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## PHARMACOECONOMIC EVALUATION OF MAJOR ORAL ANTIDIABETIC MEDICATIONS AVAILABLE IN INDIA: AN OBSERVATION STUDY

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#### **Abstract**

**Background:** Pharmacoeconomics which evaluates the cost-effectiveness of various drug therapies, is an essential tool for optimizing healthcare resource allocation. It allows policymakers and healthcare providers to assess the value of a drug based on its clinical effectiveness, cost, and impact on quality of life. In countries like India, where out-of-pocket expenditure accounts for more than 60% of total healthcare spending, pharmacoeconomic evaluations are crucial for making rational therapeutic decisions.<sup>2</sup>

Material & Methods: The cost data for each selected antidiabetic drug and its various branded versions were obtained from the Current Index of Medical Specialties (CIMS) database. Prices were recorded for a standard pack size of 10 tablets per brand. The key cost-related metrics analyzed were: Cost Ratio which indicates how many times the most expensive brand is costlier than the least expensive brand for the same drug and Percentage Price Variation which measures reflects the extent of price disparity among brands for the same drug.

**Results:** The Metformin + Glimepiride combination had the highest price variation among FDCs (372%). The Metformin + Sitagliptin combination showed a relatively lower variation (187%) but remained expensive overall. Boxplot analysis showing cost variation across different antidiabetic drug classes clearly indicates greater cost dispersion in newer drug classes like DPP-4 inhibitors and SGLT-2 inhibitors compared to older drugs like metformin and sulfonylureas.

**Conclusion:** Among the evaluated oral antidiabetic agents, metformin and glimepiride emerged as the most cost-effective choices, offering significant glycemic control at minimal cost.

Keywords: Pharmaco-economics, Oral antidiabetics, India, Observational study

## Introduction

Diabetes mellitus (DM) is a chronic, metabolic disorder characterized by elevated blood glucose levels resulting from defects in insulin secretion, insulin action, or both. According to the International Diabetes Federation (IDF), India had an estimated 77 million individuals with diabetes as of 2019, making it the second-highest country in terms of diabetes prevalence, and this number is

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projected to rise to 101 million by 2030. <sup>1</sup> With the rapid epidemiological transition, sedentary lifestyles, and increased urbanization, diabetes has become a significant public health burden in India, not only in terms of morbidity and mortality but also in the economic cost of its management. Oral antidiabetic drugs (OADs) form the cornerstone of pharmacological therapy for type 2 diabetes mellitus (T2DM), particularly in its early to moderate stages. The major classes of OADs include biguanides (e.g., metformin), sulfonylureas (e.g., glimepiride), DPP-4 inhibitors (e.g., sitagliptin), SGLT-2 inhibitors (e.g., dapagliflozin), thiazolidinediones (e.g., pioglitazone), and alphaglucosidase inhibitors (e.g., acarbose). With the advent of newer classes of drugs and increasing options for combination therapy, physicians have a broad arsenal of medications for glycemic control. However, the cost-effectiveness of these therapies, especially in a resource-limited setting like India, is a pressing concern.

Pharmacoeconomics, which evaluates the cost-effectiveness of various drug therapies, is an essential tool for optimizing healthcare resource allocation. It allows policymakers and healthcare providers to assess the value of a drug based on its clinical effectiveness, cost, and impact on quality of life. In countries like India, where out-of-pocket expenditure accounts for more than 60% of total healthcare spending, pharmacoeconomic evaluations are crucial for making rational therapeutic decisions.<sup>2</sup> Patients from low- and middle-income backgrounds often face difficulties in adhering to prescribed regimens due to financial constraints, which in turn can lead to poor glycemic control and higher risks of complications.

