

## ALGORITHMIC APPROACHES FOR COST-EFFECTIVE MANAGEMENT OF TYPE 2 DIABETES: INSIGHTS FROM A MULTISPECIALTY HOSPITAL STUDY

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### ABSTRACT

With the rise in prevalence of Type 2 Diabetes Mellitus (T2DM) globally, particularly in India, understanding its economic impact is crucial for healthcare sustainability. This retrospective observational study explores the pharmaco-economic landscape of T2DM within a multispecialty hospital setting in India. The study examines patient demographics, prescribing patterns, drug effectiveness, complication management, and associated costs. Findings reveal a predominance of male patients aged 60-70, with systemic hypertension as the most common comorbidity. Metformin and Sulphonyl Ureas were frequently prescribed, with certain combinations proving cost-effective in reducing fasting blood sugar levels. Complications management focused on systemic hypertension, foot ulcers, dyslipidemia, and acute coronary syndrome. Laboratory investigations incurred the highest healthcare expenditure. Proposed solutions include a cost-effectiveness algorithm for personalized, cost-effective medication recommendations. These findings inform strategies for improving diabetes management and reducing economic burden.

**KEYWORDS:** Diabetes mellitus; Pharmacoeconomics; Algorithm; Cost-effectiveness.

## INTRODUCTION

Diabetes refers to a cluster of metabolic disorders marked by elevated blood sugar levels stemming from deficiencies in insulin secretion, insulin activity, or both. Prolonged hyperglycemia in diabetes is linked to long term damage, impairment, and even organ failure, particularly affecting the eyes, kidneys, nerves, heart, and blood vessels. Patients with Type 2 Diabetes mellitus have relative insulin deficiency due to insulin resistance.<sup>[1]</sup>

The global prevalence of Type 2 diabetes mellitus is escalating rapidly, almost at epidemic levels. Approximately 285 million individuals were estimated to have diabetes worldwide back in 2011, with around 51 million being Indian. This number is projected to surge to 438 million worldwide diabetes cases by 2030.<sup>[2]</sup> Assessing the economic impact of diabetes in India holds significant importance. Majority of the diabetes cases in developing nations have been estimated to occur within the 45-to-64-year age bracket, posing a threat to the nation's economic productivity as well as individuals' earning potential. Moreover, management of diabetes and its associated complications can also result in substantial expenditure, presenting a challenge to the strengthening of the healthcare system in India and the government's pursuit of universal health coverage.<sup>[3,4]</sup>

A recent study conducted in India revealed that the average annual expenditure on diabetes care was around Rs. 6,260 in rural areas and Rs. 10,000 in urban areas.<sup>[5]</sup> The lower treatment costs in rural areas may be due to challenges related to limited accessibility and affordability rather than reduced need for care, contrary to assumptions. Moreover, late detection of disease could also result in significant financial burden.<sup>[6]</sup> Socioeconomic disparities and the urban-rural divide indicate contrasting disease outcomes. Urban residents, typically wealthier, tend to spend more on diabetes care and experience better health outcomes, while those in rural areas face accessibility issues causing them to spend less and have poorer outcomes.<sup>[7]</sup>

In a Pharmacoeconomics study, both direct and indirect costs must be taken into consideration. Direct costs are related to the medical expenses including drugs, procedures, laboratory tests, and healthcare provider salaries, along with non - medical expenses like patient transportation cost. These primarily affect individuals and families. Indirect costs on the other hand are related to the society and government and are associated with loss of productivity.<sup>[8,9]</sup>

A wide range of oral anti-diabetic agents are commonly prescribed, such as biguanides, sulphonylureas, meglitinides, alpha – glucosidase inhibitors, Thiazolidinediones and DPP-4 inhibitors, and they are used either as monotherapy or in combinations of two or three agents. The likelihood of diabetes burdening overall healthcare expenditure is expected to rise, potentially resulting in significant implications for the sustainability of healthcare financing. The objective of this study is to evaluate the cost-effective therapy for diabetes to develop a pharmacoeconomic algorithm for sustainable management.

