DPCO ceiling price to find out price variation and price range. **Results:** A total of 8 anti-diabetic drugs included in NLEM were analyzed. Total 198 brands were available in CIMS/IDR out of which 77(39%) brands were above the ceiling price. Out of the total 38 brands available in pharmacy stores, 18 (53%) brands were above the ceiling price. Percentage variation between minimum and maximum price in IDR/CIMS was 39.1%-676.5% and 3.4%-900% variation was seen at pharmacy stores. **Conclusion:** A wide variation in the price range of different anti-diabetic branded drugs is observed. Strict implementation of price control regulations of anti-diabetic drugs is recommended.

Keywords: Ceiling price, DPCO, IDR/CIMS, Pharmacy store

INTRODUCTION

Diabetes is a chronic disorder that requires lifelong treatment. Diabetes due to its prevalence rate and increasing cost of treatment causes economic and health burdens on both patients as well as the healthcare system [1]. India is known as the “Diabetes capital” of the world. A total of 387 million people suffering from diabetes globally and is estimated to become the seventh leading cause of death in the world by the year 2030 [2]. As per the International Diabetes Federation (IDF), India with 65.1 million diabetes patients was at the second position after China (98.4 million) in terms of a total number of diabetic subjects in 2013 [3].

The number of diabetic patients in India is increased to 69.1 million as per the statistic survey done in 2019 [4]. Chronic illness like diabetes mellitus requires compliance to treatment for the illness to be under control. When a chronic illness is inadequately managed, the condition may worsen. Non-compliance can lead to unmet treatment expectations. As diabetes is lifelong disease treatment effectiveness depends mainly upon the treatment compliance of patients. In a developing country like India where the majority of the population comes under a lower socioeconomic class cost of the treatment is one of the important factors affecting the treatment compliance of patients. If drugs are not available at affordable prices then people with lower socioeconomic status won't continue the treatment. So, anti-diabetic drugs should be available at an affordable price to the majority of the population for better adherence to the treatment.

The price of medicines is monitored in India by Drug Price Control Order (DPCO) legislation, which has been effective since 1979 when the price of the majority of the drugs was brought under the control of DPCO [5]. Under the latest DPCO 2013 issued by the Ministry of Chemicals and Fertilizers for fixing the ceiling prices of 348 drugs included in the National List of Essential Medicine 2011 by the independent body-National Pharmaceutical Pricing Authority (NPPA), the latest DPCO was further updated in August 2018, covering around 851 formulations of 376 drugs appearing in the National List of Essential Medicines 2015 to be brought under the pricing control [5].

India is a hub for drug manufacturing, exporting medicines to almost every country in the world. But at the same time, this leads to a great price variation which causes a huge economic burden on our healthcare system as well as on consumers [6]. To reduce this burden whenever any pharmaceutical company launches a new drug, whether branded or generic it should be below or equal to the ceiling price fixed by the government for that specific formulation. This fixed price of drugs will lead to better treatment outcomes in patients.

In India despite the price control order has set by the government many pharmaceutical companies are still selling branded drugs above the recommended price and violating the price limit set by DPCO. Due to this supreme court of India has called the price control order “Unreasonable and Irrational” and it has also asked the government to re-examine our drug pricing policy [7].

In India, Out-Of-Pocket (OOP) expenditure for health care and medicines account for about 89 percentages of the expenses of households, and the scene is frighteningly similar in developing countries, due to increased medical costs [8]. Because of the above, resource-poor countries must realize the need to implement judicious pharmaceutical policies. Moreover, policy implementation should be coupled with the calculation of its impact on the end-users (consumers) to ensure effective outcomes [9].

Multiple brands are available for a single drug in India and variations are known to be prevalent in the prices of these brands because an open competitive market system entertaining both domestic and foreign manufacturers is followed [10]. With the implementation of price control, such price variations are expected to have come down. The DPCO states that reducing such inter-brand price variations in major therapeutic groups is one of its major aims [5]. Hence the present study was conducted to compare prices of various branded formulations of anti-diabetic drugs available in NLEM with their fixed ceiling prices given in the DPCO 2013 (updated in August 2018) and assess the compliance with DPCO.

