

Cost variation analysis of Oral Hypoglycaemic agents available in Indian market: An Economic Perspective

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ABSTRACT

Introduction: Diabetes, a chronic disorder and requires life-long treatment. Cost of drug treatment is a major hurdle related to medication compliance in Type2 Diabetes Mellitus.

Objective: To compare the cost and percentage price variation of single and combination therapy of oral hypoglycaemic agents across the different brands available in the Indian market.

Methods: India's medical research body, particularly Indian Council of Medical Research (ICMR) issue guidelines for the management of T2DM. ICMR guidelines were perused to understand the management of T2DM. Current Index of Medical Specialities (CIMS) Oct.-Jan.2015 edition and Indian Drug Review (IDR) Issue 1, Jan.2015 were used to capture the price of oral hypoglycaemic agents across the different brands available in the Indian market. Percentage price variations between minimum and maximum cost of drugs were computed.

Results: In the single drug therapy sulfonylurea group of drugs like Glipizide 5mg shows maximum variation of 780% followed by Glimpiride 2mg formulation by 682%, while the non-sulfonylurea groups of drug say, Pioglitazone 15mg shows maximum variation of 600%. In combination therapy Glimpiride 1mg + Metformin 500mg shows maximum price variation of 533%. Positive correlation exists between the number of manufacturing companies and percentage price variation of drugs.

Conclusion: There is wide variation exist between the minimum and maximum cost among single as well as combination therapy of oral hypoglycaemic agents. A maximum of 9 & 6 fold price variation was reported in single and combination therapy respectively.

Key words: Branded drugs, Manufacturing companies, Diabetes Mellitus, Oral Hypoglycaemic agents, Percentage price variation.

Introduction:

Cost of drug therapy is the major hurdle in effective treatment of disease and compliance towards the drug regimen [1]. Effectiveness of the intervention depends upon the compliance of drug therapy. Improvement in compliance can reduce the total healthcare cost involved in the management of Type2 Diabetes Mellitus (T2DM) [2]. In Indian market, there is tough competition between the domestic and foreign manufacturers. There is inundation of brands in Indian markets for a single drug which is manufactured by various companies and consequently, leads to wide variation in prices for the same drug [3]. There are more than 100,000 formulations available for all the category of drugs under the umbrella of various brand names, there is no system of registration of these formulations [4].

Diabetes is a chronic disorder which requires lifelong treatment. Diabetes causing economic and health burden on both patients as well as the healthcare system. The main reason for this is increasing cost of treatment and prevalence rate of diabetes [5]. 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 [6-7]. As per the International Diabetes Federation (IDF), India with 65.1 million was at the second position after China (98.4 million) in terms of total number of diabetic subjects in 2013 [8].

Prescription drug expenditures are the fastest growing component of healthcare costs. Due to diabetes global health expenditure in the year 2013 was \$548 billion which will rise by \$79 billion up to 2035 [9]. Economic cost of diagnosed diabetes was increased by 41 percent over a five year period (2007-2012). In the year 2012 approximate cost of diagnosed diabetes was \$245 billion, including \$176 billion in direct medical costs. 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 [10].

Cost related non adherence was frequently seen in chronic diseases like diabetes mellitus. Sacks et al showed that branded co-payments for purchasing antidiabetic drugs increases non adherence rate [11]. Cost involved in diabetes treatment can be cut down by reducing the burden of complications which is directly associated with essential compliance to antidiabetic drugs. Apart from above said reason rise in burden of diabetes can be due to high price variation among different brands of same drug which was evident from literature [12-14]. Due to this, there exists a wide range of price variation. In spite of government of India's attempt to prevent unjustifiable pricing of drugs by enacting the Drug Price Control Order (DPCO), 1970 as well as incorporating the National List of Essential Medicine (NLEM), there exist a wide variation of drug prices within one drug with availability of various brands [15-16].

Rational prescribing involves selecting the cost effective treatment. However, there exists confusion for prescribers due to the availability of wide number of brands. Researchers showed significantly higher price variations in different brands within a single drug and also changing trend of price variation in different time periods [12-14]. As per the author knowledge very few studies available that compared the cost of drug across the different brands. Present study aimed to compute the costs and percentage price variation of oral hypoglycaemic agents across the different brands available in the Indian market.

