



ANALYSIS OF COST VARIATION OF ORAL ANTIDIABETIC DRUGS AVAILABLE IN INDIAN MARKET: AN ECONOMIC PERSPECTIVE

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ABSTRACT

INTRODUCTION: Diabetes mellitus is a spectrum of metabolic disorders arising from a myriad of pathogenic mechanisms, all resulting in hyperglycaemia. It is one of the major causes of morbidity, mortality and needs lifelong treatment. There are various drugs available in the Indian market with different brand names and with wide variations in the prices. Thus, this study was planned to find out cost variation among different brands of same active oral anti-diabetic drug.

METHODS: The cost of a particular oral hypoglycaemic drug being manufactured by different companies, in the same strength and dosage forms, was referred from "Current Index of Medical Specialities" (May- July 2021). The difference between the maximum and minimum prices of same drug manufactured by different pharmaceutical companies was analysed and percentage variation in the prices and cost ratio were calculated.

RESULTS: In Single drug therapy, among sulfonylureas group of drugs, Glimpiride (2mg) showed maximum price variation of 1733.33% followed by Glimpiride(1mg) which was 1583.33%. The price variation of Metformin (500 mg), Pioglitazone (30 mg) and Vildagliptin were 811.36%, 630.91 % & 466% respectively. In -glucosidase inhibitors, Voglibose(0.3mg) showed maximum price variation of 664.48 %. Among meglitinides, Repaglinide(0.5mg) showed maximum price variation of 345.73%. The least price variation was seen in SGLT-2 inhibitor (Canagliflozin 1mg) of 0.92%. In combination therapies, Glipizide + Metformin (5 mg + 500 mg) combination showed the maximum variation of 1991 % followed by Glimpiride + Metformin (1mg + 500 mg) of 1117.57%. Positive correlation exists between the number of brands and percentage price variation of drugs.

CONCLUSION: This study shows a very wide percentage cost variation among different brands of the same oral anti-diabetic drugs available in India. To increase the benefits for patients, use of cheaper brands of same strength prescribing should be encouraged among physicians.

KEYWORDS : Pharmacoeconomics, cost, diabetes, price variation

INTRODUCTION:

The WHO defines Diabetes Mellitus as "A metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in the insulin secretion, insulin action, or both."⁽¹⁾ Diabetes, together with its host of micro and macrovascular complications is a common cause of morbidity, reduced quality of life and premature mortality.⁽²⁾

International Diabetes Federation (IDF) estimates that nearly 500 million people worldwide are currently living with diabetes, a number that is projected to increase by a further 30% in 2045.⁽³⁾ Nearly 10% of the global all-cause mortality (20–99 years age group) is attributable to diabetes.⁽³⁾

Diabetes is a chronic disorder which requires lifelong treatment.⁽⁴⁾ The management of type 1 diabetes mellitus includes mainly insulin, whereas the management of type 2 diabetes mellitus depends on oral antidiabetic drugs (OADs) as the first line treatment⁽⁵⁾. The level of morbidity and mortality due to diabetes and its potential problems are enormous, and pose significant healthcare burdens on both families and society.⁽⁶⁾ Cost of treatment is the major hurdle in effective treatment of disease and compliance towards the drug regimen⁽⁴⁾. In India which is a developing nation, the majority of diabetes patients experience a substantial cost burden due to out of pocket (OOP) expenditure. Also, the lack of insurance policies and government policies escalate the cost of diabetes care.⁽⁷⁾ On an average a person spends 20% of his or her income for the treatment of diabetes per year.⁽⁸⁾

Selection of oral antihyperglycemic agents as first-line drug or combined therapy should be based on both the pharmacological properties of the compounds (efficacy and safety profile) and the clinical characteristics of the patient (stage of disease, body weight, etc.)⁽⁹⁾ In Indian

pharmaceutical market there is a tough competition between the domestic and foreign manufacturers. India is the third largest market in terms of volume but thirteenth largest market in terms of value.⁽¹⁰⁾ There is an abundance of brands for a single drug which is manufactured by various companies and this consequently leads to a wide variation in prices for the same drug. Due to lack of information on comparative drug prices and quality, it becomes difficult for the physician, to decide the drug of choice for individual patients, keeping in mind, their socio-economic status.⁽¹¹⁾

National Pharmaceutical Pricing Authority (NPPA) is an organization of the Government of India which works to fix/revise the prices of controlled bulk drugs, formulations and to enforce prices and availability of the medicines in the country, under the Drugs Prices Control Order (DPCO), 1995. Once medicine is brought under DPCO, it cannot be sold at a price higher than that fixed by the government. In spite of all these efforts taken by government of India there exist a wide variation of prices within one drug due to availability of various brands.

