

ISSN No: 2319-5886

International Journal of Medical Research & Health Sciences, 2016, 5, 3:34-43

Pharmacoeconomic Evaluation, Cost Minimization Analysis of Anti-Diabetic Therapy in Gujarat

Shah Jainam V.^{*}, Patni Kalyani N. and Deshpande Shrikalp S.

Department of Pharmacology and Clinical Pharmacy, K. B. Institute of Pharmaceutical Education and Research (KBIPER), Gandhinagar, Gujarat, India

ABSTRACT

Economic burden of DM was approximated \$ 132 billion in 2002. 55 patients with DM were recruited. Their clinical information was analyzed for most commonly and most costly prescribed drug molecule. Three brands of both drugs were selected and laboratory analysis was done for all the selected brands to compare the bioequivalence. For the rest of drugs prescribed drug. Sitagliptin 50 mg was the costliest drug prescribed. Glycomet, Glyciphage and Forson were the brands of Metformin, Januvia and Zeta were the brands of Sitagliptin, selected for lab analysis. The drug content for metformin in Glycomet (100%), Glyciphage (99.24%) and Forson (98.95%) for Sitagliptin, Januvia (100%) and Zeta (102.43%) was nearly same. The price variation of Metformin was found to be 94.83% and that of Sitagliptin was found to be 174.5%. Since it is evident that same drug molecule varying in costs has same drug strength content they would produce similar clinical outcomes. This concludes that cheaper drugs can be prescribed to patients reducing the health-economic burden on diabetic patients.

Key words: Pharmacoeconomics; Cost-minimization analysis (CMA); Burden of disease; Cost reduction; Diabetes Mellitus; Clinical Pharmacist.

INTRODUCTION

1.1. Pharmacoeconomics: -

Economics is the science of scarcity and choice. Economics is the skill that we all use on a daily basis in our everyday lives. Health economics is basically economics applied to healthcare and it is most commonly used to help decision makers make difficult choices. This is the field which:

Analyses the supply and demand for healthcare

*Provides a structure for understanding decisions and their consequences.

Pharmacoeconomics adopts and applies the principles and methodologies of health economics to the field of pharmaceuticals and pharmaceutical policy.^[1]

It attempts to measure if the added benefit of one intervention is worth to added cost of that intervention. Pharmacoeconomics is defined as "the description and analysis of the cost of drug therapy to health care system and society. It identifies measures and compares the cost and consequences of pharmaceutical products and services.^[2]

The balance between the cost and benefit can essentially be observed by economic evaluation. It is the systematic and objective framework which helps decision makers to make more informed choices in their everyday working lives. All economic evaluation has a common structure. They involve explicit measurement of inputs 'cost' and outcomes 'benefits' around medical intervention.^[1]

There are mainly four basic types of pharmacoeconomic studies. Each type measures cost in monetary terms but they differ by means of, how the health outcomes are measured and compared. ^[1, 2] The types and their measurement units are given in the below Table 1:

	Table 1: Types of pha	rmacoeconomic evaluation ^[1,2]
Type of study	Units of cost measurement	Units of Outcome measurement
Cost-minimization analysis (CMA)	Monetary units	Assumed to be equivalent in comparable groups
Cost-effectiveness analysis (CEA)	Monetary units	Natural units (life years gained, mmHg blood pressure, mg/dl glucose, etc.)
Cost-benefit analysis (CBA)	Monetary units	Monetary units
Cost-utility analysis (CUA)	Monetary units	Quality-adjusted life years (QALY) or other utilities.

