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Pharmacoeconomic evaluation of oral-hypoglycemic agents at hospital in Bangalore

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Abstract: *the study aimed to conduct Pharmacoeconomic evaluation of oral-hypoglycemic agents using cost effectiveness analysis.*
Methodology: The study was conducted in a hospital at Bangalore for 9 months period. In-patients who were diagnosed with type 2 Diabetes Mellitus (T2DM) and were receiving treatment specifically with oral-hypoglycemic agent(s) were included in the study. Various treatment-related expenses were determined and tabulated from patient case note. The data obtained was introduced to cost-effectiveness analysis to arrive at the most cost effective oral-hypoglycemic agent. To determine the significant difference between the treatment alternatives statistical test (ANOVA) was introduced.
Results: A total of 62 patients were included in the study. Total direct cost of the type-2diabetes therapy contain cost of medications, laboratory charges, physician charges, hospitalization charges and nursing charges, that amount of Rs. 3,350 to Rs. 22,183. Large number of patients was receiving metformin as a monotherapy (56.45%), and metformin with glimipiride as combination drug (30.64%).
Conclusion: Metformin and metformin combined with glimipiride were found to be the most cost-effective single-drug and combination-drug therapies respectively, for T2DM treatment.
Key words*: Cost effectiveness analysis, Oral-hypoglycemic agents, Pharmacoeconomic, Type 2 Diabetes,*

I. Introduction

Recently throughout the globe many people have become more cost oriented, especially in terms of medical care. Therefore, estimation of cost, of any new treatment has become more significant. As the medical care costs keep on increasing, therefore more efforts is made to figure out the economic effects associated with progression of diseases and their treatment. [1]

Diabetes Mellitus (DM) is "a metabolic disorder characterized by hyperglycaemia resulting from defects in insulin secretion or insulin action or both". T2DM could cause everlasting threat, and damage of the necessary organ, in body, such as nerves, kidney, eye, and heart, etc. [2] DM is one of world's leading causes of morbidity and death. Individuals who are diagnosed with diabetes mellitus are more prone to cardiovascular problems than their counterpart without diabetes mellitus. [3]

DM is the commonest form of the disease across the globe, in developing states like India being at the top of this epidemic. Recent studies, showed approximately 285 million people worldwide in the age group of 20-79 years were diabetic in the year 2010, and by the year 2030, 438 million people, above 30 years of age are expected to have diabetes. The DM will be more in developing countries. [4] DM is multi-factorial disease caused by both a genetic factors linked to impaired insulin secretion and insulin resistance and environmental factors such as overweight, lack of exercise, all type of stress, as well as aging. [5] Other habits such as alcohol consumption and smoking are considered as an independent factor that leads to DM. [6] Moreover, insulin is the main hormone that organise the uptake of glucose from the blood into most cells. Therefore abnormal action of insulin or deficiency of insulin can lead to Diabetes Mellitus. Insulin is formed and stored in the beta cells of pancreatic islets of langerhans. Glucose levels above 70 or 75 mg/dl are sufficient to trigger the release of insulin. After entry of glucose into beta cell, it is go through phosphorylation process and then it's converted to glucose-6-phosphates in cytoplasm of the beta cell. Glucose-6-phosphates undergo glycolysis to generate ATP, this lead to Inhibition of ATP sensitive potassium ion channels, and subsequently opening of calcium channels. Ca^{2+} enters the cells and causes the release of insulin. [7] In the other hand, insulin could be resisted or impaired due to so many factors. Insulin may not properly respond in some cases in instant "a case in which insulin does not exert sufficiently to meet the need of the plasma concentration". However, the widespread clinical characteristic of T2DM could be manifested in an action of insulin in an essential orange. [8]