MATERIALS AND METHOD

The present study was conducted at the department of pharmacology, B.J. Medical College and civil hospital Ahmedabad, a tertiary care teaching hospital which is located in the western region of India. All anti-diabetic drugs with different dosage forms available in NLEM 2015 were included in this study analysis and the ceiling price of these drugs was obtained from DPCO 2013 (updated in August 2018). Indian Drug Review (IDR) and Current Index of Medical Specialities (CIMS) are considered as trusted and authentic sources of commercial drug information and were chosen as sources of drug information. IDR; 24th year, 2018 issue 4 and CIMS; 40th year, July-oct-2018 were referred to get information regarding several different brands and price of the aforementioned groups of drugs. In the present study market price that patient pay to buy the same drug was also analyzed and compared with fixed ceiling price for different anti-diabetic drugs. For this purpose, the investigator collected information about the market price of these drug formulations at different pharmacy stores in Ahmedabad city. Information regarding several pharmacy stores situated in Ahmedabad city was obtained from www.medicineindia.org. Out of the total number of pharmacy stores registered at www.medicineindia.org, 10% of pharmacy stores were selected. Ahmedabad city is divided into five different zones by Ahmedabad Municipal Corporation. To select several pharmacy stores for one zone we used the following formula to maintain the proportion of selected in that particular zone.

$$\frac{\text{No. of pharmacy stores in particular zones}}{\text{Total no. of pahrmary stores}} \times 10\% \text{ of total pharmacy stores}$$

Then pharmacy store was selected by simple randomization method from all pharmacy stores situated in the respective zone. Investigator visited selected pharmacy stores and obtained data regarding the availability and price of branded anti-diabetic drugs in predefined record form (Annexure-1). The (single) unit prices (in rupees) for all the available branded drugs were taken, as the DPCO also fixes ceiling prices for one unit. The prices of all the brands of anti-diabetic drugs from IDR, CIMS, pharmacy stores were compared with ceiling prices of the same dosage formulation of drugs from DPCO 2013 (updated in August 2018). The price of each anti-diabetic drug formulation is described in terms of Rs /unit where 1unit is equal to 1 tablet of the solid dosage form or 1 ml of the liquid dosage form.

The following parameters were analyzed:

- Total number of brands available for every drug formulation
- Range of price difference (minimum-maximum) for each formulation
- Percentage of price variation between maximum and minimum prices [11]:

$$\frac{\text{Price of most expensive brand (max)} - \text{price of least expensive brand (min)}}{\text{Price of least expensive brand (min)}} \times 100$$

- Percentage deviation of maximum/minimum from the ceiling price:

$$\frac{\text{Maximum price} - \text{Ceiling price} * 100}{\text{Ceiling price}}$$

$$\frac{\text{Ceiling price} - \text{Minimum price} * 100}{\text{Ceiling price}}$$

- Number of brands having price more than DPCO ceiling price
- Number of brands having price less than DPCO ceiling price

RESULTS

A total of eight different dosage forms of five anti-diabetic drugs are available in NLEM 2015 that includes Tab. Glimepiride 1 mg and 2 mg, Tab. Metformin 500 mg, 750 mg and 1000 mg, Soluble Insulin 40 IU/ml, Intermediate-acting insulin (NPH) 40 IU/ml and Premix insulin 30:70 injection (Regular:NPH) 40 IU/ml.

The total number of brands available for anti-diabetic drugs in IDR/CIMS was 54 for glimepiride 1 mg, 53 for glimepiride 2 mg, 58 for metformin 500 mg, 21 for metformin 1000 mg, 9 for soluble insulin 40 IU/ml and 3 for Premix insulin 40 IU/ml. While in pharmacy stores, the total number of brands available for these drugs were 12 for glimepiride 1 mg and 2 mg each, 7 for metformin 500 mg, 3 for metformin 1000 mg, 3 for soluble insulin 40 IU/ml, and 1 for Premix insulin 40 IU/ml. Hence more brands were available for Glimepiride than other anti-diabetic drugs while very few brands were available for premix insulin in IDR/CIMS as well as in pharmacy stores. However, we couldn't find any brand for metformin 750 mg and intermediate-acting insulin in pharmacy stores as well as in IDR/CIMS.