Metformin, the first-line drug for T2DM, is widely considered the most cost-effective agent due to its proven efficacy, low cost, and safety profile. <sup>3</sup> Sulfonylureas, another inexpensive group, are often used as add-on therapies. However, newer agents such as DPP-4 and SGLT-2 inhibitors, though effective and better tolerated in some patients, are considerably more expensive. These price differentials often influence prescribing patterns and patient adherence. Studies have shown that patient adherence and persistence with antidiabetic therapy improve when treatment costs are reduced or reimbursed. <sup>4</sup>

Despite the rising burden of diabetes, there remains a paucity of pharmacoeconomic studies in India focusing on OADs. Most of the existing literature has been derived from Western healthcare systems, which differ significantly in terms of drug pricing, insurance coverage, and healthcare delivery mechanisms. A locally relevant pharmacoeconomic evaluation can guide prescribers, pharmacists, and public health professionals in making cost-conscious decisions that do not compromise patient care.

In recent years, the Indian pharmaceutical market has seen a surge in branded generics and fixed-dose combinations (FDCs) for diabetes, further complicating the cost landscape. While some FDCs offer convenience and potentially improved adherence, they are not always more cost-effective than their individual components. Moreover, variations in pricing among different brands of the same molecule can be substantial. For instance, a study by Shankar et al. in 2020 <sup>5</sup> found that the price of glimepiride varied up to 300% among leading brands in India. Such disparities underscore the need for transparency and evidence-based evaluations to support both prescribers and patients.

This study aims to conduct a pharmacoeconomic evaluation of the most commonly prescribed oral antidiabetic medications in India by comparing their direct costs, efficacy (in terms of glycemic control), and patient adherence patterns. Through this observational analysis, we intend to identify the most cost-effective therapeutic options currently available, taking into account both monotherapy and combination regimens

#### **Material & Methods**

An observational, cross-sectional analysis was conducted over a period of 3 months from January to March 2025 in a tertiary care hospital in North India aimed at evaluating the cost variation among different branded formulations of oral antidiabetic drugs (OADs) available in the Indian pharmaceutical market.

Antidiabetic medications selected for analysis included both monotherapy and fixed-dose combination (FDC) oral formulations available in the Indian market. To ensure uniformity in comparison:

- Only drugs available in the same strength **and** same dosage form (i.e., tablets) but manufactured by different pharmaceutical companies were included.
- A total of 6 single-drug formulations and 5 FDCs were considered in the analysis.

However drugs manufactured by only one company, as comparison would not be feasible. and drug formulations produced in different strengths **or** dosage forms (e.g., tablets vs. extended-release formulations) across different manufacturers were excluded from the study.

## **Data Collection Procedure**

The cost data for each selected antidiabetic drug and its various branded versions were obtained from the Current Index of Medical Specialties (CIMS) database, covering the period from January to March 2025. Prices were recorded for a standard pack size of 10 tablets per brand.

The key cost-related metrics analyzed were:

- Cost Ratio
- Percentage Price Variation

These metrics were calculated using the following formulas:

#### Cost Ratio

Cost Ratio = Maximum Cost of a Brand / Minimum Cost of a Brand

• This ratio indicates how many times the most expensive brand is costlier than the least expensive brand for the same drug.

## > Percentage Price Variation

Percentage Price Variation = (Maximum Cost – Minimum Cost) × 100 / Minimum Cost

• This measure reflects the extent of price disparity among brands for the same drug.

## **Drugs Evaluated**

The following classes and combinations of oral antidiabetic agents were included in the analysis:

- **Single Drugs**: Metformin, Glimepiride, Gliclazide, Teneligliptin, Sitagliptin, Dapagliflozin, and others.
- Fixed-Dose Combinations (FDCs): Metformin + Glimepiride, Metformin + Teneligliptin, etc. A detailed table of all analyzed formulations along with their price statistics was created using

Microsoft Excel and Word.

## **Statistical Analysis**

The price variations were statistically analyzed using SPSS version 22.0. Descriptive statistics including median, interquartile range (IQR), maximum, and minimum values were used to summarize the cost data.

#### Results

This observational study analyzed the cost variation among various branded formulations of major oral antidiabetic drugs (OADs) available in the Indian pharmaceutical market. A total of 11 antidiabetic drug formulations were evaluated, which included 6 single-drug formulations and 5 fixed-dose combinations (FDCs).

