International Journal of Research in Pharmacy and Pharmaceutical Sciences
www.pharmacyjournal.in
ISSN: 2455-698X
Received: 28-11-2021, Accepted: 13-12-2021, Published: 29-12-2021
Volume 6, Issue 6, 2021, Page No. 14-18

A prospective observational study on cost-effective analysis of oral hypoglycemic agents

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Abstract
Diabetis is a chronic metabolic disorder characterized by polyurea, polydipsia and polyphagia due to defect in insulin secretion or absorption. It requires lifelong treatment to maintain normal blood glucose level. The study was planned to analyze the cost variation in different brands of oral hypoglycemic drugs. Cost of particular drug manufactured by different companies in the same strength is determined and analyzed from many websites and the percentage price variation of branded drug from generic brand (Janaushadhi) was determined and Percentage variation of oral hypoglycemic drugs in Indian market and generic drug price was analyzed. The study result makes the people aware about the variation in price of various brands of oral hypoglycaemic drugs and Janaushadhi. The maximum price variation was found in Pioglitazone 15mg and the minimum price variation was found in Glibenclamidde 2.5mg compared to janaushadhi.

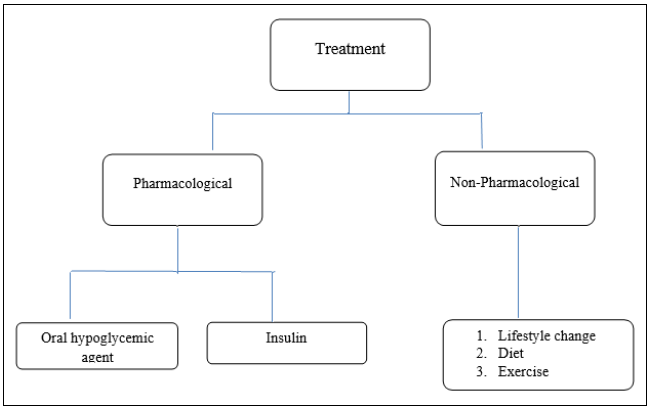
Keywords: pharmacoeconomics; type 2 diabetes mellitus; oral hypoglycemic drugs; branded and janaushadi drugs

Introduction
Diabetes mellitus [DM] is a chronic disorder is a group of metabolic disorder characterized by a high blood sugar level over a prolonged period of time. This happens when the cells become insensitive to insulin and blood sugar gradually gets too high, which requires regular monitoring. Oral hypoglycemic agents are the choice of treatment in treating type 2 diabetes mellitus. Since it requires a long-term treatment the cost of drugs has to be major concern. Hence it is important to analyze the cost of drug therapy. There are number of brands available to treat type 2 DM. The aim of this observational study review is to perform the cost percentage change in the branded and Janaushadi drug [1].

Hyperglycemia is a condition where postprandial blood glucose level is greater than 125 mg/dL while fasting blood glucose is greater than 180 mg/dL 2 hours.

Hyperglycemia if left untreated, can lead to many serious life-threatening complications that include damage to the eye, kidneys, nerves, heart, and peripheral vascular system. Hence it is very important to control hyperglycemia efficiently and competently to avoid complications of the disease and improve patient outcome [2, 3, 4].

Treatment: [5, 6]



Oral hypoglycemic agents: agents which are given orally to reduce the blood glucose levels in diabetic patients Five classes of oral hypoglycemic drugs are presently in use

Bigunides: Metformin

Sulfonylureas: Glimepiride, glyburide, tolbutamide, Glibenclamide, glipizide.

Meglitinides: Nateglinide, repaglinide

Thiazolidinediones: Pioglitazone, rosiglitazone

Alpha-glucosidase inhibitors: Acarbose, miglitol [7]

Since T2DM is a chronic disorder, it requires long term therapy. In the year 2018 INDIA has an estimated 77 million people with diabetes. One in six people [17%] in the world who is diabetic is from INDIA. T2DM is the commonest form of diabetes. It is a very big challenge for developing country like India to meet the demand and requirement of medicine. The marginalized population of India are not able to afford many branded medicines.

Compared to the branded version, generic version is available at a lesser price. In India, the generic medicines can be legally produced after the patent period of the branded medicines lapses.