## MATERIAL AND METHODS

### Study design and sample size

This is an observational retrospective pharmacoeconomic study that was carried out at a multispecialty hospital. The study was conducted over a period of 6 months and a total of 210 patients with type 2 diabetes mellitus were recruited in our study irrespective of age and gender. Patients who were severely ill, on insulin therapy, pregnant or lactating were all excluded from the study. The required data including patient demographic details, complications, laboratory

investigations, prescribed drugs, and associated charges were collected from relevant departments and out-patient files. The data from the second follow up, which was done after a month, was also collected for comparison.

### Calculation of cost and effectiveness

The average drug cost for each patient was determined based on the price of the drug and its frequency and the total mean cost of therapy per month was calculated for each category. The effectiveness of the drugs was assessed based on the mean reduction in fasting blood sugar (FBS), before and after one month of therapy. Paired t test was used to identify the significance of this reduction and the level of significance was fixed to be  $<0.05$ .

### Calculation of ACER and ICER

Average cost-effectiveness ratio (ACER) for each category was calculated by dividing the average cost per month by the mean reduction in FBS. Incremental cost-effectiveness ratio (ICER) was calculated based on the formula:  $ICER = [(Cost\ of\ therapy - Cost\ of\ control) / (Effectiveness\ of\ therapy - Effectiveness\ of\ control)]$ . In our study, treatment with Glycomet (metformin) was taken as control. Based on the ICER, each therapy was categorized into their respective quadrants to determine if they are dominant, cost effective, questionable or excluded. [Figure 1]

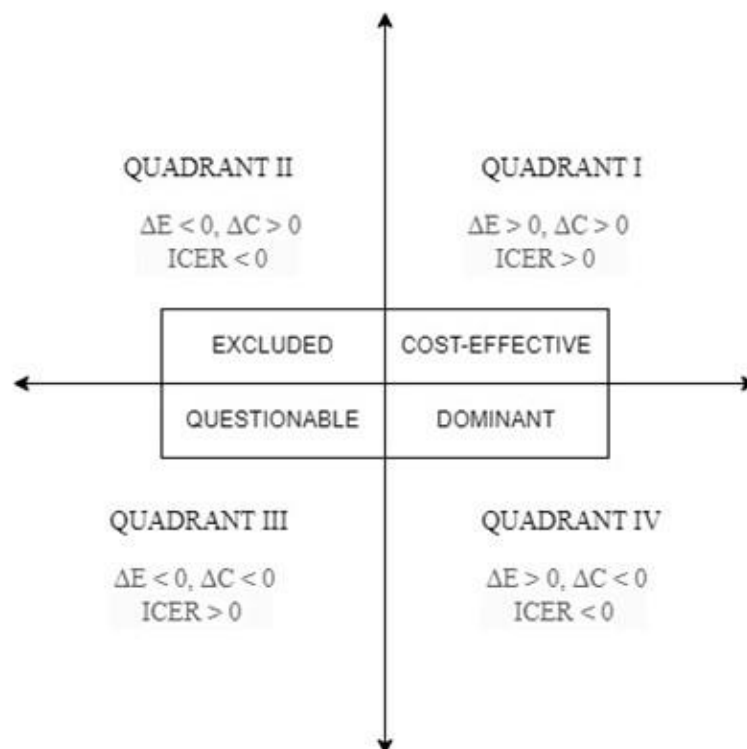


Figure 1: Incremental Cost-Effective Ratio Quadrant Plane and Decision Matrix.

## RESULTS

### Descriptive analysis

In this study of 210 patients, majority were aged 60-70 (42.85%), while the smallest group were aged 80-90 (0.95%). Males comprised 60% of the patients and the most common co-morbidity was found to be systemic hypertension (SHT), affecting 47%. Non-alcoholic patients made up 57%, and smokers accounted for 41.9%. A significant proportion of patients (28.57%) were both alcoholic and smokers. Table 1 shows the demographics of the patients.