The aim of this study was to estimate the existing situation of antidiabetic drugs in Indian market, by collecting data about the cost of oral antidiabetic drugs available either singly or in combination, number of manufacturing companies for these drugs and to evaluate the difference in cost of various brands of same active drug by calculating the range, cost ratio & percentage cost variation. Information generated from this study will be helpful for both the physicians in selecting the correct medicine for their patients and for the policy makers/government to successfully make use of the available resources.

MATERIALS AND METHODS:

The study was done in Department of Pharmacology of a Tertiary care hospital in Mumbai. In this study we analyzed the

prices of antidiabetic drugs. Current Index of Medical Specialities (CIMS) (May 2021- August 2021) was used to capture the prices of oral antidiabetic agents across the different brands available in the Indian market. Costs of drug in Indian rupees (for 10 tablets) were analysed according to the availability like single and combination therapy.

Inclusion Criteria:

- Antidiabetic drugs which are available as individual preparations.
- Antidiabetic drugs which are available as combination preparation.
- Antidiabetic drugs manufactured by two or more pharmaceutical companies.
- Antidiabetic drugs with complete verifiable information regarding strengths, formulations, brand name and cost.
- Antidiabetic drugs available as oral tablets/capsule.

Exclusion Criteria:

- The drugs being manufactured by only one company.
- Antidiabetic drugs with incomplete or non-verifiable information regarding strengths, formulations, brand name or cost.
- Antidiabetic drugs available as formulations other than oral tablets/capsule.

The retail cost of a particular drug being manufactured by different companies, in the same strength, number and dosage form was compared. The difference in the maximum and minimum price of the same drug manufactured by different pharmaceutical companies was calculated. The percentage variation in price and cost ratio was calculated. The percentage variation in price was calculated using the following formula:

$$\frac{(\text{Cost of brand with highest price} - \text{cost of brand with lowest price})}{\text{cost of brand with lowest price}} * 100$$

Cost ratio was calculated by the ratio of most expensive brand to least expensive brand of the same drug. It helps to know by how many times the most expensive formulation is costlier than the least expensive formulation of the same drug.

Statistical Analysis

The data collected was entered in Microsoft Excel 2019. Cost ratio and percentage cost variation were calculated. The data is represented in the form of tables and charts.

RESULTS:

In this study we analysed cost of various brands of 15 individual and 13 fixed dose combinations of oral antidiabetic drugs.

Overall, among the 7 categories of oral hypoglycaemic drugs available in the Indian market, the maximum price variability was seen highest with sulphonylureas (glimepiride 2mg - 1733.33%) followed by biguanides - Metformin 500mg (811.36%) which was followed by α- glucosidase inhibitor - Voglibose 0.3mg (664.48%), thiazolidinediones -Pioglitazone 30mg (630.91%), DPP4 inhibitor - Vildagliptin 50mg (466.00 %), meglitinides -Repaglinide 0.5mg (345.73%) and lowest was seen with Canagliflozin 100mg (0.92%).

The price variation among sulphonylureas is shown in Table 1. In this group, Glimepiride (2 mg) showed maximum price variation of 1733.33%, while Glimepiride (0.5mg) showed minimum price variation of 39.70%. The cost ratio ranged from

1.40 for Glimepiride 0.5mg to 18.33 for Glimepiride 2mg. The cost ratio for the most expensive Glimepiride 4mg and least expensive Glipizide 5mg was 191.28.

