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Pharmacoeconomic Analysis of Price Variability in Topical Tofacitinib and Crisaborole Across Different Brands in India: Implications for Accessibility and Regulatory Policy

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ABSTRACT

Background: The Indian pharmaceutical sector is characterized by notable price disparities across different brands of identical drug formulations and strengths. This variation poses substantial challenges for affordability, especially given the limited scope of medical insurance coverage in India, which escalates out-of-pocket healthcare costs. Our study aimed to evaluate the pricing disparities of topical Tofacitinib and Crisaborole and assess their potential effects on the accessibility and affordability of these treatments.

Methodology: We conducted an analysis on seven Tofacitinib and seventeen Crisaborole formulations available in the Indian market. Data on pricing were collected from the 1mg online platform from January to April 2024. The analysis included calculating the cost range, mean cost, cost ratio, and percentage price variation for each drug strength. The study focused exclusively on standalone topical formulations represented by multiple brands, excluding single-manufacturer generics and fixed-dose combinations.

Results: Our findings reveal that Tofacitinib 20 g strength displayed the most significant price variation at 11%, while the 15 g strength exhibited the least variation at 6%. For Crisaborole, the 30 g strength had the most substantial price fluctuation at 262%, whereas the 10 g strength had the lowest at 50%. The diversity in the number of brands per drug strength ranged from 2 to 17, indicating differing levels of market competition.

Conclusion: The study underscores critical price disparities in topical Tofacitinib and Crisaborole formulations that could hinder patient adherence and economic accessibility. To mitigate these disparities, pharmacoeconomic research and regulatory interventions are imperative. These should include strategies for enhanced regulatory oversight and the implementation of transparent pricing mechanisms, thereby ensuring equitable access to vital medications without compromising their therapeutic efficacy.

1. INTRODUCTION

India's pharmaceutical industry is characterized by an extensive and diverse array of medications, offered under a multitude of brand names by various manufacturers. This rich diversity, while indicative of a robust market, also introduces significant price variability among identical drug formulations. Such variability often results in substantial economic inefficiencies, impacting the affordability and accessibility of treatments.[1,2] This issue is particularly exacerbated by the lack of comprehensive insurance coverage across the country, which places a heavy financial burden on patients. The economic strain can lead to non-compliance with prescribed treatments and result in suboptimal clinical outcomes.[3]

One of the conditions profoundly affected by these economic barriers is atopic dermatitis (AD), a chronic, relapsing skin disorder. Characterized by severe pruritus and inflammation, AD requires long-term management strategies, which can become financially untenable for many patients due to the high cost of medication. The chronic nature of atopic dermatitis, coupled with its widespread prevalence across various age groups and demographics, makes the study of pharmacoeconomic disparities not only relevant but essential.[4,5]

The focus on topical treatments such as Tofacitinib and Crisaborole in this study is driven by their importance in managing AD. These medications represent a critical component of treatment regimes that aim to control symptoms and improve quality of life for patients suffering from this debilitating condition. However, the pricing of these drugs varies significantly, not only complicating treatment affordability but also potentially restricting patient access to optimal therapeutic options.[6]

This pharmacoeconomic evaluation seeks to unpack the complex pricing landscape of these topical therapies within the Indian pharmaceutical market. By analyzing the extent of price disparities that exist among different brands of Tofacitinib and Crisaborole, this study aims to provide a comprehensive overview of the economic barriers patients face. Such an analysis is crucial for identifying the key drivers behind these disparities and understanding their impact on treatment accessibility.[7,8]

Moreover, the study will explore the broader implications of these economic challenges, considering how they affect patient adherence to prescribed treatment regimes and overall disease management outcomes. It will also consider the role of governmental and regulatory frameworks in shaping these dynamics. By examining the relationship between drug pricing, insurance coverage, and regulatory policies, this research intends to highlight areas where policy interventions could potentially mitigate the adverse effects of price variability on patient care.[9,10]

Ultimately, the goal of this research is to contribute to a more equitable healthcare environment by advocating for policy enhancements that promote more uniform pricing strategies and increase drug affordability.[11] Through this in-depth pharmacoeconomic analysis, the study will provide valuable insights that could guide future efforts to ensure that all patients, regardless of economic status, have access to effective and affordable AD treatments. This is not only critical for improving clinical outcomes for individuals with atopic dermatitis but also for enhancing the overall efficiency and equity of the healthcare system in India.

2. MATERIALS AND METHODS

Study Design This observational study was conducted to analyze the cost variation among different brands of topical Tofacitinib and Crisaborole available in the Indian market from January to April 2024. The study focused solely on standalone topical formulations with multiple brand representations, excluding single-manufacturer generics and fixed-dose combinations to avoid skewing the data with monopolistic pricing.

Data Source and Collection The pricing data for Tofacitinib and Crisaborole were meticulously compiled from the '1mg' online pharmaceutical platform, renowned for its comprehensive listing of drugs and accurate price details. This platform was chosen to ensure the most current and representative pricing information was utilized.