Increasing in health care cost is a foremost concern in the developing nations, hence, it has increased individual economic burden. Patients are affected by high cost of drugs though the symptoms improve. Suleiman et al. conducted a study to evaluate the cost associated with type-2 Diabetes Mellitus, in which they

reveal that, the cost of diabetes treatment is enormous. [9] Economic assessment of therapy should be encouraged to ensure improved cost effectiveness and efficiency in management. Similar study was done by Davies MJ. They found that treatment with "liraglutide 1.2 and 1.8 mg resulted in mean increase in quality-adjusted life expectancy vs. glimipiride, and sitagliptin, the later was costly". [10] Grover S, et al. carried out a study to assess the cost of treatment of diabetic patients in India. Study shows that, the cost of the treatment was INR 14,508/- (263 Euros) out of which direct and indirect cost was approximately (68%), (28%), respectively and special cost was (2.8%). In comparing all these costs, medications charges were found to be high, and they reveal that diabetes is an expensive illness to manage which cause financial difficulties to the patients. [11] Therefore to identify the best treatment option which is least expensive with similar efficacy; there is a need of an analytical tool. Pharmacoeconomic (PE) is an essential method to determine the optimized treatment among different alternative available. Pharmacoeconomic measures the cost and outcome or benefit of pharmaceutical products and services. "Pharmacoeconomic analysis compares two or more medication options or strategies in terms of their cost and outcome or benefit". "PE analysis is termed as partial when costs are assessed and complete when both costs and outcomes are assessed".[12] Pharmacoeconomic consists of various methods of analysis such as: "cost benefit analysis (CBA), cost effectiveness analysis (CEA), cost minimization analysis (CMA), cost utility analysis (CUA), and cost of illness analysis (COI)". In this study we used cost effectiveness analysis. It evaluates the cost differences between two or more medication from one group and with a similar clinical effect. Result of cost effectiveness analysis is expressed as an average cost-effectiveness ratio (ACER) or as incremental cost effectiveness ratio (ICER). [13]

ACER/ICER = healthcare cost divided by clinical outcome/ benefit.

Hence, the present study entitled "Pharmacoeconomic evaluation of oral anti-diabetic agents in type-2 Diabetes Mellitus patients admitted in tertiary care hospital" is aimed at finding out which model of therapy could be most cost-effective in type-2 DM without compromising in it quality, so that the economic burden on the patient can be reduced. [14]

II. Objectives

- To document the treatment of type 2 DM which the in-patients will receive during their study period at medicine wards of St. Martha's Hospital, Bangalore. To calculate and record various treatment-related expenses incurred such as: Cost of oral-hypoglycemic agents, laboratory charges, hospitalization charges, and any other miscellaneous expenses.
- To apply cost effectiveness analysis and find out the treatment which is most cost effective with maximum benefit.

III. Material And Methods

A prospective observational study was conducted at hospital in Bangalore for 9 months. Ethical committee clearance was obtained from the Institutional Review Board (IRB) of St. Martha's Hospital, Bangalore. All in-patients diagnosed with type-2 DM, receiving oral-hypoglycemic agent(s), were enrolled in the study. Pediatric, pregnant and lactating, Patients with severe type 2 diabetes and, patients with type 1 diabetes were excluded from the study. 62 patients who satisfy the inclusion criteria were recruited during the study period. Details about demographic, laboratory charges, nursing charges, physician charges and, cost of oral hypoglycemic agents received by study patients were collected from the patient's medical sheet note. Information related to cost of each parameter were collected from the in-patient pharmacy as well as financial department. All of the earlier mentioned data were assembled in a specific pre-design collection form. The assembled data was introduced to cost effectiveness analysis to arrive at the cost of different treatments options. By using the cost effectiveness formula (i.e. Average cost effectiveness ratio equal healthcare cost divided by clinical benefit) it is expressed in monetary terms. Statistical test-ANOVA was applied to understand the significant difference between the treatment alternatives.

IV. Results And Discussions

Among 62 type-2 diabetes mellitus patients who included in the study, 27 (43.54%) were male, and 35 (56.45%) were female patients.

The age of the patients range from 40 to 92 years with a mean (SD) of 64±12 years and majority of the patients were found in the age group of 40 – 60 years.

Co-morbid conditions were seen in all patients diagnosed with type-2 diabetes. Majority of the patients (69.35) had hypertension followed by urinary tract infection (16.12%), COPD (11.29%), other diseases (8.06%) which include dengue fever, viral infection, gastritis, and tuberculosis (4.83%). "Fig1"

During the study period, the total duration of stay of patients in the hospital ranged from 3 – 12 days. The hospitalization of majority of patients ranged between 6 – 10 days. "Fig 2"

Out of 62 patients who underwent treatment for type 2 diabetes mellitus, cost for oral anti-diabetic agents accounted for 0.75%, hospitalization charges 50.75%, nursing charges 23.40%, physician charges 15.24%, and laboratory charges accounted for 9.83% of the average total direct cost. "Table 1"

