

Pharmacoeconomics of Antidiabetic Drugs

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Abstract

Context: Diabetes mellitus is a severe chronic lifelong disease due to a combination of insulin release and insulin secretory defect characterized by polyuria, polydipsia, and polyphagia. Antidiabetic drugs are available in different formulations that create wide price variation in regulated (India) and less regulated market (US). **Objective:** The objective of this study was to analyze price variation of unit dosage form manufactured by different companies for the same formulation with the same strength in both markets by calculation percentage price variation among the market. **Materials and Methods:** Cost of particular unit drug manufactured by different companies, in the same strength, was obtained from “current index of medical specialties” and “Indian Drug Review” for regulated market and from “GoodRX” and “Online Pharmacies” for less regulated market in both INR and USD. **Results:** However, percentage price variation is less in the US than in India, but prices are extremely high. In India, sitagliptin (50 mg) shows maximum price of 38.43 INR (0.5910 USD), whereas glibenclamide (2.5 mg) shows minimum price of 0.26 INR (0.0040 USD); in the US market, sitagliptin shows maximum price of 346.77 INR (5.3333 USD), whereas glipizide (2.5 mg) shows minimum price of 13 INR (0.1999 USD). **Conclusion:** Our findings revealed that the prices of various antidiabetic formulations show great variation. Modification in price regulation is required in the US to reduce unfair burden on both patient and health-care system.

Key words: Antidiabetics, drug price control order, less regulated market, price variation, regulated market

INTRODUCTION

Diabetes mellitus is a chronic disorder that involves lifelong pharmacological and non-pharmacological management to prevent complications such as cardiovascular disease, retinopathy, nephropathy, and neuropathy.^[1] In this disorder, body's ability to respond to the hormone is impaired which results in abnormalities in the function of metabolism of carbohydrates and main cause of increasing the levels of glucose in the blood. As per the WHO, it is one of the major causes of morbidity and mortality which accounts for 1.6 million deaths worldwide in 2015.^[2] The WHO projects that diabetes will be the seventh leading cause of morbidity in 2030. According to the National Diabetic Statistical Report, 2017, of the US, about 18% of the whole US population below the age of 18 years, 0.24% of the population below the age of 20 years, and approximately 5% of the population are suffering from Type 1 diabetes and all over prevalence keep increasing as the rate of obesity and overweight rises.^[3,4]

It requires lifelong treatment, so the cost of the drug is the major concern to both physician

and patient.^[5] The main cause of type 1 diabetes is that body immune system recognizes the beta cell as a foreign material and destroys them completely. That is why it is also termed as autoimmune disease. Hence, insulin-producing beta cells in the pancreas get damaged and the body is not able to produce insulin. Normal blood glucose level is not maintained and a patient suffering from type 1 diabetes requires regular insulin administration either through insulin injection or insulin pump.

Symptoms of type 1 include polyphagia, polydipsia, polyurea, blurred vision, fatigue, weight loss, and ketoacidosis as the complication of diabetes.^[6] Due to the destruction of autoimmune beta cell, most of the people are suffering from type 1 diabetes. All patients with type 1 diabetes eventually become insulin dependent, whereas type 2 diabetes is known as non-insulin-dependent diabetes mellitus/maturity onset

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diabetes mellitus. In type 2 diabetes, there is no loss or destruction of beta cells, but body becomes resistant to insulin and not able to use it effectively for the normal function of the body. It may occur due to genetic and unhealthy lifestyle. Over 90% cause of diabetes is type 2 diabetes.^[7,8]

The American Diabetes Association suggests that blood sugar before meals should be 70–130 mg/dL and blood sugar after meals should be <180 mg/dL. At the time of diagnosis, it is estimated that 50% of β -cell function has been lost in individuals with type 2 diabetes 1. In recent years, pharmaceutical industry has grown with tremendous pace globally due to which markets are available with huge number of branded formulations with large difference in the manufacturing cost and their maximum retail price of the drugs, and it creates economic implications for the patients.^[9,10] Pharmacoeconomics is the branch of pharmaceutical science which deals with description and analysis of the cost of different drug formulations available in market.^[11]

Lack of proper knowledge of the cost of various antidiabetic drugs in regulated and less regulated market leads to difficulties in prescribing most cost-effective drug to the patient. Furthermore, no study was done to compare the cost of different brands in different markets. Hence, the aim of this study was to carry out pharmacoeconomic analysis of different antidiabetic formulations. The objective of this study is to evaluate the cost of antidiabetic medications of different generic classes and different brand names of one compound available in price-regulated and less regulated market by calculating the percentage price variation.

MATERIALS AND METHODS

The drug costs were obtained from “current index of medical specialties (CIMS),” “Pharma Sahi Daam by National Pharmaceutical Pricing Authority (NPPA),” “GoodRX,” and “Online Pharmacies”. The data are updated regularly on these portals. The drug price acquisition was calculated for unit tablet for the comparison. The author took only one dosage form, i.e., tablets for the uniformity of the data in both markets.