Table 2 shows price variation in Biguanides (Metformin), Thiazolidinediones (Pioglitazone), Dipeptidyl peptidase – 4 inhibitors (Vildagliptin, Teneigliptin) and - glucosidase inhibitors groups of drugs. Among these, Metformin (500 mg) & Pioglitazone (30 mg) showed maximum price variation of 811.36 & 630.91% respectively. Vildagliptin has only one formulation with price variation of 466%. The cost ratio of Metformin ranged from 1.85 for 250 mg to 9.11 for 500mg. The cost ratio for the most expensive 1000mg and least expensive 500mg tab is 13.05. The cost ratio of Pioglitazone ranged from 1.59 for 45mg to 7.31 for 30mg. Among the Dipeptidyl peptidase 4 inhibitors, Vildagliptin and Teneigliptin showed cost variation of 466% and 174.55 respectively. Among the - glucosidase inhibitors Voglibose 0.3 mg showed maximum price variation of 664.48% and Acarbose 25 mg showed minimum price variation of 80%. The cost ratio ranged from 1.80 for Acarbose 25 mg to 7.64 for Voglibose 0.3 mg. The cost ratio for the most expensive drug Miglitol 50 mg and least expensive drug Voglibose 0.2 mg is 10.63.

Among Meglitinide group, (Table 3) Repaglinide (0.5 mg) showed maximum price variation of 345.73 % whereas Nateglinide 60 mg showed minimum price variation of 179.58%. (Table 4). The cost ratio of Repaglinide ranged from 3.09 for 2mg to 4.46 for 0.5mg. The cost ratio for Nateglinide ranged from 2.80 for 60 mg to 3.35 for 120 mg. Among the Sodium Glucose Cotransport- 2 inhibitor (SGLT -2) the cost variation ranged from 0.92% for Canagliflozin 100mg to 288.57% for Dapagliflozin 5 mg.

Combination Therapy

In Combination therapy, total 13 combination preparations were analysed out of which 9 were two drug combinations and 4 were three drug combinations. In the two drug combinations, Glimepiride + Metformin (1 mg + 500 mg) showed the maximum variation of 1117.57%, while Glimepiride + Pioglitazone (2 mg + 15 mg) showed minimum variation of 31.44% (Table 4). Among the three drug combinations, maximum cost variation of 1003.40% was seen Glimepiride + Metformin + Pioglitazone (2 mg + 500 mg + 15mg) whereas lowest cost variation was seen in Glimepiride + Metformin + Voglibose (1 mg + 1000 mg + 0.2 mg).

We also observed that the percentage price variation increases as the no. of manufacturing companies increases. For example, Glimepiride 0.5 mg has total of 4 brands available in Indian market and shows cost variation of 39.70% whereas Glimepiride 2 mg has total of 149 brands available and shows cost variation of 1733.33%. This suggests that there exists linear correlation between the no. of manufacturing company and the percentage price variation. (Graph 1)

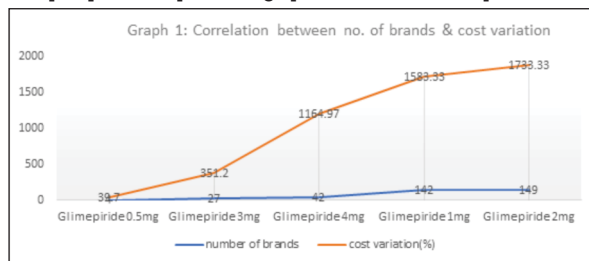


Table 1: Cost Variation Among Sulphonylureas

Drug	FormL	Dose in mg	No. of brands	Least expensive (INR)	Most expensive (INR)	Mean ± S.D.	Cost Ratio	Cost Variation (%)
1 Glibenclamide	2	2.5	10	2.66	19.14	5.97 ± 5.15	7.20	619.55
		5	19	3.73	13.34	7.87 ± 2.95	3.58	257.64
2 Gliclazide	4	30	21	18.22	83.55	52.99 ± 20.48	4.59	358.56