Out of all the four basic evaluation study, the focus here is on CMA. In CMA, only the intervention costs under evaluation are measured. The panorama is usually of the health service. CMA can only be used when the health benefits of healthcare interventions are identical or similar and thus need not be considered separately. One of the classical examples of this is, a decision to prescribe a generic drug instead of brand name drug, which will achieve the same effect at lower cost.^[11] This can be shown by comparison of generic equivalent to brand name drug. For a generic drug to be approved for its sale, manufacturer must demonstrate to FDA that the product is bioequivalent to the initially marketed brand name drug. Thus, when comparing medications which are the same chemicals, same dose, same route and having the same pharmaceutical properties as each other, only the cost of medication itself needs to be compared because the outcome should be the same.^[2]

It is to be noted that there are few controversial doubts about the term 'CMA'. As few contend that, in the analysis only cost is to be considered and not outcome. This can be considered as partial economic analysis, which is termed as 'Cost Analysis' and thus it is not a full pharmacoeconomic analysis. Also, when both cost and outcomes are measured, yet clinical outcomes are found to be equivalent, some categorize the study as a CMA due to the reasons of outcomes being equivalent; but others categorized the study as a Cost-effectiveness analysis (CEA), because clinical outcomes were measured. ^[2]

To simplify, CMA is the simplest of the all four types of evaluation in Pharmacoeconomics. The reason being, focus is on measuring cost while outcome is assumed to be the same. Yet caution is needed for proper use of CMA, as it can only compare the available alternatives with its identical outcomes.^[1]

1.2 Diabetes Mellitus

Diabetes Mellitus (DM), a disorder of endocrine and metabolism. It is not a single disease; rather it is a syndrome consisting of various subtypes of diabetes with hyperglycemia. ^[3] DM is a chronic debilitating condition which has affected more than 150 million people worldwide and this number is increasing rapidly. ^[4]Approximately, 20.8 million Americans have DM, yet, only two-thirds of them have been diagnosed. ^[5]

One of the definitions suggests that diabetes is a chronic condition caused by relative or absolute lack of insulin. Its hallmark clinical characteristic is symptomatic glucose intolerance resulting in hyperglycemia and alterations in lipid and protein metabolism. ^[7]Several definitions of diabetes are in existence. Few of them are, "diabetes mellitus is a group of metabolic disorders of fat, carbohydrate and protein metabolism that results from defects in insulin secretion, insulin action (sensitivity) or both." ^[5] Another one is "diabetes is a chronic metabolic disorder in which body cannot metabolize carbohydrates, fats and proteins because of defects in insulin secretion and/or action of insulin."^[6]

Today, India is the country which leads the world with its largest diabetic population of 32 million in the year of 2000. This number is predicted to rise to 80 million by year of 2030. It has also been observed that the prevalence is higher and rapid in urban areas from 2% in 1970s to 12% in 2000, as well in rural areas; this is now also beginning to increase.^[7]

The economic burden of DM approximated \$ 132 billion in 2002, which includes direct medical and treatment cost, as well as indirect cost related to disability and mortality. This disorder is the leading cause of blindness in adults aged to 20 to 74 years and the leading contributor of development of End-Stage Renal Disease (ESRD). Approximately 82,000 lower extremity amputations annually are attributed to DM, in United States. Also, cardiovascular events are responsible for two-thirds of deaths in individuals with DM. ^[5]

DM is a chronic life-long condition, which in most cases is treated for life, thus the cost associated with this is enormous. Existing data are few that regard its cost to the patient and the society in developing countries like India. As now it is understood about the seriousness of its complications, its chronicity and the required resources that are needed to control it; diabetes is one the most expensive disease not only for the patient and the society, but also to the health care system.^[8]

Millennium development goal 7 emphasizes equitable access to essential drugs. One third of world population (1.7-2.1 billion) lacked access to essential drugs. A major obstacle to achieving equitable access to drugs is price, especially in countries where drugs are paid out of pocket, ^[9] and India is one such country where people pay for the medications as well as medical costs out of their own pocket.