Table 1 shows the total number of brands available for each anti-diabetic drug formulation available in IDR/CIMS along with a range of minimum to maximum price, percentage price variation between maximum and minimum price for the respective dosage form and percentage deviation of maximum and minimum price from ceiling price. Amongst 8 different dosage forms, a wide range (1.7 Rs/unit-13.2 Rs/unit) of price along with the highest percentage price variation (676.5%) was found between different brands of glimepiride 2 mg. While the narrow range of price (14.3-19.9 Rs/unit) along with the lowest percentage price variation (39.1%) was found between different brands of premix insulin (30:70). Similarly, the highest percentage deviation (146.7%) of maximum price from ceiling price was found for glimepiride 2 mg while the lowest % deviation (40.8%) of maximum price from ceiling price was found for premix insulin (30:70). It was also found that glimepiride 2 mg has the highest percentage deviation (68.22%) and soluble insulin has the lowest percentage deviation (8.70%) of minimum price from ceiling price. Surprisingly all 3 brands available for premix insulin were found above ceiling price and not a single brand was found having equal/less price than CP.

Table 1 Comparison of brand-price with DPCO ceiling price for anti-diabetic drug formulations available in IDR/CIMS

Sr. No.	Name of drug	Ceiling price (Rs/unit #)	Number of brands in IDR/CIMS			Range (min-max) (Rs/unit #)	Price variation (max-min /min × 100)	Deviation of max. price from CP (%)	Deviation of min. price from CP (%)
			Total no.	No. brands above CP	No. brands below CP				
1	Glimepiride 1 mg	3.37	54	11 (20%)	43 (80%)	1.1-6.9	527.30%	104.70%	67.36%
2	Glimepiride 2 mg	5.35	53	10 (19%)	43 (81%)	1.7-13.2	676.50%	146.70%	68.22%
3	Metformin 500 mg	1.41	58	35 (60%)	23 (40%)	0.6-3.2	433.30%	126.90%	57.45%
4	Metformin 750 mg	2.85	---	---	---	---	---	---	---
5	Metformin 1000 mg	3.38	21	11 (50%)	10 (50%)	2.2-5.5	150%	62.70%	34.91%
6	Soluble insulin 40 IU	14.13	9	7 (78%)	2 (22%)	12.9-21.8	68.90%	54.30%	8.70%
7	Intermediate acting insulin (NPH)	14.13	---	---	---	---	---	---	---
8	Premix Insulin (30:70)	14.13	3	3 (100%)	---	14.3-19.9	39.10%	40.80%	---

#1 unit=1 tablet in solid dosage form, 1 unit=1 ml in liquid dosage form

We also analyzed the total number of brands available for each anti-diabetic drug formulation available in Pharmacy stores along with the range of minimum to maximum price, percentage price variation between maximum and minimum price for the respective dosage form and percentage deviation of maximum and minimum price from ceiling price (Table 2).

Table 2 Comparison of brand-price with DPCO ceiling price for anti-diabetic drug formulations available at different pharmacy stores

Sr. No.	Name of drug	Ceiling price (Rs/unit#)	Number of brands in Pharmacy stores			Range (min-max) (Rs/unit)	Price variation (max- min /min × 100)	Deviation of max. price from CP (%)	Deviation of min. price from CP (%)
			Total no.	No. brands above CP	No. brands below CP				
1	Glimepiride 1 mg	3.37	12	4 (33%)	8 (67%)	0.6-6	900%	78.00%	82.19%
2	Glimepiride 2 mg	5.35	12	5 (42%)	7 (58%)	0.9-7.8	766.70%	45.80%	83.18%
3	Metformin 500 mg	1.41	7	4 (57%)	3 (43%)	0.8-6.5	712.50%	360.90%	43.26%
4	Metformin 750 mg	2.85	---	---	---	---	---	---	---
5	Metformin 1000 mg	3.38	3	2 (67%)	1 (33%)	3-4.5	50%	33.10%	11.24%
6	Soluble insulin 40IU	14.13	3	3 (100%)	0	14.8-15.3	3.40%	8.30%	---
7	Intermediate-acting insulin (NPH)	14.13	---	---	---	---	---	---	---
8	Premix insulin (30:70)	14.13	1	0	1 (100%)	13-14.5	7.70%	---	7.99%