**Table 1: Demographic characteristics of the Patients.**

Category	No. of Patients	Percentage (%)
<b>Age wise distribution of Diabetes Mellitus Patients</b>		
30-40	11	5.2%
40-50	11	5.2%
50-60	62	29.5%
60-70	90	42.85%
70-80	34	16.19%
80-90	2	0.95%
<b>Gender wise distribution of Diabetic Mellitus Patients</b>		
Male	126	60%
Female	84	40%
<b>Co-morbidities of Diabetes Mellitus Patients</b>		
SHT	100	47%
Foot Ulcer	33	15%
DLP	24	11.4%
ACS	20	9.5%
UTI	11	5.2%
COPD	15	7.14%
Others	7	3.33%
<b>Social History of Diabetic Mellitus Patients</b>		
Alcoholic	91	43%
Non alcoholic	119	57%
Smoker	88	41.9%
Non smokers	122	58.09%
Both alcoholic and smokers	60	28.57%

**Analysis of prescribing pattern**

Out of the 210 patients, 78 patients (37%) received monotherapy, with Biguanides (Metformin), being the most prescribed drug class representing 23.8% of the total patients. The remaining 132 patients received combination therapy (63%), with combination of Biguanides + Sulphonyl Ureas being the most prescribed drug classes covering 28.09%. This was followed by Alpha Glucosidase Inhibitors + Others (10.95%), Sulphonyl Ureas + DPP4 inhibitors (10.47%) and Biguanides + DPP4 Inhibitors (2.85%). Combinations involving more than two drugs were given to 22 patients (10.47%). Prescribing pattern of agents given has been depicted in Table 2.

**Table 2: Prescribing pattern of Oral Hypoglycemic agents.**

Classification of Oral Antidiabetic Drugs	No. of Patients	Percentage (%)
<b>Monotherapy (n=78) [37%]</b>		
Biguanides (Glycomet)	50	23.80%
Sulphonyl Ureas( Amaryrl, Glycinorm)	23	10.95%
Meglitinides (GlucoNorm)	5	2.38%
<b>Combination Therapy (n= 132) [63%]</b>		
<b>Combinations with Biguanides and Sulphonyl Ureas (n=59) [28.09%]</b>		
Gemer (Glimepiride+ Metformin)	3	1.42%
Glycomet (Metformin)+ Gemer	4	1.90%
Glycomet +Dianorm (Gliclazide)	10	4.76%
Glyciphage(Metformin)+ Semiglynase (Glipizide)	5	2.38%
Glimisave(Glimepiride)+ Glycomet	6	2.85%
Glycomet+ Reclimet(Metformin + Gliclazide)	3	1.42%
Glide(Glipizide)+ Glycomet	9	4.28%
Glycomet+Amaryl (Glimepiride)	11	5.22%
Glycomet+ Glycinorm (Gliclazide)	8	3.80%
<b>Combinations of Sulphonyl Ureas and DPP4 Inhibitors (n=22) [10.47%]</b>		
Glycinorm+ Galvus(Vidagliptin)	3	1.42%

Amaryl+ Istavel (Sitagliptin)	15	7.14%
Dianorm+Galvus	4	1.90%
<b>Combination of Biguanides and DPP4 Inhibitors (n=6) [2.85%]</b>		
Janumet(Metformin + Sitagliptin)	2	0.95%
Galvusmet(Vidagliptin+Metformin)	1	0.47%
Galvus + Glycomet	3	1.42%
<b>Combination of more than twoDrugs (n=22) [10.47%]</b>		
Gemer + GlucoNorm (Repaglanide)	9	4.28%
Glucobay (Acarbose) + Glycinorm+ Janumet	3	1.42%
Reclimet+ Istavel (Sitagliptin)	4	1.90%
Janumet + Amaryl	6	2.85%
<b>Combination of Alpha Glucosidase Inhibitors and Other Drugs (n=23) [10.95%]</b>		
Glycomet+ Glucobay	7	3.33%
Gemer+ Glucobay	4	1.90%
Glycinorm+ Vobose (Voglibose)	6	2.85%
Glycinorm+ Glucobay	6	2.85%

### Management of complications of type 2 diabetes mellitus

A total of 100 patients were identified to have SHT and among them, the most commonly prescribed drugs were Ramipril (28%), Telmisartan(19%), Losartan(15%), Furosemide(15%), Amlodipine(10%), Lisinopril (10%), and Doxazosin(3%). The occurrence of foot ulcers was observed in 33 patients and the most common drugs prescribed for foot ulcer treatment were Clindamycin (90%), Pregablin (75%), Neurobion forte (30%) and Ultracet (45%). Among the 24 patients diagnosed with dyslipidemia, 70% received Atorvastatin, while the remaining 30% were prescribed Rosuvastatin. For the management of acute coronary syndrome (ACS) in 20 patients, all received Aspirin and Clopidogrel, with Atorvastatin administered to 70% of them.