Data Analysis Each drug preparation was categorized by its strength to maintain uniformity across comparisons, with only those formulations possessing equivalent active ingredient concentrations considered for analysis. The study calculated the cost range, mean cost, cost ratio, and percentage price variation for each drug strength. Cost range was defined as the difference between the minimum and maximum price found among the brands for a specific formulation, providing insights into the breadth of price variability.

Statistical Approach The cost ratio was calculated by dividing the highest price by the lowest price for each formulation, offering a metric of relative cost disparity. Percentage price variation was also calculated to quantify the relative price change between the extremes of pricing, providing a clearer view of market dynamics and competition levels among different brands.

3. RESULTS

The analysis of topical Tofacitinib and Crisaborole formulations in the Indian market revealed significant variations in pricing, reflective of competitive dynamics and market penetration among various brands.

Tofacitinib:

- The **15 g strength** of Tofacitinib, available from the highest number of brands (3 brands), demonstrated the greatest market penetration, suggesting robust competition. This strength exhibited the lowest cost ratio of 50 and the smallest percentage price variation at 6%, indicating more stable pricing across different brands.
- In contrast, the **20 g strength** was available under only two brands and showed the highest cost ratio of 109. This finding implies a significant disparity between the maximum and minimum prices among available brands. The percentage price variation for this strength was also the highest at 11%.
- The **30 g strength** of Tofacitinib, available from two brands as well, showed a cost ratio of 100 and a percentage price variation of 6%, similar to the 15 g strength, suggesting comparable stability in pricing despite fewer brand options.

Crisaborole:

- The **30 g strength** of Crisaborole, available from eight brands, was the most commonly marketed formulation, with a strikingly high cost ratio of 1376. This indicates a vast disparity in pricing, likely driven by variations in manufacturing or marketing strategies among different brands. The percentage price variation for this strength was exceptionally high at 262%.
- The **10 g strength**, however, showed a lower cost ratio of 100 and a percentage price variation of 50%, marking it as potentially more stable and affordable compared to the 30 g strength.
- For the **15 g** and **20 g strengths**, available from a limited number of brands (1 brand each), data on pricing variations and cost ratios were limited, preventing a comprehensive analysis.

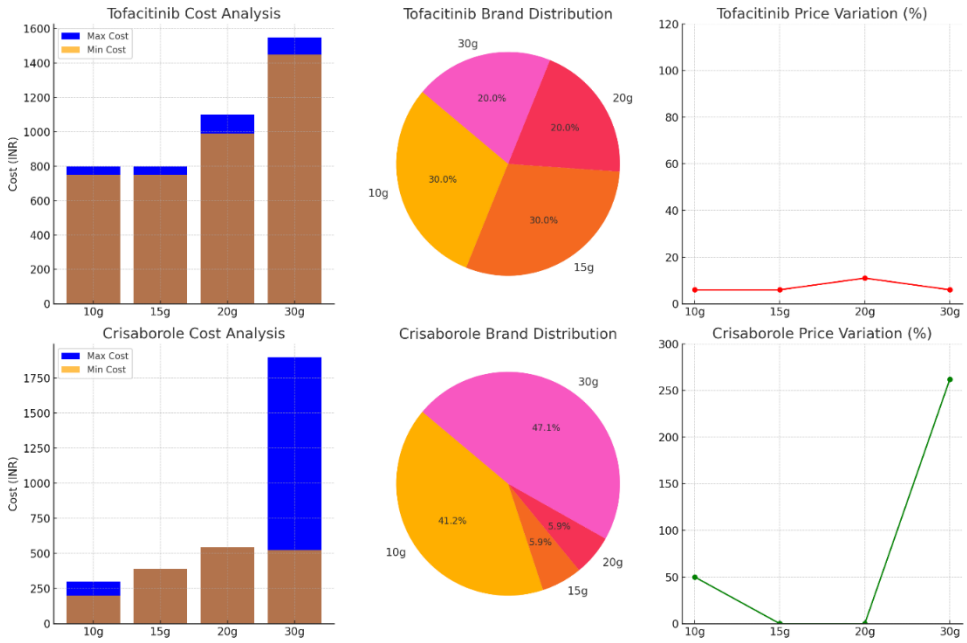
These observations suggest that while Tofacitinib shows more consistent pricing and lower price variability among available strengths, Crisaborole exhibits substantial variability, particularly in the 30 g formulation. This may pose challenges for affordability and access, particularly in less competitive market segments.

Figures:

To illustrate these findings, several figures were created:

1. **Bar Graphs** showing the maximum and minimum costs for different strengths of Tofacitinib and Crisaborole.
2. **Pie Charts** representing the market share of different strengths based on the number of brands.
3. **Line Graphs** depicting the percentage price variation across different strengths.