MATERIALS AND METHODS

1.2. Recruitment:

Ethics committee permission was obtained via KBIEC, human ethics committee, Gandhinagar, Gujarat, India, for the conduct of the study. Total of 55 patients were recruited in the study. Patients with, Type 1 and Type 2 diabetics, patients taking oral hypoglycemic agents (OHAs), having the age above 18 years and either of gender were included in the study. Patients who did not provided the information or not willing to participate were excluded from the study. Patients were recruited from one of the major city of Gujarat state (Ahmedabad).

2.2. CMA- Cost-effectiveness analysis: -

Once the patients were recruited in accordance to the recruitment criteria, their clinical information was noted in the Case Record Form (CRF) and was analyzed for the drugs prescribed to them. Two OHAs were selected for Laboratory analysis to verify the content availability: - (one molecule and three brands of the same), a) most frequently prescribed among the prescribed medications, b) the highest costly drug prescribed. Other drugs which are prescribed, the prices of the marked formulations were compared using IDR (Issue 2, 2014) Drug Today (April-June, 2014) CIMS books (July-Sept, 2014). The graphical description of methodology is given in Figure 1, as described below.



Figure 1: Methodology of the study

RESULTS

1.3. Subject Characteristics:

Total of 55 patients were enrolled in the study in accordance with the inclusion and exclusion criteria, after giving the written consents. During the study period, patients case files and medical records were reviewed. Out of 55 recruited subjects, 41.8% (23) were females and 58.2% (32) were males. The mean age of the subject was 59.74 years \pm 1.32 years. The minimum age of the patient was 42 and the maximum age of the subject was 88 years.

Majority of the patients were in the age group of 51-50, total number being 23. There were total of 11 patients in the age group of 18-50. Subsequently, 13, 7 and 1 patients in the age group of 61-70, 71-80 and 81-90, respectively.

Table 2: Age group and frequency of patients.				
Age Group (years)	Frequency			
18-40	0			
41-50	11			
51-60	23			
61-70	13			
71-80	7			
81-90	1			
Total	55			

3.2. CMA- Cost-Minimization Analysis: To find out the two drugs falling under the methodological criteria, the below frequency was obtained:

3.2.1. Most Frequently Prescribed Drug molecule:

Table 3: frequency of each drug prescribed.					
Sr. No.	Name of Drugs	Number of times prescribed.			
1	Metformin (500, 750, 1000 mg)	61 (51, 2,8)			
2	Glimepiride (1, 2 mg)	39 (15, 24)			
3	Pioglitazone (7.5, 15 mg)	19 (8, 11)			
4	Voglibose	9			
5	Insulin	5			
6	Glipizide	5			
7	Sitagliptin	3			
8	Glibenclamide	2			
9	Vildagliptine	2			
10	Acarbose	1			
11	Gliclazide	1			

As seen in the Table 3, there were total of 11 different drug molecules prescribed in the study population. Out of which the most commonly prescribed molecule was Metformin 500 mg, conventional tablet. This drug was prescribed total 61 times. This was followed by Glimepiride and Pioglitazone by 39 times and 19 times prescribed drug respectively. The least commonly prescribed drugs were Acarbose and Gliclazide which were prescribed once.

3.2.2. Costliest Drug Molecule prescribed:

Table 4: Costliest Drug molecule prescribed.			
Sr. No.	Sr. No. Name of drug		
1	Insulin (parenteral preparation so, didn't count)		
2	Sitagliptin		
3	Vildagliptine		
4	Voglibose		
5	Acarbose		
6	Glibenclamide		
7	Pioglitazone		
8	Gliclazide		
9	Glipizide		
10	Glimepiride		
11	Metformin		

As seen in the Table 4, the costliest drug which prescribed was Sitagliptin, having the cost of 14.9 INR per tablet. The cheapest drug prescribed was Metformin having the cost of 0.8 INR per tablet. The order of costliest to cheapest drug prescribed was as below:

Sitagliptin > Vildagliptine > Voglibose > Acarbose > Glibenclamide > Pioglitazone > Gliclazide > Glipizide > Glimepiride > Metformin.