### Distribution and cost of laboratory investigations among study patients

The study examined four types of laboratory investigations conducted on 210 patients. These investigations included fasting blood sugar (FBS), random blood sugar (RBS), postprandial blood sugar (PPBS), and glycosylated hemoglobin (HbA1c). FBS tests, priced at 80 each, were administered to all 210 patients, covering 100% of the participant pool, making it a suitable comparator for our study. RBS tests, also priced at 80 each, were conducted on 102 patients, representing 48% of the total participants. PPBS tests, similarly priced at 80 each, were carried out on 177 patients, accounting for 84.2% of the total participants. HbA1c tests, the most expensive at 600 each, were performed on 120 patients, constituting 57.14% of the total participants.

### Cost effectiveness analysis

A total of 27 different drug combinations were analyzed for their impact on FBS levels before and after therapy initiation. The reduction in FBS was found to be significant for all the agents ( $p < 0.05$ ). A detailed examination of the cost-effectiveness profiles of each category is provided. Table 3. The analysis encompasses several key parameters, including cost per month, mean reduction in FBS levels, average cost-effectiveness ratio (ACER), incremental effect, incremental cost, incremental cost-effectiveness ratio (ICER), and quadrant classification. Quadrant I indicates positive effects with higher costs making it a cost effective option, while Quadrant II shows negative effects with higher costs making it an option that could be excluded.

**Table 3: Cost-effectiveness analysis of various drug combinations for managing fasting blood sugar levels in diabetes mellitus.**

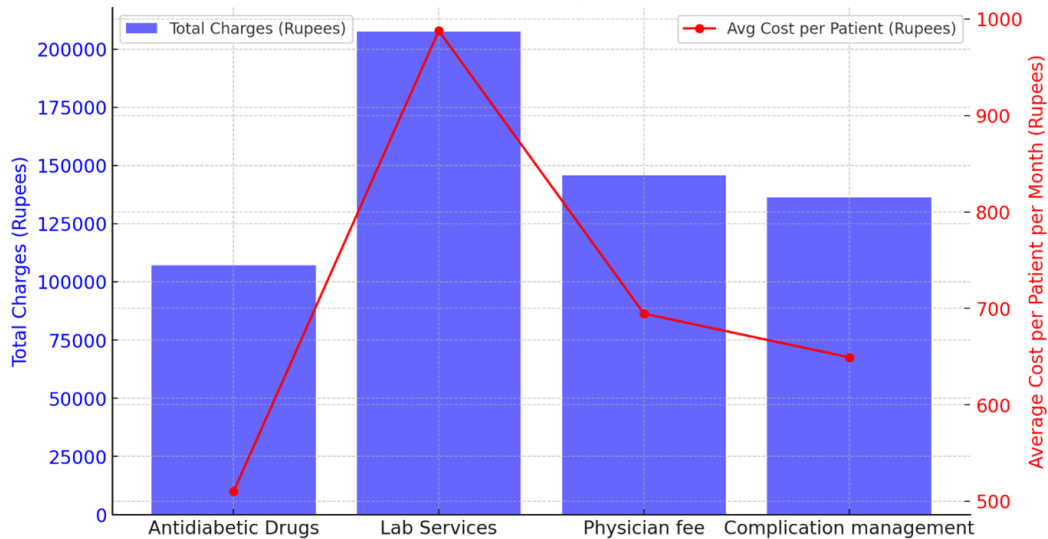
S. No	Brand Name	Cost per month	Mean FBS Reduction <sup>a</sup>	ACER	Incremental Effect	Incremental cost	ICER	Quadrant
1.	Glycomet <sup>b</sup>	56.7	45.16	1.26	-	-	-	-
2.	Amaryl	194.4	19	10.23	-26.16	137.7	-5.26	II
3.	Glycinorm	148.2	15.5	9.56	-29.66	91.5	-3.08	II
4.	GlucNorm	264	7.4	35.68	-37.76	207.3	-5.49	II
5.	Gemer	421.8	30	14.06	-15.16	365.1	-24.08	II
6.	Glycomet + Gemer	478.5	56.5	8.47	11.34	421.8	37.2	I
7.	Glycomet +Dianorm	233.7	5	46.74	-40.16	177	-4.41	II
8.	Glyciphage + Semiglynase	70.5	19.6	3.6	-25.56	13.8	-0.54	II
9.	Glimisave + Glycomet	251.1	44.8	5.6	-0.36	194.4	-540	II
10.	Glycomet + Reclimet	568.2	36.67	15.49	-8.49	511.5	-60.25	II
11.	Glide + Glycomet	68.7	17.56	3.91	-27.6	12	-0.43	II
12.	Glycomet + Amaryl	251.1	47.71	5.26	2.55	194.4	76.24	I
13.	Glycomet + Glycinorm	204.9	81	2.53	35.84	148.2	4.14	I
14.	Glycinorm + Galvus	804.6	20	40.23	-25.16	747.9	-29.73	II
15.	Amaryl + Istavel	449.4	12.6	35.67	-32.56	392.7	-12.06	II
16.	Dianorm +Galvus	833.4	71	11.74	25.84	776.7	30.06	I
17.	Janumet	750	32	23.44	-13.16	693.3	-52.68	II
18.	Galvusmet	657	39.66	16.57	-5.5	600.3	-109.15	II
19.	Galvus + Glycomet	713.1	39.66	17.98	-5.5	656.4	-119.35	II
20.	Gemer + GlucNorm	685.8	39.87	17.2	-5.29	629.1	-118.92	II
21.	Glucobay + Glycinorm + Janumet	1384.2	136	10.18	90.84	1327.5	14.61	I
22.	Reclimet + Istavel	766.5	48.8	15.71	3.64	709.8	195	I
23.	Janumet + Amaryl	944.4	130.33	7.25	85.17	887.7	10.42	I
24.	Glycomet + Glucobay	542.7	78	6.96	32.84	486	14.8	I
25.	Gemer + Glucobay	907.8	75.5	12.02	30.34	851.1	28.05	I
26.	Glycinorm + Vobose	487.2	65.16	7.48	20	430.5	21.53	I
27.	Glycinorm + Glucobay	634.2	89.50	7.09	44.34	577.5	13.02	I