The minimum and maximum price of the same dosage form and the same formulation was collected, respectively, for regulated and less regulated markets. The percentage price variation was calculated for both. For the calculation of percentage price variation, the formula used is as follows:

$$\text{Percentage price variation} = \frac{\text{Maximum price} - \text{Minimum price}}{\text{Maximum price}} \times 100$$

Statistical analysis

Data collected from the database were transferred to Microsoft Office Excel for evaluation. Prices of both markets

were collected for the entire list of drugs of both markets which was filtered through MS Excel, and then, percentage price variation was calculated.

RESULTS

The cost of eight monotherapy antidiabetics which are available in 23 different strengths and manufactured by different pharmaceutical companies was evaluated.

Data in Figure 1 reflect the maximum and minimum price of oral single formulations of antidiabetics in regulated market (India) in both rupees (INR) and dollars (USD) in which sitagliptin (50 mg) shows the maximum price of 38.43 INR (0.5910 USD), whereas glibenclamide (2.5 mg) shows the minimum price of 0.26 INR (0.0040 USD).

Data in Figure 2 reflect the maximum and minimum price of oral single formulations of antidiabetics in less regulated market (US) in both rupees (INR) and dollars (USD), in which sitagliptin (100 mg) shows maximum price of 346.77 INR (5.3333 USD), whereas glipizide (2.5 mg) shows the minimum price of 13 INR (0.1999 USD).

It is clear from the Figure 3 that there are wide fluctuations of prices in regulated and less regulated market for antidiabetic formulations.

DISCUSSION

The study was carried out with the aim of computing the costs and difference in cost among antidiabetic drugs across the different brands available in regulated and less regulated market. Findings reveal that the prices of most of the antidiabetics in less regulated market have higher prices as compared to regulated market which is not acceptable for patient leading to unfair burden on the customers. There are not even single formulations which have more prices in regulated market.

There are different brand names for the same drug with different prices. In regulated market, the drug prices are controlled by drug price control order (DPCO) 2013. NPPA established in 1997 and DPCO along with the Government of India fix the ceiling price of 11 bulk drugs and make sure that no Indian company should take advantage of it. The drug prices are revised every year according to wholesale pricing index. DPCO, 1970, is the main objective to achieve adequate production, also to maintain the supply of the drugs, and to avail it at fair price. It was introduced when most of India's drugs were under strict price controls.^[12]

Regulated markets are the medium for the exchange of goods or services over which a government body has a control. It may require market participants to conform the environmental standards, product-safety specifications, information disclosure

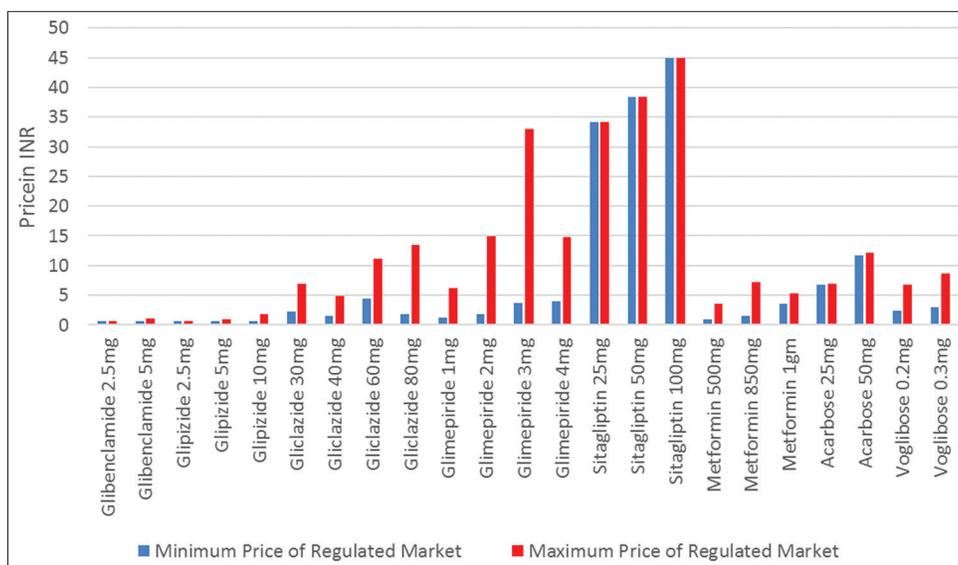


Figure 1: The cost variation of antidiabetic drugs available in different formulations in regulated market. It is clear from the graph that there is a huge variation of prices among regulated market also