Government of India [GOI] launched janaushadhi [JAS] in 2008 by Pradhan Manthri Bharathiya Janaushadhi Pariyojana [PMBJP] is a campaign launched by the department of the pharmaceutical in association with central pharma public sector undertaking, to offer a quality medicine at reasonable prices to the masses through committed outlet called Pradhan Mantri Bharathiya Janaushadhi Kendra. These provide generic medicine at much lesser price. The potency of these medicines is same as compared to expensive branded medicine available in open market. The JAS aims to redefine the treatment cost per person by ensuring quality medicine at cheaper prices through Jan Aushadhi Stores (JASt) where generic

medicines are available to every section of the public.

Pharmacoeconomics

Pharmacoeconomics is a scientific discipline concerned with the cost and value of drug, cost-benefit, cost-effectiveness, cost-minimization, cost of illness and cost-utility analysis to compare pharmaceutical products and treatment strategies.

Pharmacoeconomics has been defined as the description and analysis of the costs of drug therapy to health care systems and society. It identifies, measures, and compares the costs and consequences of pharmaceutical products and services.

Economic evaluations help decision makers determine whether the cost of this extra effectiveness provide by the new drug is worthwhile [8, 9].

Cost effective analysis (cea)

- CEA is the most commonly applied form of economic analysis in the literature, and especially in drug therapy.
- CEA is a technique designed to assist a decision maker in identifying a preferred choice among possible alternatives.
- CEA evaluates multiple drug treatments for the same condition.

The cost of the drug treatments is weighed against the effectiveness of the drug [10, 11, 12].

Methodology

1. Initial phase of the study was to find out the percentage price variation of different branded drugs and to carry out literature survey. Based on the inclusion and exclusion criteria pharmacies were enrolled in the study after obtaining the informed constant and price of branded. All relevant data required for the study was obtained. Mentioned in a suitably designed data collection for MS word.

Study site and design

This is a Prospective obeservational study on cost effective analysis carried out at community Pharmacy and Janaushadhi stores for a period of 4 months.

Study Criteria

Inclusion criteria

a. Different brands of 11 oral hypoglycaemic drugs were selected pharmacy providing drug information, Pharmacies selling two or more of same drug.
b. Top 10 brands of each drug was selected from online pharmacies; 1mg, Netmeds, Sasti medicines Medindia Janaushadhi, Medplus smart drug updates

Exclusion criteria

Non cooperating pharmacies, Pharmacies not disclosing the price of the drugs

Data collection procedure

Primary data was collected from different community pharmacies near to us, based on inclusion and exclusion criteria. Also visited the pharmacies and had direct conversations with responders and collected real time data from them by providing them forms regarding drug information. Since each pharmacy was providing different price for different brands we collected data for top 10 Oral hypoglycaemic agent brands in India from online sources. Also we visited Janaushadhi generic medicine centres to collect the data.

Results

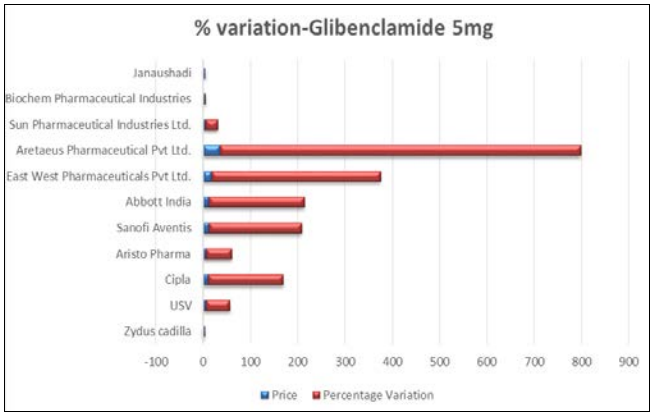


Fig 1

The price variation range (in %) of glibenclamide 5 mg lies between -1.2 to 764.2 with mean = 10.70818 and standard deviation = 9.276451

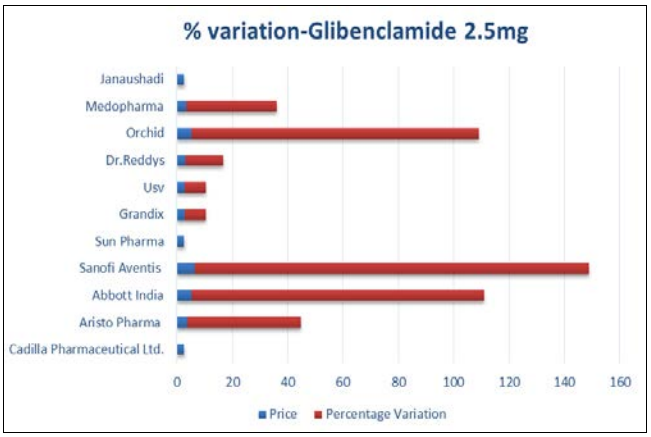


Fig 2

The price variation range (in %) of glibenclamide 2.5 mg lies between 0 to 142.7 with mean = 3.676363 and standard deviation = 1.339755