			40	31	6.00	50.00	28.07 ± 12.65	8.33	733.33
			60	26	39.00	138.33	90.67 ± 31.09	3.55	254.69
			80	65	16.66	80.00	44.05 ± 16.57	4.80	380.19
3	Glipizide	3	2.5	8	2.75	12.40	5.16 ± 3.84	4.51	350.91
			5	25	1.48	13.03	6.72 ± 2.91	8.80	780.41
			10	7	7.20	25.00	16.91 ± 5.48	3.47	247.22
4	Glimepiride	5	0.5	4	39.37	55.00	50.01 ± 7.27	1.40	39.70
			1	142	6.00	101.00	30.48 ± 13.45	16.83	1583.33
			2	149	9.00	165.00	49.62 ± 22.35	18.33	1733.33
			3	27	31.25	141.00	76.72 ± 33.31	4.51	351.20
			4	42	22.38	283.10	90.25 ± 49.01	12.65	1164.97

FormL - Formulation

Table 2: Cost variation among Biguanides, Thiazolidinediones, DPP-4 inhibitors, - glucosidase inhibitors

Drug	FormL	Dose in mg	No. of brands	Least expensive (INR)	Most expensive (INR)	Mean ± S. D.	Cost Ratio	Cost Variation (%)	
1	Metformin	4	250	6	7.70	14.23	10.85 ± 2.58	1.85	84.81
			500	148	4.40	40.10	17.53 ± 6.74	9.11	811.36
			1000	83	10.00	57.46	33.57 ± 8.84	5.75	474.60
			850	29	10.00	43.80	21.12 ± 10.72	4.38	338.00
2	Pioglitazone	4	7.5	10	33.50	71.25	55.51 ± 15.47	2.13	112.69
			15	67	16.37	79.75	36.38 ± 14.73	4.87	387.17
			30	63	18.47	135.00	56.50 ± 24.29	7.31	630.91
			45	3	58.00	92.32	70.10 ± 19.26	1.59	59.17
3	Vildagliptine	1	50	12	50.00	283.00	155.67 ± 89	5.66	466.00
4	Teneligliptin	1	20	72	55.00	151.00	102.83 ± 22.37	2.75	174.55
5	Acarbose	2	25	13	45.00	81.00	62.40 ± 12	1.80	80.00
			50	18	65.00	142.00	101.24 ± 25.24	2.18	118.46
6	Miglitol	2	25	10	48.00	146.66	75.06 ± 34.24	3.06	205.54
			50	10	90.00	223.33	134.66 ± 47.79	2.48	148.14
7	Voglibose	2	0.2	89	21.00	124.00	65.54 ± 20.68	5.90	490.48
			0.3	95	25.90	198.00	92.74 ± 32.86	7.64	664.48

Table 3: Cost variation among Meglitinides, SGLT-2 Inhibitors

Name of Drug	FormL	Dose in mg	No. of brands	Least expensive (INR)	Most expensive (INR)	Mean ± S.D.	Cost Ratio	Cost Variation (%)	
1	Repaglinide	3	0.5	9	19.90	88.70	45.46 ± 24.84	4.46	345.73
			1	9	39.90	145.00	75.62 ± 40.37	3.63	263.41
			2	7	75.00	231.65	117.06 ± 56.44	3.09	208.87
2	Nateglinide	2	60	3	30.76	86.00	52.33 ± 29.53	2.80	179.58
			120	3	51.27	172.00	117.12 ± 77.61	3.35	235.48
3	Dapagliflozin	2	5	3	140.00	544.00	392.88 ± 220.38	3.89	288.57
			10	4	185.00	573.50	360.75 ± 193.05	3.10	210.00
4	Canagliflozin	1	100	3	545.00	550.00	548 ± 2.64	1.01	0.92