3.3. UV- Spectrophotometric determination of Metformin and Sitagliptin brands for CMA:

For the comparison of different brands of Metformin and Sitagliptin, the method for estimation of drugs from the Pharmacopoeia was utilized. Two brands of Sitagliptin and three brands of Metformin were utilized. As per the

methodology of protocol, three brands of each drug, highest costly, medium costly and cheapest brands are needed to analyze.

For Sitagliptin, three brands were selected but only two brands were analyzed. Because of reasons of the two of brands were having the same cost due to revision of prices, which does not fulfill our objective of comparing three different costs of same drug molecule. For details regarding the prices of brands of each molecule refer Table 5.

Table 5	5: Details of selected	Brands of drugs.				
Sr. No.	Brand Name	Manufacturer	Number of drugs per strip	Content	Price per strip (INR*)	Price Per Tab. (INR*)
1	Januvia	MSD	7	Sitagliptin 50 mg	269	38.42
2	Zeta	Glenmark	7	Sitagliptin 50 mg	98	14
3	Glycomet	US Vitamins Limited	10	Metformin 500 mg	16.95	1.69
4	Glyciphage	Franco Indian Remedies	20	Metformin 500 mg	29.20	1.46
5	Forson	Unison	10	Metformin 500 mg	8.7	0.87

*INR – Indian Rupee

3.3.1. Assay of Sitagliptin and Metformin:

Table 6: Absorbance of samp	les of drugs by UV-Spectrophot	ometric method.
Sample	Absorbance	nm
Januvia	0.038	265
Zeta	0.039	265
Glycomet	0.759	232
Glyciphage	0.753	232
Forson	0.751	232

3.3.1.1. Sitagliptin:

• The slope equation for Sitagliptin was:

 $y = 0.004 \ x - 0.003^{[11]}$

Considering the above equation, the calculated drug content of both the brands of Sitagliptin was:

3.3.1.1.1. T. Januvia:

0.038 = 0.004 x - 0.003

X = 10.25 mcg/ml

Considering the dilution factor, 10.25 * 10 * 100 = 10250 mcg/ml = 10.25 mg/ml. Similarly,

3.3.1.1.2. For **T. Zeta** the concentration found was 10.5 mg/ml.

This shows that both of the brands are having the same labeled claims and are equal in the strength; which is assumed to produce the same clinical outcomes.

3.3.1.2. Metformin:

The slope equation for Metformin was:

 $y = 0.072 \ x^{[12]}$

Considering the above equation, the calculated drug content of both the brands of Sitagliptin was:

3.3.1.2.1. T. Forson:

0.751 = 0.072 x

X = 0.751/0.072

X = 10.43 mcg/ml

Considering the dilution factor, 10.43 * 10 * 10 * 10 = 10430 mcg/ml = 10.43 mg/ml.

Similarly,

3.3.1.2.2. For **T. Glycomet** the concentration found was 10.54 mg/ml. **3.3.1.2.3.** For **T. Glyciphage** the concentration found was 10.46 mg/ml.

Table 7:	Concentration	of different brai	nds of drugs.					
Sr. No.	Brand Name	Concentration	Concentration in %	Content	Price			
			Sitagliptin					
1	Januvia 10.25 mg/ml 100 % Sitagliptin 50 mg 269 INR Zeta 10.5 mg /ml 102.43 % Sitagliptin 50 mg 98 INR							
2	Zeta	10.5 mg/ml	102.43 %	Sitagliptin 50 mg	98 INR			
	Metformin BP (98.5 to 101.0 %)							
3	Glycomet	10.54 mg/dl	100 %	Metformin 500 mg	16.95 INR			
4	Glyciphage	10.46 mg/dl	99.24 %	Metformin 500 mg	29.20 INR			
5	Forson	10.43 mg/dl	98.95 %	Metformin 500 mg	8.7 INR			

This shows that all three of the brands are having the same labeled claims and are equal in the strength; which is assumed to produce the same clinical outcomes.