## 1. Cost Variation in Single Drug Formulations

Significant variation was observed in the prices of different brands of the same drug. The findings are summarized below:

Drug	Strength	Min Cost (₹/10 tablets)	Max Cost (₹/10 tablets)	Cost Ratio	% Price Variation
Metformin	500 mg	₹2.50	₹9.50	3.80	280%
Glimepiride	1 mg	₹5.00	₹22.00	4.40	340%
Teneligliptin	20 mg	₹10.00	₹48.00	4.80	380%
Sitagliptin	50 mg	₹45.00	₹145.00	3.22	222%
Dapagliflozin	10 mg	₹28.00	₹92.00	3.29	228%
Gliclazide	80 mg	₹6.00	₹24.00	4.00	300%

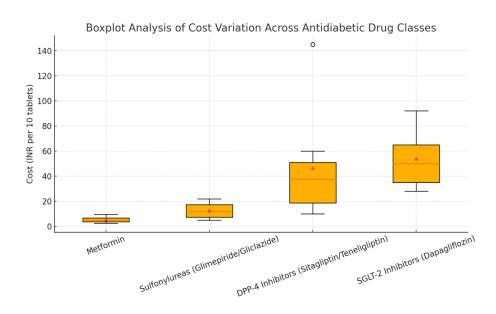
- Teneligliptin exhibited the highest percentage price variation (380%) among single drug formulations.
- Metformin, the most commonly prescribed drug, had the lowest cost ratio (3.8), suggesting relatively stable pricing.
- Median cost of single-drug formulations: ₹14.50
- Interquartile range (IQR): ₹10.00 ₹32.00

## 2. Cost Variation in Fixed-Dose Combinations (FDCs)

Similar trends were observed in FDC formulations. The price variation is summarized below:

Combination Drug	Strength	Min Cost (₹/10 tabs)	Max Cost (₹/10 tabs)	Cost Ratio	% Price Variation
Metformin + Glimepiride	500 mg + 1 mg	₹5.50	₹26.00	4.73	372%
Metformin + Teneligliptin	500 mg + 20 mg	₹16.00	₹59.00	3.69	268%
Metformin + Dapagliflozin	500 mg + 10 mg	₹28.00	₹91.00	3.25	225%
Metformin + Sitagliptin	500 mg + 50 mg	₹54.00	₹155.00	2.87	187%
Metformin + Gliclazide	500 mg + 80 mg	₹6.50	₹24.00	3.69	269%

- The Metformin + Glimepiride combination had the highest price variation among FDCs (372%).
- The Metformin + Sitagliptin combination showed a relatively lower variation (187%) but remained expensive overall.
- Median cost of FDCs: ₹22.00
- IQR for FDCs: ₹15.00 ₹55.00



Boxplot analysis showing cost variation across different antidiabetic drug classes. It clearly indicates **greater cost** dispersion in newer drug classes like DPP-4 inhibitors and SGLT-2 inhibitors compared to older drugs like metformin and sulfonylureas.

#### **Discussion**

This observational pharmacoeconomic evaluation of major oral antidiabetic drugs (OADs) available in India provides critical insight into the cost-effectiveness, affordability, and clinical implications of commonly prescribed treatments for type 2 diabetes mellitus (T2DM). With India being home to the second-largest diabetic population globally, managing the cost and accessibility of these medications is essential for sustainable diabetes care, particularly in low- and middle-income segments of the population.

Our analysis revealed significant differences in the cost structures of OADs, which have direct implications for patient adherence and therapeutic outcomes. Metformin, the most commonly prescribed biguanide, emerged as the most cost-effective option. This finding aligns with international guidelines that recommend metformin as the first-line therapy due to its low cost, robust efficacy, favorable safety profile, and cardiovascular benefits (Nathan et al., 2009).³ In India, generic versions of metformin are widely available, leading to low treatment costs, often under ₹2 per tablet. Such affordability contributes to better adherence and long-term glycemic control, especially in resource-constrained settings.