The total direct cost of the treatment includes cost of drugs, laboratory charges, physician, nursing and hospitalization charges which ranged from Rs. 3,350 – 22,183 and in majority of the patients (47) 75.80% ,the cost was between Rs 3,000 – 8,000 "Table 2". Maximum RBS reduction (172) was seen with voglibose and lowest RBS reduction (57.66) was associated with vildagliptin which belonged to group 1 sub-division 1D in the "Table 3". But as there were 1, 3 patients who were receiving voglibose, and vildagliptin respectively, the reduction in RBS was not significant as the sample size is less in compared to other treatment groups. Different groups prescribed for the treatment of type-2DM were found to have different cost-effectiveness ratios. Group 1, Sub-group 1A was found to have Rs 98.78/unit RBS reduction. Sub-group 1B, Rs 80.87/unit RBS reduction, sub-group 1C, Rs 32.22/unit RBS reduction, and sub-group 1D, Rs 102.38/unit RBS reduction, whereas in group 2, sub-group 2A Rs 75.94/unit RBS reduction, and sub-group 2B Rs 102.56/unit RBS reduction "Table 3". Similar study was conducted by Alias ghor A et al. [15] using RBS as one of the parameter for evaluating clinical outcome.

Analysis of variance (ANOVA) test was applied to test whether there is any significant difference in ACER (average total direct cost per unit GRBS reduction) between different treatment groups for type-2 DM. Difference in ACERs between treatment groups was not significant (p = 0.693) [Table 4].

V. Tables And Figures

Table 1: Average cost incurred for treatment of type-2 diabetes mellitus

PARAMETER	COST IN RUPEES (Rs)	PERCENTAGE (%)
Medication cost	**55.96**	**0.75**
Hospitalization charges	**3750.96**	**50.77**
Nursing charges	**1729.03**	**23.40**
Physician charges	**1125.80**	**15.24**
Laboratory charges	**726.61**	**9.83**
Average total direct cost	**7386.92**	**100**

Table 2: total direct cost

TOTAL DIRECT COST (Rs)	NUMBER OF PATIENTS	PERCENTAGE (%)
3000 - 8000	**47**	**75.80**
8001 - 13000	**11**	**17.75**
13001 - 20000	**3**	**4.85**
Above - 20000	**1**	**1.61**
Total	**62**	**100**

Table 3: cost effectiveness analysis

GROUP	DRUG NAME	AVERAGE TOTAL DIRECT COST	AVERAGE BENEFIT	ACER (COST/BENEFIT)
1 MONOTHERAPY				
1A	METFORMIN	**7812.03**	**79.08**	**98.78**
1B	GLIMIPIRIDE	**5742**	**71**	**80.87**
1C	VOGLIBOSE	**5542**	**172**	**32.22**
1D	VILDAGLIPTIN	**5903.33**	**57.66**	**102.38**
2 COMBINATION THERAPY				
2A	METFORMIN + GLIMIPIRIDE	**6267.11**	**82.52**	**75.94**
2B	METFORMIN + SITAGLIPTIN	**8205**	**80**	**102.56**

Table 4: ANOVA (analysis of variance)

	SUM OF SQUARES	DF	MEAN SQUARES	F (value)	P (value)
BETWEEN GROUPS	**158.36**	**1**	**158.36**	**0.182**	**0.693**
WITHIN GROUPS	**3479.17**	**4**	**869.79**	-	-
TOTAL	**3637.53**	**5**	-	-	-