#1 unit=1 tablet in solid dosage form, 1 unit=1 ml in liquid dosage form

Among 8 different dosage forms, a wide range (0.6 Rs/unit-6 Rs/unit) of price along with the highest percentage price variation (900%) was found between different brands of glimepiride 1 mg. While the narrow range of price (14.8 Rs/unit-15.3 Rs/unit) along with the lowest percentage price variation (3.4%) was found between different brands of soluble insulin. In contrast to IDR/CIMS, the highest percentage deviation (360.9%) of maximum price from ceiling price was found between different brands of metformin 500 mg, while the lowest percentage deviation (8.3%) of maximum price from ceiling price was found between different brands of soluble insulin.

Similarly, the highest percentage deviation (83.18%) of minimum price from ceiling price was found between different brands of glimepiride 2 mg in pharmacy stores also, however, the lowest percentage deviation (7.99%) of minimum price from ceiling price was found between different brands of premix insulin (30:70). It was also found that only one brand of premix insulin was available and that too was below ceiling price.

Among different branded anti-diabetic drugs available in IDR/CIMS drug, Premix insulin 30:70 had the highest percentage of brands (100%, n=3) having price more than DPCO ceiling price followed by soluble insulin 40 IU/ml (78%, n=9) and metformin 500 mg (60%, n=58). While glimepiride 2 mg had highest percentage (81% n=53) of brands below ceiling price followed by glimepiride 1 mg (80%, n=54) and metformin 1000 mg (50%, n=21) (Table 1). Whereas in pharmacy stores, soluble insulin 40 IU/ml was found to have the highest percentage of brands (100%, n=3) with price more than DPCO ceiling price followed by metformin 1000 mg (67%, n=3) and metformin 500 mg (57%, n=7). While premix insulin 30:70 had the highest percentage (100%, n=1) of brands below ceiling price followed by glimepiride 1 mg (67%, n=12) and glimepiride 2 mg (58%, n=12) as shown in Table 2.

We also found that out of a total number of brands for all anti-diabetic drug formulations available in IDR/CIMS, the majority of the brands (61%, n=198) were found to have a price less than DPCO ceiling price, while in pharmacy stores, number of brands having price less than DPCO ceiling price (53%, n=38) and brands having above the ceiling price (47%, n=38) are found almost similar (Figure 1).

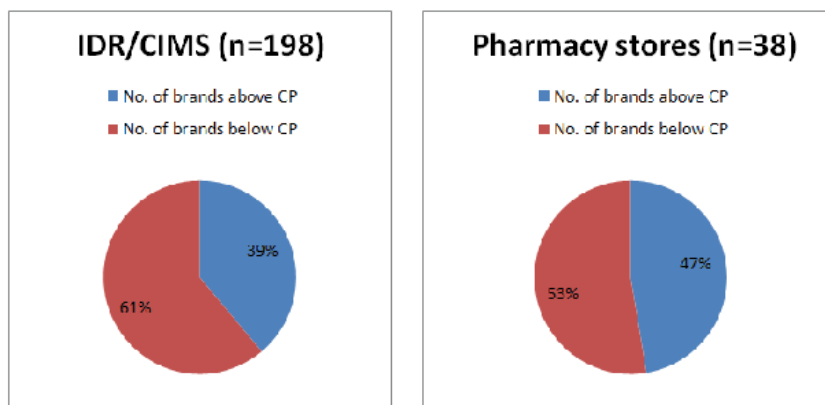


Figure 1 Showing total brands having price more than the ceiling price

DISCUSSION

Pricing of medicines is a very sensitive issue for a developing country like India. It has direct economic implications on patients and plays a significant role in determining compliance to treatment; the plethora of brands available in India for the majority of drugs further complicates this problem [1]. To ensure that vital drugs are available at affordable prices, the government of India exercises control over the prices of certain drugs defined as 'Essential' through an order called Drugs Prices Control Order commonly referred to as the DPCO. The current DPCO became effective in May 2013 and updated in August 2018 [5]. The National Pharmaceutical Pricing Authority (NPPA) implements this DPCO [12,13].