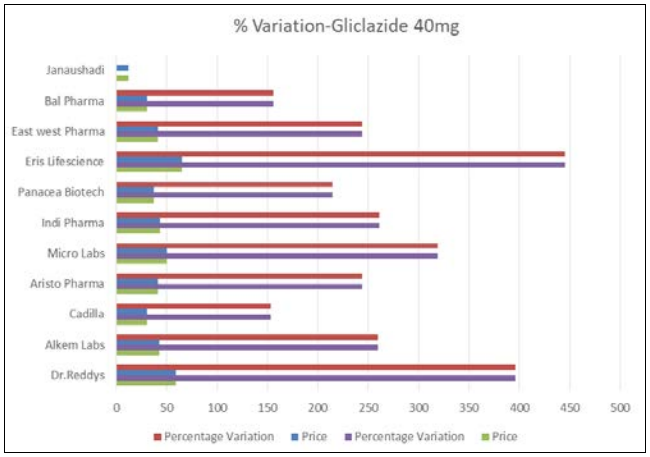


Fig 3

The price variation range (in %) of gliclazide 40 mg lies between 0 to 396.1 with mean = 41.1209 and standard deviation = 14.43168

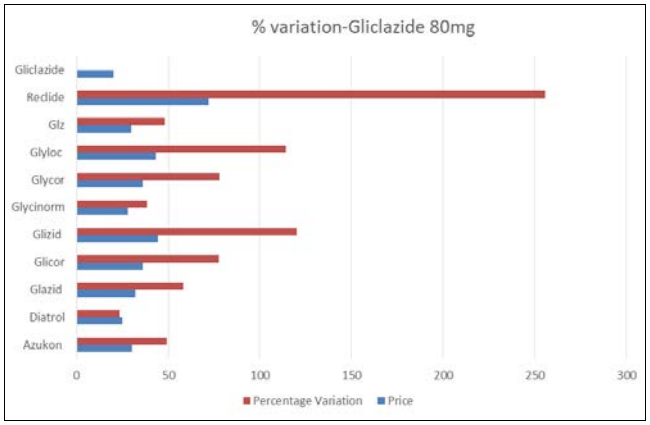


Fig 4

The price variation range (in %) of gliclazide 80 mg lies between 0 to 255.6 with mean = 36.12727 and standard deviation = 13.9348

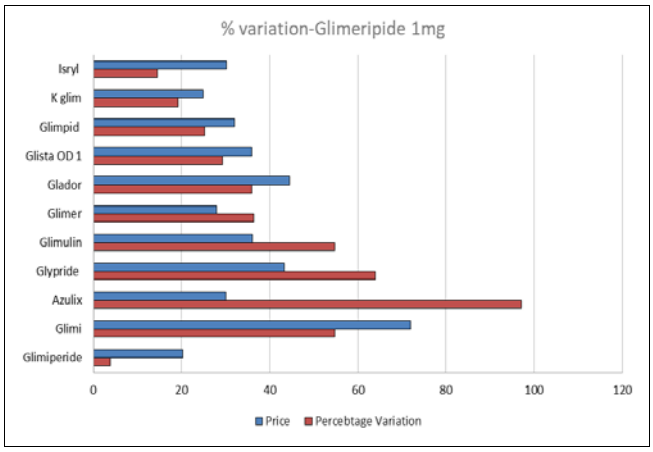


Fig 5

The price variation range (in %) of glimeperide 1 mg lies between 0 to 2457.9 with mean = 68.759 and standard deviation = 19.14152