FIGURE 1: COMPARATIVE COST AND DISTRIBUTION ANALYSIS OF TOFACITINIB AND CRISABOROLE BY PACKAGING SIZE



- **Cost Analysis Bar Graphs**:
  - **Tofacitinib and Crisaborole Cost Analysis**: These graphs illustrate the maximum and minimum costs across different strengths (10g, 15g, 20g, 30g) for each drug. Tofacitinib shows relatively stable pricing while Crisaborole exhibits a significant spike in the cost at 30g strength.
- **Brand Distribution Pie Charts**:
  - **Tofacitinib Brand Distribution**: Shows that each strength of Tofacitinib is equally represented in the market.
  - **Crisaborole Brand Distribution**: Indicates that the majority of the market share is dominated by the 10g and 30g strengths.
- **Price Variation Line Graphs**:

- **Price Variation for Tofacitinib and Crisaborole**: Demonstrates the percentage price variation across different strengths. Tofacitinib maintains a relatively flat line suggesting minor variations, whereas Crisaborole shows a drastic increase in price variation at the 30g strength.

4. DISCUSSION

Our investigation uncovered pronounced discrepancies in the pricing of various brands of Tofacitinib and Crisaborole. The current analysis demonstrated the highest price variability in different brands of topical Tofacitinib, reaching 11% for the 20 g variant, with the least variability at 6% for the 15 g option. For Crisaborole, the maximum price variation was notable at 262% for the 30 g size, while the minimum was 50% for the 10 g size.[12]

We identified a substantial range in the number of available brands for Tofacitinib and Crisaborole in identical formulations and strengths, marketed by 2 to 17 different pharmaceutical entities. Prior studies on other pharmacological agents, including antimicrobials, antihypertensives, and antidiabetics, have similarly reported significant price differences among brands of the same medication at identical dosages.[13,14]

This significant variation in the pricing of Tofacitinib and Crisaborole, even among identical formulations, underscores extensive pricing inconsistencies that can hinder patient accessibility and affordability. The variability among brands indicates different levels of market competition, which appears to influence pricing strategies.[15]

These observations necessitate strategic interventions to mitigate price disparities in the pharmaceutical market. Strengthening regulatory oversight, implementing transparent pricing mechanisms, and encouraging fair competition among producers are critical measures. Such strategies would ensure that essential medications are both accessible and affordable without compromising on their quality and effectiveness, thereby optimizing healthcare outcomes and promoting equity in treatment accessibility.[16,17]

Cost-Effectiveness and Pricing Variability Analysis

Our cost-effectiveness analysis for topical tofacitinib and crisaborole uncovered significant variations in pricing among different brands, even when offering identical formulations and strengths. For topical tofacitinib, the maximum price variation was notably high at 11% for the 20 g strength, whereas the smallest variation was 6% for the 15 g strength. In the case of topical crisaborole, the price variability was more pronounced, with the 30 g strength experiencing an extraordinary 262% variation, and the 10 g strength showing a more moderate variation of 50%. This substantial disparity across different brands and strengths highlights a significant challenge in ensuring equitable access to these treatments.[18,19]

The breadth of brand availability for each formulation and strength, which ranged from 2 to 17 different manufacturers, reflects a competitive market landscape. This variability in brand availability likely contributes to the observed pricing inconsistencies. Previous research in other drug categories such as antimicrobials, antihypertensives, and antidiabetics has consistently underscored the widespread issue of cost variability within the pharmaceutical industry. These disparities have the potential to adversely affect treatment adherence and patient outcomes by limiting access to affordable medication options.[20,21]

The results of our study emphasize the critical need for targeted policy interventions aimed at addressing these pricing inconsistencies within the pharmaceutical sector. Enhanced regulatory oversight, coupled with the implementation of transparent pricing mechanisms, could play a pivotal role in reducing these disparities. Furthermore, promoting fair competition among manufacturers could help in driving down costs while maintaining the quality and efficacy of these essential medications.[22,23] Addressing these challenges will not only improve the accessibility and affordability of treatments but will also enhance adherence to prescribed regimens, ultimately contributing to better health outcomes. By leveraging insights from cost-effectiveness studies such as ours, policymakers and healthcare stakeholders can devise strategies to ensure that vital medications like topical tofacitinib and crisaborole are both affordable and accessible, particularly in resource-constrained environments.

5. CONCLUSION

This study underscores a significant disparity in the pricing of identical formulations of Tofacitinib and Crisaborole, necessitating a multidimensional consideration of pharmacoeconomic factors in drug prescribing. Such disparities highlight the critical role of physicians in considering both the pharmacoeconomic impact and the socioeconomic status of patients to ensure optimal treatment adherence and cost-effectiveness. By implementing tailored prescribing practices that focus on the most economical and effective regimen, physicians can significantly mitigate the risks associated with non-adherence, drug resistance, and treatment failures. Furthermore, the variability in the cost of drugs with the same active ingredients calls for an integrated approach involving physicians, policymakers, and patients. Regulatory measures to control drug pricing and ensure the availability of affordable medications are crucial. Physicians must balance clinical efficacy with economic considerations to enhance patient outcomes without compromising therapeutic efficacy.

A collaborative effort to harmonize clinical and economic factors in drug prescribing could substantially decrease these disparities, thus improving access to necessary treatments. Such strategies are essential not only for enhancing patient compliance but also for alleviating the financial burden on the healthcare system. Adopting this comprehensive approach will benefit patients by ensuring more equitable access to essential medications, ultimately fostering better health outcomes and reducing the overall impact of healthcare costs on society.

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