Multiple brands are available for a single drug in India and variations are known to be prevalent in the prices of these brands because an open competitive market system entertaining both domestic and foreign manufacturers is followed [10]. With the implementation of price control, such price variations are expected to have come down. The DPCO

states that reducing such inter-brand price variations in major therapeutic groups is one of its major aims [5]. Different brands of the same drug are the alternatives available for a patient, expected to provide the same therapeutic outcome. Analysis of their costs can highlight the phenomenon of 'inter-brand price variation' which can put a substantial financial burden on patients along with posing moral and ethical concerns [14].

Six of the top 10 drugs sold in India are anti-diabetes brands. For most multinational drug makers the diabetes market has been highly lucrative. Indian diabetic market consists of 1,954 million USD in 2018. India is the country that leads the world with its largest diabetic population of 32 million in the year 2000. This number is predicted to rise to 80 million by the year 2030. It has also been observed that the prevalence is higher and rapid in urban areas from 2% in the 1970s to 12% in 2000, as well in rural areas; this is now also beginning to increase [15].

Among medical expenditure, anti-diabetic agents and diabetes supplies contribute 12%. People with diagnosed diabetes incur average medical expenditures of about \$13,700 per year, of which about \$7,900 is attributed to diabetes [11]. Despite the government of India's attempt to prevent unjustifiable pricing of drugs by enacting the DPCO, 1970 as well as incorporating the National List of Essential Medicine (NLEM), there exists a wide variation of drug prices within one drug with the availability of various brands [16,17].

Hence, the present study was carried out with the objectives of comparison of cost and percentage price variation among anti-diabetic drugs across the different brands available not only in the drug compendia like IDR/CIMS but also at pharmacy stores from where patients buy their medicines.

In our study, we have analyzed a total of 8 anti-diabetic drugs available in NLEM for which a total of 198 different brands were available in IDR/CIMS and 38 brands at pharmacy stores. So the number of brands available at pharmacy stores are very limited as compared to brands available in IDR/CIMS, similar observations are found in a study done by Millard, et al. in Maharashtra in 2018 regarding the available brands of six essential medicines in pharmacy stores, where only a small proportion was available in the study pharmacies as compared the brands that were available in India as per four databases like CIMS, Medindia, Medguide and Pharmatrac. Market competition has certainly led to the approval of a very large number of brands. The frequency of the availability of brands in the study pharmacies showed that only a small number of products were dominating the market [5]. Which leads the consumers to have very limited choice to buy the medicine at pharmacy stores even though several branded products available for each drug is more in the database that may influence the cost of the therapy?

Our study findings showed a wide range of the minimum and maximum price of anti-diabetic drugs manufactured under different brand names. In our study, maximum price variation among different brands of anti-diabetic drugs available in IDR/CIMS was seen for Glimepiride 2 mg (677%) followed by Glimepiride 1 mg (527%) and Metformin 500 mg (433%). Similar findings were observed in an Indian study done by Salman Hussain in 2015, where price variation of 682% was found between different brands of Glimepiride 2 mg, while 445% of price variation was found for Metformin 500 mg [18]. Price variation is quite common in India as observed in three different studies done in which, 788.88% of price variation between different formulations of Theophylline was found by Dharani Devangi, et al., quite a huge price variation of 2060.8% was found for Diclofenac 25 mg/ml formulation by Atal, et al. in 2016 and price variation of 2757% was found between different brands of Rosuvastatin 10 mg in another study done by Lakdawala A published in 2018 [14,19,20].