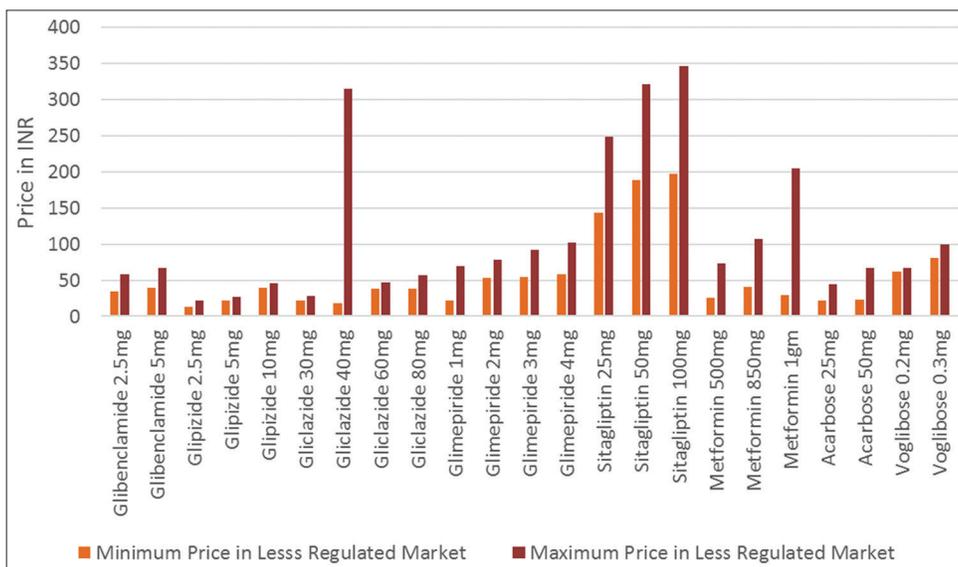


Figure 2: The maximum and minimum price of antidiabetic drugs in less regulated market

requirements, etc. The market for prescription as well as over-the-counter drugs is an example of a regulated market. The Indian market for prescription as well as over-the-counter drugs is an example of a regulated market.^[12-14] Less regulated markets are those on which there is no control of government to fix the minimum or maximum price. They set their price with their own wish. In less regulated markets like United States there is no control of government to fix the minimum or maximum price. They set their price with their own wish.^[15] The journal of the American Medical Association published the reason of higher prices in less regulated market that are as follows:

United States follows cGMP regulations enforced by the US Food and Drug Administration (FDA) that assures the identity, strength, and quality of the pharmaceutical preparations but impose no regulation on pricing of the

product, this is the main factor of high prices of drugs.^[16] India follows DPCO and NPPA for the control of maximum and minimum prices of drugs, so the manufacturers do not have authority to change the prices of pharmaceuticals by their own.^[17] On the other side, there is no regulation scheme in the US, so drug manufacturers can set their own price that leads to higher prices of drugs. The cost of labor and material (API, excipients, and equipment) is different in regulated and less regulated market like in India; the amount is less for both labor and the cost of API, whereas in the US, they pay a significant amount to the labor and for the raw material. There are government and private payers (insurance companies) that charge different to different people and location, so depending on the payer, the cost of particular drug going to be change leads to higher prices in pharmaceuticals. Some of the pharmaceutical markets based on their earlier structure



Figure 3: The price variation between regulated market and less regulated market. The blue color in the graph represents minimum price in regulated market; red represents maximum price in regulated market; green represents minimum price in less regulated market; and orange shows maximum price in less regulated market

existence lead to price variation of the drugs depending on their location. There are many formulations, prices of which are directly controlled by inventors (patented drugs) which leads to the fluctuations in the prices.^[18]

FDA is a federal government body, it control and protect the health of public by having a strong policy for drug approvals as a result the quality, safety and efficacy of drugs that is sold in the market is maintained. It also have strict guidelines on how a drug should be advertised and prescribed for public use. In 1947, at the time of independence, India's pharmaceutical market was under the control of Western MNCs. About 99% of all formulations under patent by the foreign companies, so the prices were too high in India. The Indian pharmaceutical market remained import dependent because 80–90% of drugs were imported in foreign countries. To terminate the dominance of foreign drug companies, the Indian government enacted a series of policies designed for the production of basic drugs and these amendments laid the foundation for a highly competitive domestic industry that is capable of offering some of the lowest drug prices in the world. Now, the Indian Pharmaceutical Industry in the world became the fifth largest producer of bulk drugs and the highly regulated market.^[19]

The pharmacist also has a role in the price variation of the drugs. There is some pharmacist that does not give the actual brand written by the prescriber, and they change the brand and give some costly drug. Pharmacists are earning from that costlier brand.^[20] Pharmacoeconomics should be introduced in the undergraduate medical curriculum in which students should learn how to use CIMS or MIMS for selecting the cheapest available formulation of a particular drug.^[21]

CONCLUSION

The study results make the prescriber and people aware about various brands of antidiabetics available throughout the world with their difference in prices in regulated and less regulated markets so that this variation in the prices can be reduced by regulating the areas and pharmaceutical companies who actually do not follow it. This will help in reducing the economic and health-related burden on both patient and prescriber. The generic drugs can reduce the expenditure of patients on the drugs. Hence, the changes in the pharmaceutical policies are mandatory and the prices in less regulated area should be controlled in an effective way.

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