Table 4: cost analysis of two drug preparations

Drug	For mL	Dose in mg	No. of brands	Least expensive (INR)	Most expensive (INR)	Mean ± S.D.	Cost Ratio	Cost Variation (%)	
1	Glibenclamide + Metformin	3	1.25 + 250	3	12.50	29.00	19.33 ± 8.60	2.32	132.00
			2.5 + 400	11	8.15	48.28	24.45 ± 13.57	5.92	492.39
			5 + 500	44	8.75	75.89	28.18 ± 14.21	8.67	767.31
2	Gliclazide + Metformin	5	80 + 500	123	9.90	116.68	59.77 ± 24.26	11.78	1078.57
			60 + 500	19	40.90	217.00	102.28 ± 39.52	5.31	430.56
			40 + 400	3	25.27	56.20	43.82 ± 16.36	2.22	122.40
			40 + 500	12	15.00	130	58.11 ± 30.06	8.67	766.67
			30 + 500	15	26.90	95.37	63.46 ± 22.04	3.55	254.54
3	Glimepiride + Metformin	12	1 + 500	200	11.95	145.5	57.41 ± 24.18	12.18	1117.57
			2 + 500	212	22.16	235.94	78.70 ± 37.12	10.65	964.71
			1 + 1000	57	31.9	195.5	84.39 ± 29.73	6.13	512.85
			1 + 850	5	53.46	75.85	64.89 ± 12.60	1.42	41.88
			2 + 1000	56	33.9	159.5	95.87 ± 28.38	4.71	370.50
			2 + 850	8	55	145.5	83.06 ± 17.27	2.65	164.55
			0.5 + 500	7	29.75	108	59.40 ± 37.56	3.63	263.03
			3 + 1000	23	68	157.5	117.50 ± 26.33	2.32	131.62
			3 + 500	9	70.8	168	103.22 ± 33.90	2.37	137.29
			3 + 850	6	61.5	120.78	90.15 ± 23.80	1.96	96.39
			4 + 1000	13	69	243	127.23 ± 45.46	3.52	252.17
			4 + 500	7	77.8	121	97.50 ± 13.49	1.56	55.53

4	Glipizide + Metformin	2	5 + 500	24	6.72	140.52	22.75 ± 28.47	20.91	1991.07
			2.5 + 400	6	4.75	26.25	9.70 ± 8.57	5.53	452.63
5	Pioglitazone + Metformin	3	7.5 + 500	7	35	127.5	74.79 ± 34.81	3.64	264.29
			15 + 500	56	20	83.15	52.28 ± 20.61	4.16	315.75
			30 + 500	29	31.9	142	68.77 ± 27.88	4.45	345.14
6	Voglibose + Metformin	2	0.2 + 500	62	30.9	158.4	77.3 ± 26.77	5.13	412.62
			0.3 + 500	60	34.9	150	92.71 ± 30.2	4.30	329.80
7	Vildagliptine + Metformin	3	50 + 500	7	62	277.7	134.59 ± 98.12	4.48	347.90
			50+ 1000	3	108	285.1	225.62 ± 101.86	2.64	163.98
			50 + 850	7	62.95	277.56	137.24 ± 78.36	4.41	340.92
8	Glimepiride + Pioglitazone	1	2 + 15	3	58.2	76.5	66.73 ± 9.21	1.32	31.44
9	Sitagliptin + Metformin	1	50 + 500	3	160	245	214.76 ± 47.50	1.53	53.13

Table 5: cost variation among three drug combinations

	Drug	FormL	Dose in mg	No. of brands	Least expensive (INR)	Most expensive (INR)	Mean ± S.D.	Cost Ratio	Cost Variation (%)
1	Glibenclamide + Metformin + Pioglitazone	1	5 + 500 + 15	11	10.78	86.5	66.10 ± 21.21	8.02	702.41
2	Glimepiride + metformin + Voglibose	7	1 + 500 + 0.2	67	54	176.25	114.67 ± 29.32	3.26	226.39
			2 + 500 + 0.2	74	69	232.32	140.76 ± 40.75	3.36	236.70
			1 + 1000 + 0.2	3	122	138.90	130.96 ± 8.49	1.14	13.85
			1 + 500 + 0.3	23	80	165.97	111.79 ± 20.96	2.07	107.46
			2 + 1000 + 0.2	3	130	186.15	164.04 ± 29.91	1.43	43.19
			2 + 1000 + 0.3	3	129.9	227.70	167.86 ± 52.43	1.75	75.29
			2 + 500 + 0.3	25	98	254.00	140.18 ± 33.98	2.59	159.18
3	glimepiride + metformin + pioglitazone	7	1 + 500 + 15	95	20	170	77.37 ± 27.01	8.5	750.00
			1 + 1000 + 15	6	82.5	137.3	103.03 ± 20.23	1.66	66.42
			1 + 500 + 7.5	18	32	83	59.87 ± 13.92	2.59	159.38
			2 + 1000 + 15	6	95	151.9	119.1 ± 21.31	1.60	59.89
			2 + 1000 + 7.5	3	81	98.9	87.3 ± 10.05	1.22	22.10
			2 + 500 + 15	97	25	275.85	97.79 ± 40.10	11.03	1003.40
			2 + 500 + 7.5	18	44	102.6	72.10 ± 15.75	2.33	133.18
4	gliclazide + metformin + Pioglitazone	1	60 + 500 + 15	3	86.3	120	99.13 ± 18.23	1.39	39.05