*a* - Reduction in FBS was found to significant for all the drugs ( $p < 0.05$ )

*b* - Control group for other agents

#### Direct medical costs incurred by type ii diabetes mellitus patients on oral antidiabetics

The healthcare expenditure across various cost categories associated with the management of diabetes mellitus has been illustrated in Figure 2. The analysis encompasses oral antidiabetic drugs, laboratory services, physician consultations, and managing complications. Among these categories, laboratory services represent the highest expenditure, accounting for 34.76% of the total charges, followed closely by physician consultations at 24.44% and cost of managing complications at 22.84%. The actual cost of diabetes therapy using oral antidiabetic drugs constituted only 17.94%.



**Figure 2: Direct Healthcare Expenditure.**

## DISCUSSION

Among the 210 patients who were included in the study, majority were found to be male (60%) than female (40%) and they were mostly within the 60-70 years age bracket similar to the findings of an Indonesian study by Tri Murti et al.<sup>[10]</sup> Older adults face a heightened risk of developing Type 2 diabetes due to increased insulin resistance and declining pancreatic function with age.<sup>[11]</sup> Hypertension was identified to be the most common complication in diabetic patients (47%) similar to the findings of Abdelaziz et al. However, it should be noted that though hypertension may not always stem from diabetes, research suggests that excess sugar intake may contribute to it.<sup>[12]</sup>

Sudha et al found biguanides, particularly metformin, to be the most prescribed antidiabetic drugs, aligning with our study's findings. Metformin's effectiveness in reducing blood sugar and cardiovascular risk, along with its safety profile, could explain its popularity.<sup>[13]</sup> Meglitinides were the least prescribed due to risk of side effects such as weight gain and hypoglycemic risk.