Methods:

India's medical research body, particularly Indian Council of Medical Research (ICMR) issue guidelines for the management of T2DM. ICMR guidelines were perused to understand the management of T2DM. Current Index of Medical Specialities (CIMS) Oct- Jan 2015 edition and Indian Drug Review (IDR) Issue 1, Jan.2015 were used to capture the price of oral hypoglycaemic agents across the different brands available in the Indian market. Costs of drug (for 10 tablets) were analysed according to the availability like single and combination therapy. The drugs were further divided into groups like sulfonylurea and non-sulfonylurea. Costs of individual drug being manufactured by all the companies in the same strength, number and dosage form were compared. The drugs being manufactured by only one company or being manufactured by different companies however, in different strengths were excluded. Variations in the maximum and minimum price of Individual drug being manufactured by several companies across the different brands were calculated. This formula [1] was used to calculate the variation in price:

$$\frac{\text{Cost of brand with highest price} - \text{Cost of brand with lowest price}}{\text{Cost of brand with lowest price}} \times 100$$

Spearman correlation analysis was done to observe the correlation between no. of manufacturing companies and their percentage price variation with the help of IBM Statistical Package for Social Sciences (SPSS v.20, SPSS Inc.)

Results:

Percentage price variation of 11 drugs cost in single therapy and eight in combination therapy were computed. A total of 55 different formulations were available for single and combination therapy, which was manufactured by various companies.

Single Drug therapy among the sulfonylurea group of drugs: Table I shows the price variation in single drug therapy among sulfonylurea group of drugs. In this category, Glipizide 5mg shows maximum price variation of 780%. All the four formulations of Glimpiride shows a huge fluctuation in minimum and maximum price. On contrary to that, Glipizide 10mg shows minimum price variation of 39%.

Single Drug therapy among the non-sulfonylurea groups of drugs: Table II shows the price variation in single drug therapy among non-sulfonylurea group of drugs. It comprises of eight drugs, out of which Pioglitazone 15mg & 30mg shows maximum variation of 600% & 522% respectively, followed by Metformin 500mg (445%) & 1000mg (380%). Miglitol 25mg shows a minimum variation of 57% only.

Price variation among fixed dose combination (FDC) therapy: Table III shows the price variation of FDC category of drugs. A total of 8 oral hypoglycaemic fixed dose combinations were available. Among the combination therapy Glimpiride 1mg + Metformin 500mg shows maximum price variation of 533%, followed by Glimpiride 2mg + Metformin 500mg 472%. On the other hand Glipizide 2mg + Metformin 400mg formulation shows minimum price variation of 1%.

Percentage price variation increases as the no. of manufacturing companies increases. There is linear correlation exist between the no. of manufacturing company and the percentage price variation. Spearman correlation analysis shows a positive correlation between the no. of manufacturing companies and the percentage price variation.

Discussion:

This study was carried out with the objectives of computing the costs and percentage price variation among oral hypoglycaemic agents across the different brands available in the Indian market. Drug prices were captured from

CIMS and IDR because these are regularly updated. Selection of cost effective brand will improve the compliance and the consequence of the treatment.

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 Glipizide 5mg showed the highest price variation (780%) followed by Glimepride 2mg (682%) among all oral hypoglycaemic agents. However, Jadhav et al reported that Glimepride 1mg showed maximum price variation of about 650% [12]. Date et al also showed that Glimepride 2mg (830%) has the highest price variation [14].

In our study Glimepride 1mg and Metformin 500mg combination showed the highest price variation of 533% among all recommended oral FDC. However, Jadhav et al reported that combination of Glipizide 2.5mg and Metformin 400 mg showed maximum price variation of about 400% [12]. Date et al showed that combination of Glimepride 1mg and Metformin 500mg has variation of 360% only [14].

Spearman rank correlation revealed interesting result. We observed that a significant positive correlation exists between the percentage price variation and the number of manufacturing companies (Fig.1). This observation reiterates the fact that as the number of manufacturing company's increases the percentage price fluctuation also increases. Our results showed that there is an urgent need of controlling price variation among different brands of available oral hypoglycaemic agents.