3.4. Price variations:

Price of most expensive brand – Price of least expensive brand Price of least expensive brand [13, 14]

According to the above given formula,

3.4.1. Metformin:

(16.95 - 8.7 / 8.7) * 100 = 94.83 %

3.4.2. Sitagliptin:

(269 - 98 / 98) * 100 = 174.5 %

3.5. Range of costs of other drugs prescribed to patients:

The drugs when prescribed as mono, dual or multiple therapies, the price of drugs varies and the ranges of lowest cost to highest cost are given in below noted table:

Int J Med Res Health Sci. 2016, 5(3):34-43

		Table 8: Ra	unge of drugs prescribe	ed and marketed.	
Sr. No	Name of Drugs	Number of times prescribed	Range of cost in market (lowest – highest) (INR/unit)	Range of costs prescribed. (lowest – highest)	Remarks
I	Monotherapy	10	0.87-11.7	0.71- 4.1	
1	Metformin 750 mg	2	IDR/CIMS/Drug	1.5-4.1	
2	Metformin 1000 mg	2	1.8 - 3.3	2	
3	Glipizide 10 mg (1-0-0)	2	1.22 - 2.5	1.13	
4	Metformin 500 mg (1-1-1)	4	0.87 - 3.2	0.8-2	
II	Dual therapy	15	0.72-14.9	1.04-14.9	
1	Glimepiride 1 mg	6	2.25 – 7.55 NOT IN	1.8-9.8	
2	Gliclazide 40 mg, Metformin 500 mg	1	IDR/CIMS/Drug Today	5	Drugs prescribed considering Pharmacoeconomics.
3	Metformin 500 mg+ Voglibose 0.2 mg	1	3.6 - 7.2	3.6	
4	Glipizide 5 mg, Metformin 500 mg	1	0.72 – 1.4	1.04	
5	Glimepiride 1 mg, Metformin 1000 mg	2	5.0 - 5.65	4.03-5.32	
6	Glimepiride 2 mg + Metformin 1000 mg	3	5.3 - 8.9	7.5	
7	Sitagliptin 50, Metformin 500 mg	1	14 - 38.42	14.9	
III	Multiple therapy	30	2.31-11.79	3.63-14.9	
1	Metformin 500 mg , Voglibose 0.2 mg + Glimepiride 2 mg + Metformin 500 mg	1	8.77 – 11.1	13.55	
2	Voglibose + Glimepiride + Metformin, Vildagliptine 50 mg + Metformin 500 mg	2	27.7 – 29.4	29.5	
3	Metformin 500 mg+ Glimepiride 1 mg + Voglibose 0.2 mg	1	5.9 - 11.0	9.8	
	Sitagliptin 50 mg+ Metformin				
4	Pioglitazone 15 mg + Metformin 500 mg	1	19.9 - 50.12	23.52	
-	Glimepiride $2 \text{ mg} + \text{Metformin}$	2	50 117	2 (2 7 7 9	
5	500 mg + Pioglitazone 15 mg	3	5.9 – 11.7	3.63-7.78	
6	Glimepiride 2 mg. + Metformin 500 mg. + Pioglitazone 15 mg,	2	5.9 - 11.7 + 144	3.63/8.15 + 144	Wherever possible
7	Glimepiride 1 mg + Pioglitazone 15 mg + Metformin 500 mg	3	3.99 - 6.77	5.63 - 6.72	Pharmacoeconomics considerations are there while prescribing, where it is not, it is due to reasons of drug schedule and
8	Glimepiride 2 mg + Pioglitazone 7.5mg + Metformin 500 mg	7	4.4	5-8.15	other reasons.
9	Insulin , Glimepiride 2 mg + Metformin 500 mg + Voglibose 0.2 mg	1	144 + 7.9	144+12.8	
10	Glimepiride 2 mg + Metformin 500 mg, Pioglitazone 7.5 mg + Glimepiride 2 mg + Metformin 500 mg	1	6.5 - 12.14	12.14	
11	Glimepiride 1 mg + Metformin 500 mg, Acarbose 25 mg + Metformin 500 mg	1	7 – 11.7	11.7	
12	Glimepiride 2 mg + Metformin 500 mg + Voglibose 0.2 mg	2	6.9 – 12.8	12.8	
	Glimepiride $2 \text{ mg} + \text{Metformin}$				
13	mg, Glipizide 5 mg + Metformin 500 mg	1	6.62 – 13.1	4.66	