The most commonly used combination in the study was sulfonylureas with biguanides, likely due to their complementary mechanisms of action. Biguanides improve insulin sensitivity in muscle tissue, while sulfonylureas stimulate insulin secretion from pancreatic beta cells.<sup>[10]</sup> The least common combination was biguanides with DPP4 inhibitors, possibly because DPP4 inhibitors are typically used as third-line agents for higher postprandial glucose. Sitagliptin and metformin exhibit additive glycaemic improvements, but cost and limited long-term data may limit sitagliptin use.<sup>[14]</sup> Adding a second drug is often preferable to increasing the dosage of an agent that has already been given in a nearly maximum dosage. Three-drug therapy was seen in 10.47% of prescriptions in this study. Though it is less common, three oral agents can be considered for patients with HbA1c values near the goal (<8.5%) due to its superior blood sugar control.<sup>[15]</sup>

The average cost per month for each drug as well as combination therapy was calculated and then compared with the efficacy. The oral antidiabetic efficacy was assessed using FBS similar to a study by Singh et al., as all the patients had it evaluated after a month unlike other units of reduction.<sup>[16]</sup> PPBS values are not reliable as it can change due to many variables, such as physical activity, gastric emptying rate, insulin sensitivity, and meal composition. HbA1c is not



avored for diagnosis either due to potential variability from hemoglobin or red cell abnormalities, making FBS a preferable predictor.<sup>[17]</sup>

Metformin was the cheapest monotherapy at Rs 56.7 per month, while GlucoNorm was the most expensive at Rs 264 per month. In dual combination therapy, combination of Gerner and Glucobay was the most expensive at Rs. 907.8, while Glide and Glycomet combination was the cheapest at Rs. 68.7. Despite being the cheapest option, Metformin showed significant effectiveness, making it the most cost-effective therapy and it is optimal for first line therapy. Similar to the findings of Sheu WH et al and Abdelaziz et al, combination of Glycomet with Amaryl was preferable and it falls under Quadrant I making it a highly cost-effective option.<sup>[12,18]</sup> The results of our study showed that all the combinations involving alpha glucosidase inhibitors were cost effective, while none of the combinations of DPP4 inhibitors + biguanides were cost effective. The higher cost of the alpha glucosidase inhibitor combinations was found to be worth the higher effectiveness. This was completely contrary to a study by Li H et al, which showcased that gliptin-biguanide combinations were far more cost effective than acarbose combinations in the Chinese health care setting.<sup>[19]</sup> Most of the three-drug therapy performed well which was also proved by Rajeshwari et al.<sup>[20]</sup> However, it is considered only if dual therapy fails to be effective enough due to its much higher cost. Another study done in Chinese patients supported the use of Acarbose combinations with Metformin and it stated that it is as safe and effective as some three-drug therapies and also has benefits on reducing the CVD risk.<sup>[21]</sup>

The total medical cost incurred for all the patients over a period of one month was 5.96 lakhs, covering drugs, lab tests, physician visits, and complication management. On average, each patient spent Rs 2841.72. This finding varies from other studies which had the average cost incurred by one patient to be Rs 7386.<sup>[22]</sup> This variation could be due to the fact that our study included only direct medical costs incurred by ambulatory patients and not hospitalization and nursing charges. Indirect costs were not included in this study but it is important to note that these are also costs that the diabetic patients incur.

Based on the results of our study, a novel algorithm for optimizing diabetes treatment regimens by prioritizing therapies based on cost-effectiveness can be suggested. The algorithm systematically organizes monotherapies and multi-drug therapies in an order that prioritizes interventions with the lowest cost and highest effectiveness. It systematically evaluates and categorizes treatments by arranging it in descending order of cost-effectiveness calculated from both incremental cost and effect, enabling healthcare providers to choose the most beneficial options. The resulting flow chart (Figure 3) guides clinicians in selecting tailored treatments, enhancing patient outcomes and promoting efficient resource allocation in healthcare.





their importance in diabetes management. Economic prescribing patterns were observed in this study and an algorithm to prioritize treatments based on both effectiveness and cost was developed along with a suggestive AI model for personalized, cost-effective medication recommendations. These findings and recommendations can guide healthcare providers, policymakers, and researchers in improving diabetes management and reducing its economic burden, with further research and implementation of cost-effective strategies warranted.

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