DISCUSSION:

Diabetes Mellitus (DM) is a complex and progressive disease which is associated with significant morbidity and mortality. It requires a long duration of treatment which affects patient's quality of life as well as imposes a huge burden on the family and society. It is visible from literature that rise in burden of diabetes can be due to high price variation among different brands of same drug. The compliance of patient depends on cost of prescribed medicines and higher cost means the compliance will be less⁽⁶⁾. Selection of cost effective brand will improve the compliance and consequence of treatment.

We conducted this study with the objective of computing the costs and percentage price variation among the oral antidiabetic drugs across the various brands available in the Indian market. The prices of drugs were captured from current index of medical specialities (CIMS) because these are regularly updated.

Our study findings showed a very high fluctuation in the minimum and maximum price of oral hypoglycaemic agents which is being manufactured by several companies across the different brands. In our study, among individual preparations, Glimepiride 2mg showed highest price variation of 1733.33%.

which was highest among the studies referred by us. However, Jadhav et al reported that Glimepiride 1mg showed maximum price variation of about 650%⁽⁵⁾. Date et al also showed that Glimepiride 2mg (830%) has the highest price variation⁽¹¹⁾. Hussain et al reported that Glipizide 5mg showed the highest price variation (780%)⁽⁴⁾. Dupaguntla et al showed Glimepiride 2mg has highest price variation of 892%⁽⁸⁾.

In our study, among fixed drug combinations Glipizide 5mg and Metformin 500 mg showed maximum price variation of 1991.07%. However Jadhav et al reported that combination of Glipizide 2.5mg and Metformin 400 mg showed maximum price variation of about 400%⁽⁹⁾. Date et al showed that combination of Glimepiride 1mg and Metformin 500mg has variation of 360% only⁽¹¹⁾. Hussain et al reported Glimepiride 1mg and Metformin 500mg combination showed the highest price variation of 533% among all recommended oral FDC.⁽⁴⁾ Dupaguntla et al showed Glimepiride + Metformin (1 mg + 500 mg) combination has the maximum variation of 346%⁽⁸⁾ Our results showed that the prices of most of the antidiabetic brands have percentage price variation above 100%, which is not acceptable situation for patients. Out of the 28 drugs studied, most of which are commonly prescribed, percentage price variation is very wide leading to the unnecessary burden

on the consumer. WHO Model list of 2021 includes the antidiabetic drugs Gliclazide, Canagliflozin and Dapagliflozin which show price variation of 733.33%, 0.92% , 288.57% respectively. In our study price variation was high in Glibenclamide 2.5mg (619.55%) and 5 mg(257.64%) and metformin 500 mg (811.36%), which are included in the essential drug list (EDL) and also comes under DPCO, thus raising questions about its price control. Furthermore, same finding was present in glimepiride, although it is not included in Essential Drug List.

Many people skip their doses because the treatment is out of pocket expense for them. Physicians on the other hand do not have information about the number of brands available and wide variation in costs of the drugs. Government should take some step in order to regulate & bring uniformity in price so that they are affordable by a common man which will improve the compliance and decrease the economic burden.

CONCLUSION:

Our study findings showed that there is wide variation in the minimum and maximum price of oral hypoglycaemic agents which are being manufactured by several companies. Cost of drugs plays an important role in treatment of diabetes mellitus as it is long term and compliance with the treatment is related to drug cost. It is high time to generate awareness among physicians about impact of cost effectiveness of drug regimen and for regulation of drug prices by the government agencies. The results of our study will make the prescriber informed about the various brands available in market and their cost variation. This will help in reducing the economic burden on patient as well as healthcare system.

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