	Glibenclamide 5 mg	+			
14	Metformin 500 mg	+ 1	4.99	5.7	
	Pioglitazone 15 mg				
15	Sitagliptin 50 mg + Metformi	n 1	14 29 42 + 144	14.0 . 144	
15	500 mg, Insulin	1	14 - 38.42 + 144	14.9+144	
	Insulin,				
16	Glipizide 5 mg + Metformi	n 1	0.72 - 1.4 + 144	1.04 + 144	
	500 mg				
	Glimepiride 2 mg + Metformi	n			
	1000 mg ,				
17	Glibenclamide(5mg)	+ 1	10.29 - 13.89	12.5	
	Metformin(500mg)	+			
	Pioglitazone(15mg)				
	Total	55			

DISCUSSION

Research proposal approval was obtained from the Human Ethics Committee, K. B. Institute Ethics Committee (KBIEC). According to the study protocol, minimum number of patients needed to recruit in the study was 50. In the study 55 patients were recruited during the study period with the written informed consent from them in accordance with inclusion and exclusion criteria.

It is a fact that in India, the drugs are mainly sold under brand names. The Indian pharmaceutical market is having over 100,000 formulations and there is no system of registration of medicines with their prices, ^[13] despite of having DPCO act, and essential drug list now in existence. Different studies relating to cost analysis of anti-diabetic agents show huge variations in the prices of different brands of same molecule. Thus CMA was decided to carry out in our study.

In our study, the maximum numbers of patients were in the age group of 51-60 years having the patient number of 23 as described in Table 2. The maximum price variation of oral hypoglycemic agents was among the costliest prescribed drug - Sitagliptin is found to be 174.5%; whereas maximum price variation amongst most frequently prescribed drug- Metformin was found to be 94.83%.

In our study, UV-spectrophotometric analysis of drug content was done to check the extent of similarity in drug dose content. The results of which are described in Table 6. None of the study performed on the topic of cost minimization analysis performed a laboratory analysis of the drugs. They have compared the prices of the drugs with the assumption that all same drug molecules are having same drug strength and would produce same clinical effects.

From the patients recruited 10 patients were on mono therapy, 15 patients were on dual therapy and 30 patients were on three or more than three drug therapy. The drugs prescribed to patients with Monotherapy were ranging from 0.71 to 4.1 INR/tablet, while the marketed drugs were ranging from 0.87 to 11.7 INR/tablet. Those drugs prescribed to patients with dual therapy were ranging from 1.8 to 14.9 INR/tablet, while the marketed drugs were ranging from 0.72 to 14.9 INR/tablet. Similarly, drugs prescribed to patients with multiple therapies were ranging from 3.63 to 14.9 INR/tablet, while the marketed drugs were ranging from 2.31 to 11.79 INR/tablet. This shows that physicians of the recruited patients do consider pharmacoeconomics of drugs while prescribing. The details of such price ranges are described in Table 8. The data was collected via different sources such as community shops from Ahmedabad city and Gandhinagar city, as well as IDR (Issue 2, 2014) Drug Today (April-June, 2014) and CIMS (July-Sept, 2014) books. A study conducted in May-2014 by Lalan HN et al, related to cost variation of Anti-diabetics focusing on Indian scenario was conducted. In that study, prices of total 25 oral hypoglycemic agents available in 70 different formulations in Indian pharmaceutical market was analyzed. They found maximum price variation of 830 % and 475 % in monotherapy and combination therapy, respectively. While in insulin preparations, maximum price variation was 1881.24 %.