Possible reasons for observing above results includes: Physician gets the information through the medical representatives about the different brands. Companies are offering a lucrative offer to the physician to promote a particular brand [16]. Market structure, skewness of information, raw material costs and government regulation and pricing policies also could be the possible reason as evident from the literature [4, 12-15, 16-19].

Most people cut their doses because the treatment is proven to be out of pocket expense for them. Physician has knowledge about that brand only they are prescribing. They don't have any information about other brands and this existence of wide variation in prices. Government should take some step in order to regulate and to bring uniformity in price. So that it can be affordable by a common man which will ultimately improve the compliance and reduce the economic burden.

Conclusion:

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. Results of our study make the prescriber informed about various brands and their price variations. So the prescriber can chose the cost effective oral hypoglycaemic agents for a patient to achieve rational prescribing. This will help in reducing the economic and health burden on both patient as well as the healthcare system.

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Table I. Price variation in single drug therapy among Sulfonylurea group of drugs

Drug	No. of Forml*	Dose (mg)	No. of Mfg.* Companies	Min. Price (INR*)	Max. Price (INR*)	% Price Variation
Glibenclamide	2	2.5	8	2.60	6.50	150
		5	9	3.60	10.91	203
Gliclazide	4	30	12	19	76	300
		40	16	14	29.50	111
		60	11	39	125	221
		80	34	19.50	79.50	308
Glimepiride	4	1	73	9.52	71.50	651
		2	73	17	132.95	682
		3	13	20.95	132	530
		4	23	25.14	133.70	432
Glipizide	2	2.5	4	2.97	5.0	68
		5	9	1.48	13.03	780
		10	4	18	25	39

Forml*= Formulation, Mfg*= Manufacturing, INR*= Indian National Rupees

Table II. Price variation in single drug therapy among Non-Sulfonylurea group of drugs

Drug	No. of Formulations	Dose (mg)	No. of manufacturing Companies	Min. Price (INR)	Max. Price (INR)	% Price Variation
Acarbose	2	25	8	42	70	67
		50	14	65	120	85
Metformin	4	250	6	4.60	9.00	96
		500	64	6.40	34.86	445
		850	17	10.60	36.50	244
		1000	38	10	48	380
Miglitol	2	25	8	50	78.70	57
		50	8	90	147.50	64
Nateglinide	2	60	3	30	55.20	84
		120	3	50	91.10	82
Pioglitazone	2	15	36	10	70	600
		30	35	18	112	522
Repaglinide	3	0.5	8	19.90	56	181
		1	8	39	92	136
		2	6	75	142	89
Voglibose	2	0.2	32	19.50	80	310
		0.3	31	29.50	110	273

Table III. Price variation in fixed dose combination category of drugs

Drug	No. of Forml*	Dose (mg)	No. of manufacturing Companies	Min. Price (INR)	Max. Price (INR)	% Price Variation
Glibenclamide+ Metformin	4	1.25+250	3	12.50	22	76
		2.5+400	8	8.15.	27	231
		2.5+500	2	16	26	63
		5+500	20	12.0	31.96	166
Gliclazide + Metformin	4	30+500	3	26	41	58
		40+500	3	35	65	86
		60+500	6	39.25	126	221
		80+500	50	21.50	80	272
Glimepiride + Metformin	5	1+500	67	12	76	533
		2+500	70	25	143	472
		1+1000	6	46	80	74
		2+1000	9	58	128	121
		2+850	2	65	76	17
Glipizide+ Metformin	2	2.5+400	2	5.20	5.26	1
		5+500	9	6.72	14	108
Pioglitazone + Glimepiride	3	15+1	11	19	70	268
		15+2	16	31	127	310
		30+2	2	69	86	25
Pioglitazone + Metformin	3	7.5+1000	3	35	46	31
		15+500	30	19	95	400
		30+500	18	32	97	203
Pioglitazone+ Metformin+ Glimepiride	2	15+500+1	19	36.50	77.90	113
		15+500+2	19	48	117.9	116
Voglibose + Metformin	2	0.2+500	17	39	100	156
		0.3+500	16	59	110	86

Forml*= Formulation

Fig. 1. Correlation between No. of manufacturing companies and percentage price variation