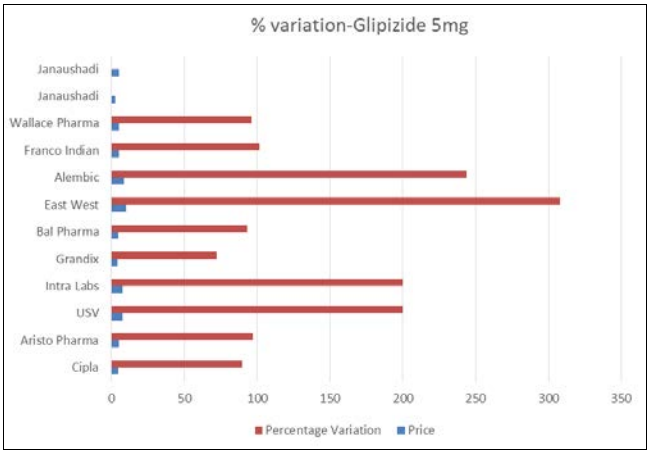


Fig 6

The price variation range (in %) of glipizide 5 mg lies between 0 to 308 with mean = 5.912727 and standard deviation = 2.240295

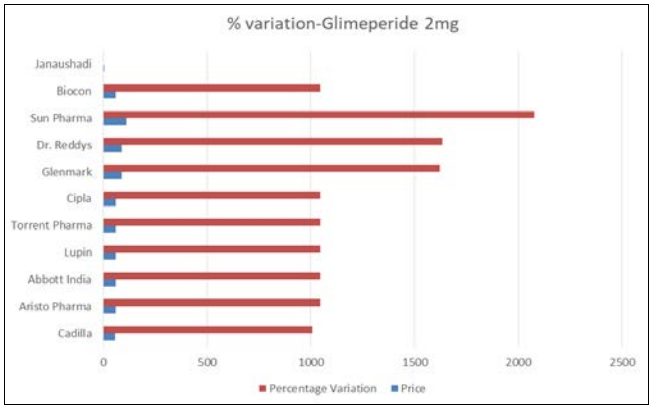


Fig 7

The price variation range (in %) of glimeperide 2 mg lies between 0 to 2078.2 with mean = 68.759 and standard deviation = 19.14152

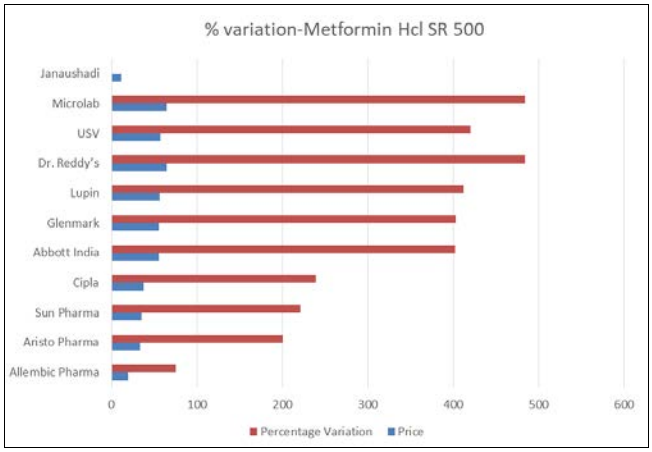


Fig 8

The price variation range (in %) of metformin HCl SR 1000 mg lies between 0 to 487 with mean = 47.974 and standard deviation = 15.35821

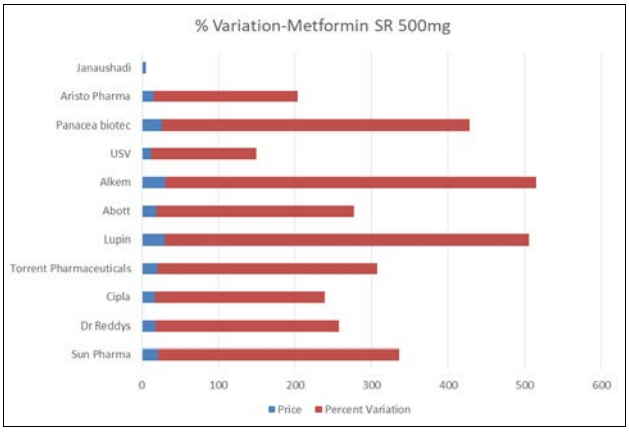


Fig 9

The price variation range (in %) of metformin HCl SR 500 mg lies between 0 to 485 with mean = 20.657 and standard deviation = 6.09818