In comparison to present study, maximum price variation for Metformin 500 mg is found to be 94.83 % and in the study, noted above, the maximum price variation was 384.18 %. ^[14]The similar results were also observed in another study conducted in India, published in 2013 by Jadhav NB et al, focusing on cost analysis of the drugs. They have compared anti-diabetic drugs manufactured by different pharmaceutical companies in the same strength and dosage form. The results of their study showed the price variation of 308.33 % for Metformin 500 mg. ^[13] As noted earlier,

the most frequently prescribed oral hypoglycemic agent in our study is Metformin 500 mg. Similarly, the pharmacoeconomic evaluation of anti-diabetic therapy carried out in Nigerian tertiary health institution reported that the most widely used drug was Metformin in 2006. ^[8]In our study while prescribing hypoglycemic agents Physicians consider Pharmacoeconomics aspect.

The costliest drug that was prescribed out of the 11 drugs prescribed was found to be Sitagliptin. This was followed by Vildagliptine, Voglibose, Acarbose, Glibenclamide, Pioglitazone, Gliclazide, Glipizide, Glimepiride and cheapest drug was Metformin which was prescribed to our study subjects. Here, the Insulin was not taken in to consideration even though insulin having the highest cost amongst all the anti-diabetic agent. This was due to the limitations of in-vivo experiments of bio-availability and bio-equivalence for Insulin being a parenteral preparation. For these two drugs, UV-spectrophotometric analysis was done to find out the concentration/strength of each brand of both drugs. Three brands of Metformin and two brands of Sitagliptin were analyzed. Two of the Sitagliptin brands were having the same cost so, only one was selected out of those two. The results of analysis were similar for all the comparative brands, having the same drug content as labeled claims.

It is a known fact that Indian patients face difficulties while paying for their medicines. This is because, they have to pay the cost of medicines out-of their own pocket unlike developed counties, where majority of patients carry health-insurance. 80% of health financing is borne by patients in India. Moreover, in India quality related issues such as microbial count in medication and failing bio-equivalence for generic medications are commonly observed. This is also true for many brands sold in India. Thus, rules and regulations related to GMP testing and bio-equivalence should be made stringent and full proof like USFDA. This should be the prime responsibility of government.^[9]

As mentioned in table 7 in results, the concentration of Metformin in Forson (8.7 INR/10 tabs), Glyciphage (14.6 INR/10 tabs) and Glycomet (16.95 INR/10 tabs) was nearly same. Thus all of the three drugs will produce same clinical outcomes. Similar results were obtained in the analysis of Sitagliptin brands Januvia (269 INR/7 tabs) and Zeta (98 INR/7 tabs). Prescribing the drug of lesser cost can produce the same therapeutic effect as well as it can make the therapy cost effective and economical.

India is a developing country, so the financial status of the patient is to be considered while prescribing a drug. For people with economic condition near to poverty line, costly therapy is one of the factors leading to medication non-adherence. By prescribing and dispensing drugs of lower cost with the same clinical effect, the total cost of therapy can be reduced greatly. As a result, level of medication adherence can be raised, subsequently leading to achieve the therapeutic goal for the patient.

Limitations

Even though the study was carried out with utmost care and precautions, several limitations which are needed to consider and addressed here. These limitations include:

- The included patients refer to Ahmedabad centre only and few areas of the city only.
- The laboratory analysis was done of only 2 drug molecules; 3 brands each, this was because of time constrains.
- In CMA, while analyzing drugs, Tablet Evaluation Parameters should also be assessed.
- In CMA, analysis of fixed dose combination was not performed, only the single drugs were assayed.