Such large brand price variation in the 'price controlled' essential drugs are alarming; An expensive brand can cost a patient much higher than the cheapest brand and actual DPCO ceiling price. It is a serious matter in developing countries like India where the concept of health insurance yet to be adopted on large scale and 50%-90% of the medical cost is borne out of pocket by the patient. One of the primary reasons for brand price variation in the Indian pharmaceutical market is the very nature and composition of the pharma sector in India which is predominantly a branded generic market i.e. multiple companies sell a particular drug under different brand names. Hence, the number of brands available in the market is very high: 60,000-70,000. This means that current price control mechanisms haven't been successful in bringing down the brand price variations effectively [14].

The DPCO is a welcome initiative by the government aimed at checking the rising drug prices. But there seems to be a fault in the DPCO ceiling price design and implementation of the order. The consequences of this unwarranted expenditure become more severe in the management of chronic diseases like hypertension, dyslipidemia, arthritis, tuberculosis, diabetes [5].

In our study, the highest percentage variation of maximum price from ceiling price was found in Glimepiride 2 mg (147%) followed by Glimepiride 1 mg (105%), and the highest percentage variation of minimum price from ceiling price was found in Glimepiride 2 mg (68%) followed by Glimepiride 1 mg (67%). Very high percentage variation of maximum price for clopidogrel (278%) and Amlodipine (227.8%) was found in a study done by Atal, et al. at the same time almost 79% price variation of minimum price from ceiling price was found for Atorvastatin and clopidogrel in the above-mentioned study [14]. Glimepiride is one of the most commonly used anti-diabetic drugs similar to clopidogrel as anti-platelet and atorvastatin as an anti-hyperlipidemic drug. Percentage variation of maximum price from ceiling price should be minimum to decrease the economic burden and improve compliance of the patient.

Indian markets are flooded with a huge number of branded formulations, available for every drug molecule, with simultaneous pricing differences between the different brands of the same formulation. This apart from creating confusion among innocent consumers, often, allows them to be misled by unfair traders. This may be due to the brand loyalty of the prescribers. If the consumers were the decision-makers the picture could have been different since the price factor would play a major role then [10].

In the present study, percentage price variation between minimum and maximum price of different brands available at pharmacy stores were analyzed showing very high variation for Glimepiride 1 mg (900%) followed Glimepiride 2 mg (767%) and Metformin 500 mg (713%). Similarly, the highest percentage variation of maximum price from ceiling price was found in Metformin 500 mg (361%) followed by glimepiride 1 mg (78%), and the highest percentage variation of minimum price from ceiling price was found in Glimepiride 2 mg (83%) followed by Glimepiride 1 mg (62%). There were no studies found for comparison of price variation among different brands available at pharmacy stores. In our study, 61% of brands available in IDR/CIMS were found to have priced less than DPCO ceiling price similar to another Indian study done by Kumar et al for anti-hypertensive branded drugs in 2019 in which 60.88% of brands were found to have a price less than DPCO recommended list [21]. However many branded drugs price are not following DPCO/NPPA.

The proposed reasons for basic price variations among marketed formulations can be lenient Government regulations and pricing policies, the economic goals of the parent company, target return on investment, the total expenditure of production, distribution and drug promotion, existing composition of the pharmaceutical industry, and prescriber's knowledge about drug costing. As in India multiple companies sell a particular drug under different brand names that will further lead to huge price variation among different branded drugs.

The strength of this study is that it analyzes different branded drugs price available at pharmacy stores to get a better picture of reality. But at the same time price variation found at the pharmacy stores in this study cannot be generalized as pharmacy stores included were only from a specific area (Ahmedabad).

CONCLUSION

A wide variation in the price range of different anti-diabetic branded drugs is observed. Pharmacy stores should also have brands for the same drug so that consumers will have more options to select cost-effective brands. DPCO pricing policies need to revise and ensure regulatory checks to bring all brand's prices within ceiling price limits. Besides price control, it is also very important to educate prescribers regarding huge price variation among different brands of the same drug and its effect on treatment compliance so that they can choose a cost-effective agent for a patient to reduce the economic burden on the patient as well as on healthcare system.

DECLARATIONS

Conflicts of Interest

The authors declared no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

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