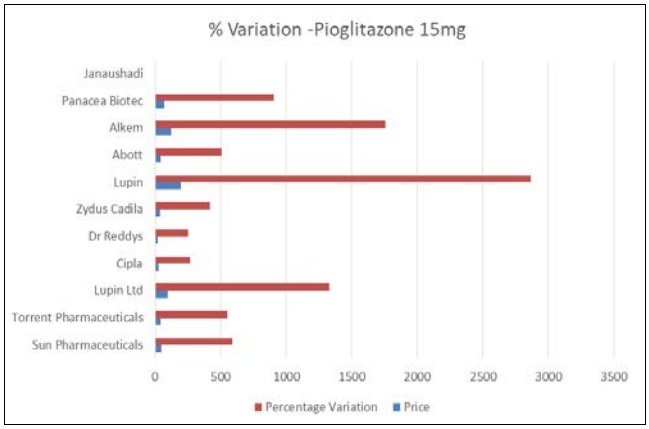


Fig 10

The price variation range (in %) of pioglitazone 15 mg lies between 0 to 2862.4 with mean = 70.465 and standard deviation = 55.9645

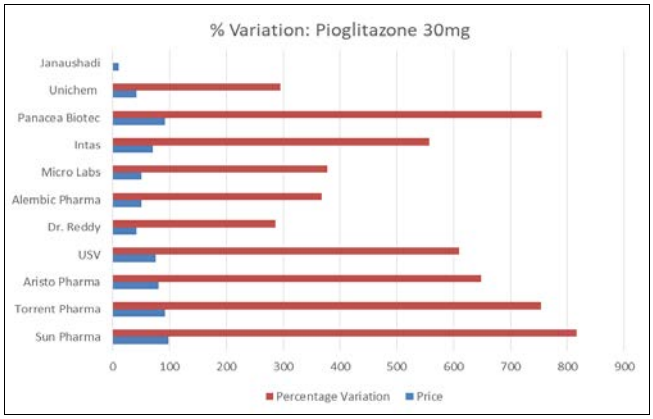


Fig 11

The price variation range (in %) of pioglitazone 30 mg lies between 0 to 816.7 with mean = 63.81363 and standard deviation = 26.98705

Table 1: Overall Comparison of Branded drugs to Generic drugs

S.No	Drug	Average(Mean)	Standard deviation	Price variation(Generic Vs Branded)	
				Min	Max
1	Glibenclamide 5 mg	10.70818	9.276451	-1.2	764.2
2	Glibenclamide 2.5 mg	3.676363	1.339755	0	142.7
3	Gliclazide 40 mg	41.1209	14.43168	0	396.1
4	Gliclazide 80 mg	36.12727	13.93484	0	255.6
5	Glimepreride 1 mg	39.5	26.5	0	2457.0
6	Glipizide 5 mg	5.912727	2.240295	0	308
7	Glimepreride 2 mg	68.759	19.014152	0	2078.2
8	Metformin HCL SR 1000 mg	47.974	15.35821	0	483.7
9	Metformin HCL SR 500 mg	20.657	6.09818	0	485
10	Pioglitazone 15 mg	70.465	55.9745	0	2864.4
11	Pioglitazone 30 mg	63.81363	26.98705	0	816.7

Discussion

The study was carried out with the aim of completing the cost of difference in cost amount of antidiabetic drugs among different brands

Due to the long term treatment duration, diabetic patients usually have higher than average monthly out-of-pocket expenses.

Compared to the branded version, generic version is available at a lesser price.

JAS aims to redefine the treatment cost per person by ensuring quality medicine at cheaper price. Through Janaushadi stores, where generic medicines are available to every stratum of the society. Even though generic medicines are available in low cost, people are preferring branded drugs.

Conclusion

The study result make the people aware about the variation in price of various brands of oral hypoglycaemic drugs and Janaushadhi. The maximum price variation was found in Pioglitazone 15mg and the minimum price variation was found in Glibenclamide 2.5mg compared to Janaushadhi.

Determining the price variation of drugs gives an idea about the different brands available in Indian market with their price so that it reduces economic burden on both patient and prescriber.

From our study we can conclude that not all the branded drugs have higher price, since some of the drugs have shown negative percentage deviation which means branded drugs are also available at lower cost or equivalent price as Janaushadhi.

Our study is an attempt of comparing the cost of different brands of drugs which gives information about the cost effectiveness of different drugs available in Indian market.

Acknowledgment

First and foremost, we would like to thank God Almighty for giving us the strength, ability and opportunity to undertake this study and to preserve and complete it satisfactorily.

We respect and thank Dr.Hanumanthachar Joshi, Principal, Sarada VilasCollege of Pharmacy, for being a great guide and Philospher and supporting us throughout our study.

We express our greatfulness to Prof. Dinesh M, Associate Professor and Head, Department ofPharmacognasy, Sarada Vilas College of Pharmacy.

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