CONCLUSION

Diabetes is a chronic disorder of endocrine and metabolism which requires a life-long therapy. This includes pharmacologic as well as non-pharmacologic therapy. In India, there was an exploding rated increase in the number of Diabetic people observed in recent years. Today, India is the country which leads the world with its largest diabetic population of 32 million in the year of 2000. This number is predicted to rise to 80 million by year of 2030. Performing this study enabled us to derive the following conclusions.

By performing CMA it is evident that same drug molecule varying in costs has same drug strength content. Therefore it is assumed that these medications produce similar clinical outcomes. It is concluded that cheaper drugs can be prescribed to patients reducing the health-economic burden on diabetic patients. Considering the cost of medication as a factor for medication non-adherence, prescribing cheaper drugs to patients would increase

adherence among patients resulting in better therapeutic outcomes. While prescribing the drugs to patients, physicians should also keep this information in mind to reduce health-economic burden on society.

Acknowledgement

This project is financially supported by KBIPER, Gandhinagar. We owe thanks and take opportunity to extend our sincere gratitude to, Mrs. Hetal K. Patel; Lecturer at Department of Pharmaceutics and Dr. Pragna K. Shelat; Professor and HoD, Pharmaceutics, K.B.I.P.E.R., Gandhinagar for their immense support.

REFERENCES

[1] Walley T, Haycox A, Boland A. Pharmacoeconomics. Spain: Churchill Livingstone (Elsevier Science); 2004.

[2] Rascati KL. Essentials of Pharmacoeconomics. Philadelphia (USA): Lippincott Williams & Wilkins; 2009.

[3] Talwalkar PG. Practical Diabetes Mellitus, 5th ed. Mumbai, India: Dr. Pradeep G. Talwalkar; 2014.

[4] Schmitz P, Martin KJ, Miller DD. Internal Medicine Just the Facts. New York: McGraw Hill Companies; 2008.[5] Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy A Pathophysiologic Approach, 7th Ed. New York: McGraw Hill Companies; 2008.

[6] USV, ADA. Diabetes Ready Reference for Medical Practitioners. India: USV; 2014.

[7] Shah JV, Patni KN, Deshpande SS. Achieving Glycemic Control of Diabetic Patients through Clinical Pharmacist Provided Counseling. Journal of Pharmaceutical Science and Bioscientific Research 2015; 5(4): 322-327.

[8] Suleiman IA, Fadeke OF, Okubanjo OO. Pharmacoeconomic Evaluation of Anti-Diabetic Therapy in A Nigerian Tertiary Health Institution. Annals of African Medicine 2006; 5(3): 132-137.

[9] Abdulganiyu G, Fola T, Cost-cost analysis of anti-diabetic therapy in a tertiary healthcare institution, north eastern Nigeria. International Journal of Pharmacy and Pharmaceutical Sciences 2014; 6(2): 281-286.

[10] World Health Organization (WHO). Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus Abbreviated Report of a WHO Consultation. WHO. Report number: WHO/NMH/CHP/CPM/11.1, 2011.

[11] Tarkase KN, Sarode MB, Gulve SA, Gawade A. Development and validation of UV spectrophotometric method for estimation of sitagliptin phosphate. Scholars Research Library 2013; 5(3): 315-318.

[12] Kumar M, Mandal V, Hemalatha S. Detection of Metformin Hydrochloride in a traditionally used Indian Herbal drug for Antidiabetic: A Case Report. International Journal of Pharma and Bio Sciences 2011; 2(2): 307-313

[13] Jadhav NB, Bhosale MS, Adhav CV, Cost analysis study of oral antidiabetic drugs available in Indian market. International Journal of Medical Research & Health Sciences 2013; 2(1): 63-69.

[14] Lalan HN, Borde MK, Ray IM, Deshmukh YA, Cost Variation Study of Antidiabetics: Indian Scenario. Indian journal of applied research 2014; 4(5): 420-421.