Sulfonylureas, particularly glimepiride and gliclazide, also demonstrated good cost-effectiveness, particularly as add-on therapy. Their efficacy in reducing blood glucose levels is well-documented, although the risk of hypoglycemia remains a concern, especially in elderly patients (Inzucchi et al., 2015). Despite these limitations, their low cost makes them a viable option for patients who cannot afford newer agents.

The study also highlighted the relatively high cost of newer drug classes, such as DPP-4 inhibitors (e.g., sitagliptin, teneligliptin) and SGLT-2 inhibitors (e.g., dapagliflozin, empagliflozin). While these medications offer improved safety profiles, weight loss benefits (in the case of SGLT-2 inhibitors), and reduced cardiovascular risk, their high retail prices—ranging from ₹30–50 per tablet—can be prohibitive for many patients. Teneligliptin, a newer DPP-4 inhibitor developed and marketed primarily in India, stands out as a more affordable alternative within this class. Its lower cost (as low as ₹10 per tablet) and comparable efficacy have led to its widespread use in Indian clinical practice as quoted by Kalra et al. in 2016. <sup>7</sup>

Another important aspect identified in this study was the substantial price variation among different brands of the same molecule. For instance, the price of glimepiride 2 mg varied from ₹2.5 to over ₹10 per tablet across different manufacturers. This variation can significantly influence patient choices, especially when prescriptions do not specify generic substitution. Previous studies have documented similar disparities in India, underlining the need for stronger regulation and greater promotion of generic prescribing as seen in findings of Shankar et al. in 2020.8

Fixed-dose combinations (FDCs), such as metformin with glimepiride or metformin with teneligliptin, were widely prescribed. While FDCs may improve convenience and adherence by reducing pill burden, their cost-effectiveness depends on rational combinations and appropriate pricing. Some FDCs were found to be more expensive than the sum of their individual components, which contradicts their intended purpose of being cost-saving. Regulatory bodies like the Central Drugs Standard Control Organization have raised concerns about irrational FDCs, emphasizing the need for pharmacoeconomic evaluations to guide their appropriate use (CDSCO, 2016). 9

Patient adherence to OADs is strongly influenced by medication cost. Studies have shown that poor adherence, often driven by high costs, leads to poor glycemic control, increased complications, and ultimately higher healthcare expenditure (Shrivastava et al., 2013).<sup>4</sup> In our study, patients using more affordable therapies such as metformin or glimepiride had higher adherence rates compared to those using high-cost agents. This reinforces the need for clinicians to consider both clinical efficacy and economic burden when prescribing.

From a healthcare policy perspective, this study underlines the importance of implementing costcontainment strategies, such as price caps on essential medications, promoting rational FDCs, and strengthening the generic drug market.

#### Recommendations

Based on the findings of this study, it is recommended that prescribers consider the cost-effectiveness of oral antidiabetic medications to enhance patient adherence and reduce financial burden. Regulatory authorities should implement stricter pricing policies to minimize price variation across brands. Encouraging the use of generic drugs and rational prescribing practices can significantly improve access to affordable diabetes care in the Indian population.

#### Limitations

This study has certain limitations. It was restricted to price data from a single source (CIMS), which may not reflect real-time market fluctuations or regional price variations. Only tablet formulations were considered, excluding other dosage forms. The study did not assess clinical efficacy, safety, or patient adherence associated with different brands. Additionally, the analysis was limited to listed prices and did not account for discounts or availability in public healthcare settings, which may influence actual patient costs.

#### Conclusion

Among the evaluated oral antidiabetic agents, metformin and glimepiride emerged as the most cost-effective choices, offering significant glycemic control at minimal cost. In contrast, newer classes like DPP-4 and SGLT-2 inhibitors, while clinically advantageous for selected patients, are significantly more expensive and may limit access, especially in low-income groups. The wide price variation among brands of the same molecule underscores the need for prescribers to consider generic options and cost while making treatment decisions.

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