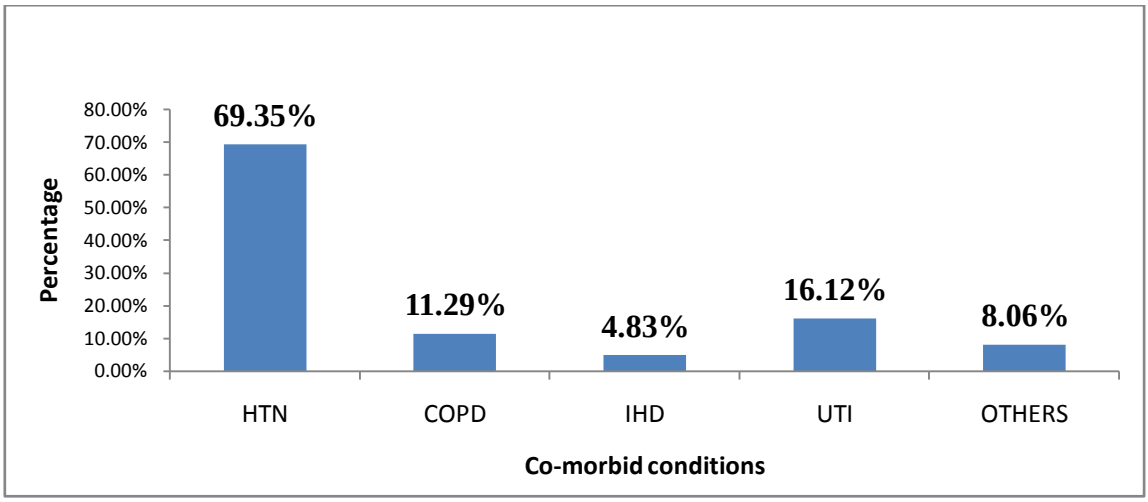

Figure 1: Distribution of patients based on co-morbid conditions

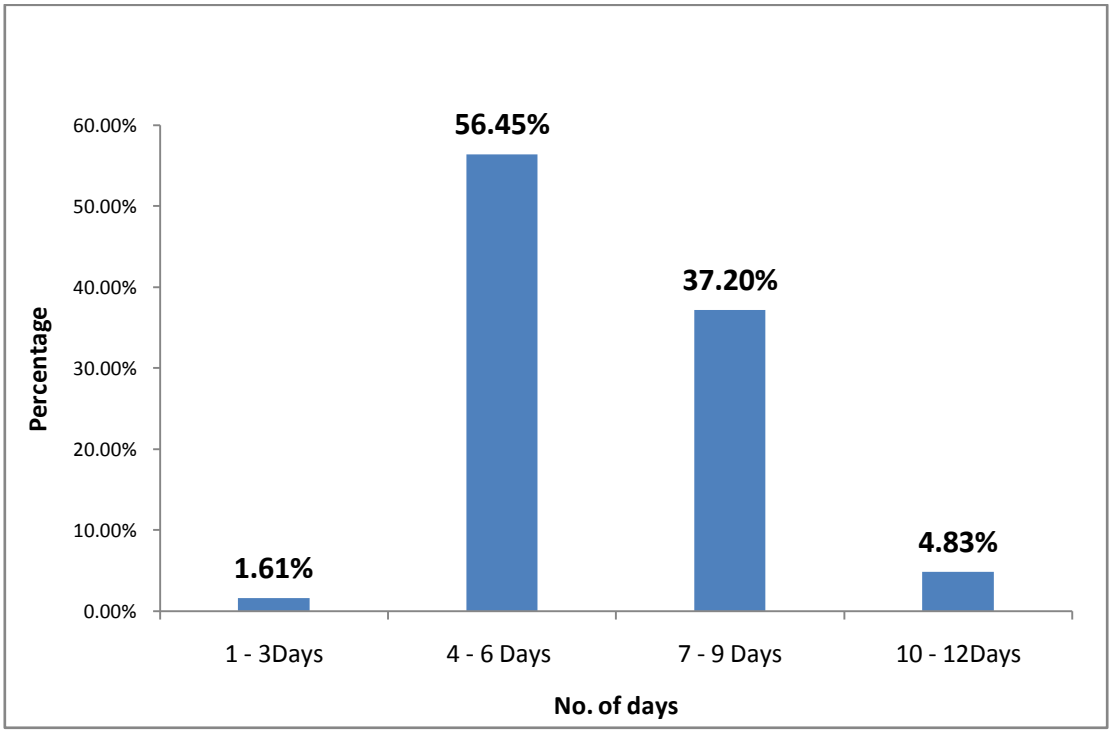

Figure 2: Distribution of patients based on durations of hospital stay

VI. Conclusion

From the study results it can be concluded that, combination of metformin + glimipiride was found to be the most cost effective drug for the treatment of type-2 diabetes mellitus with an average total direct cot of Rs.6267.11, average benefit of 82.52 units reduction in RBS value and average cost effectiveness ratio of Rs.75.94/unit RBS value reduction compared to all other regimens prescribed..

However, the differences in the costs between the treatment regimens were not statistically significant.

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