

Research Article

Cost Variation Analysis of Biological Agents (bDMARDs) Used in the Treatment of Rheumatoid Arthritis in the Indian Market*Jeyarajumanickam R, Roopa P Nayak, Chaitra S R*, Nagapati P Bhat*

Department of Pharmacology, Yenepoya Medical College, Mangalore, Karnataka, India

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Corresponding Author: **Chaitra S R** Email: chaitrasr1990@gmail.com**ABSTRACT**

Background: Rheumatoid arthritis (RA) is a chronic autoimmune disorder requiring long-term treatment with biologic disease-modifying antirheumatic drugs (bDMARDs). However, high costs and price variations among different brands pose significant barriers to treatment adherence in India.

Objective: To analyse cost variations among different brands of bDMARDs available in the Indian market.

Methods: A retrospective observational study was conducted using data from the *Monthly Index of Medical Specialties (MIMS)*. The maximum retail prices (MRP) of various bDMARDs (e.g., etanercept, infliximab, adalimumab) were collected. Cost ratio and percentage variation were calculated using descriptive statistics as per Mahajan's methods in biostatistics.

Results: The highest cost variation was observed in etanercept 25 mg (402%), with a cost ratio of 5.03, while infliximab 100 mg showed the least variation (28%, ratio: 1.5).

Conclusion: Significant price disparities exist among bDMARD brands in India, affecting affordability. Policy interventions such as price regulation, promotion of biosimilars, and differential pricing strategies are needed to improve access.

Keywords: Rheumatoid arthritis, bDMARDs, cost variation, pharmacoeconomics

1. INTRODUCTION

Rheumatoid arthritis (RA) represents a significant global health challenge as a chronic, progressive autoimmune disorder characterized by persistent synovial inflammation, progressive joint destruction, and debilitating systemic complications [1]. In addition to having a significant negative influence on patients' quality of life, this illness places a significant financial strain on healthcare systems around the globe. Effective therapeutic approaches are essential for patient outcomes since RA is a chronic condition that requires long-term therapy methods to manage symptoms and stop the illness from progressing.

The advent of biologic disease-modifying antirheumatic drugs (bDMARDs) has marked a revolutionary advancement in RA management [2]. Through improved disease control, less joint damage, and notable enhancements in patients'

quality of life, these tailored medicines have proven to be more effective than traditional treatments. A paradigm shift in the treatment of autoimmune illnesses, bDMARDs function by selectively blocking important immune system elements implicated in the inflammatory process. Despite the therapeutic advantages of bDMARDs, access to treatment is significantly hampered by their high cost, especially in low- and middle-income nations like India [3]. Many patients are unable to afford these life-changing treatments because of the high percentage of out-of-pocket healthcare expenses in these environments. The evolution of the disease and long-term results are significantly impacted by this financial load, which frequently requires difficult decisions between treatment adherence and other necessities.

Several bDMARDs, including as etanercept, infliximab, adalimumab, and rituximab, are

available on the Indian pharmaceutical market; nevertheless, there are notable pricing differences between brands [4]. Due to these discrepancies, treatment options are primarily dictated by economic position rather than clinical necessity, leading to unequal access patterns. These discrepancies bring up significant issues regarding pricing transparency, market control, and the moral implications of making crucial medications accessible in emerging healthcare systems.

Significant cost disparities that have a direct impact on patient compliance and treatment results have been demonstrated by prior pharmaco-economic studies looking at other drug classes, such as antifungals and antidiabetics [5, 6]. But even though bDMARDs are crucial for managing RA, there is still a significant lack of thorough pharmaco-economic information about these biologics in the Indian setting. This knowledge gap emphasises the necessity of conducting a thorough examination of pricing trends and their effects on the accessibility of RA treatments in India's distinct healthcare environment.

Treatment non-adherence and cessation among RA patients are caused by the high expense of bDMARDs in India's out-of-pocket healthcare system. Considerable price differences between brands make affordability issues even worse and lead to unfair treatment. In order to enhance access to these life-changing treatments and inform policy, our study fills a major gap in comparative cost evaluations for bDMARDs in India.

1.1 Objectives

1. To identify and compare the maximum retail prices (MRP) of different bDMARDs brands.
2. To calculate cost ratio and percentage variation among brands.
3. To discuss policy implications for improving affordability.

2. Methods

This retrospective observational study was conducted after obtaining ethical clearance from the Institutional Ethics Committee of Yenepoya Medical College, Mangalore (Protocol No: YEC-

1/2025/019). We reviewed the pricing information for biologic disease-modifying antirheumatic medications (bDMARDs) that were offered for sale in the Indian pharmaceutical market between December 2024 and April 2025. This information was taken from the Monthly Index of Medical Specialities (MIMS) database. To allow for useful price comparisons, the analysis excluded single-manufacturer goods and included all bDMARD formulations with numerous brands available for the same dosage strength.

For each included bDMARD we recorded the maximum retail prices (MRP) of all available brands. We then calculated two key metrics: (1) the cost ratio (price of most expensive brand divided by price of least expensive brand for identical formulations), and (2) the percentage cost variation using the formula $[(\text{maximum price} - \text{minimum price}) / \text{minimum price}] \times 100$. These calculations allowed us to quantify the extent of price disparities between different brands of the same biologic drug.

In accordance with accepted biostatistical procedures as outlined by Mahajan [13], descriptive statistics (means, percentages) were used for all statistical analyses utilising Microsoft Excel. While preserving methodological rigour in our review of the Indian biologics market, our analytical technique allowed for the systematic evaluation of pricing patterns across several bDMARD categories. Rather than evaluating clinical outcomes or patient access patterns, the study design was expressly focused on discovering and measuring pricing discrepancies.

3. Results

A thorough cost analysis of biologic disease-modifying antirheumatic medications (bDMARDs) used to treat rheumatoid arthritis in India is given in the table. With four brands ranging in price from ₹5,714 to ₹28,740, etanercept 25mg injection displayed the most extreme price variance, resulting in a 402% difference and a cost ratio of 5.02. On the other hand, there were only two brands with a moderate 65% variation for its 50mg version. Adalimumab 40mg, which has ten

manufacturers, showed moderate fluctuation (55%) between ₹16,071 and ₹25,000, whereas infliximab 100mg showed more constant cost with just a 28% difference between its two available brands.

A number of single-brand biologics for which pricing comparisons were not feasible were also included in the investigation. With prices of ₹7,000 and ₹30,000, respectively, there was only one brand of Anakinra 100mg and Abatacept 250mg available on the market. Since patients lack less expensive options for these particular medicines, the lack of competition for some biologics raises possible accessibility concerns. Treatment decisions are especially impacted by the single-brand situation when patients are unable to pay for the only option.

There were notable pricing differences between the two versions of rituximab. While the 500mg version exhibited an even greater absolute price range (₹30,285 to ₹80,000) among 20 manufacturers, reflecting a 164% difference, the 100mg version shown a 201% variation across 15 brands. These significant price differences for rituximab, particularly for the higher 500mg dosage, bring up crucial issues about affordability and market control. The data unequivocally demonstrates that pricing fluctuation patterns vary significantly not only between drug kinds but also between dosages of the same prescription, pointing to intricate market dynamics impacted by brand strategies, manufacturing costs, and competition.

Table 1. Cost Variation among the bDMARDs available in Indian market

S. NO	Drug name	Dose	Dosage form	No of Brands	Max Price (INR)	Min Price (INR)	Cost Ratio	% Cost Variation
1	etanercept	25mg	Injection	4	28740	5714	5.02	402%
		50mg	Injection	2	17170	10390	1.65	65%
2	infliximab	100mg	Injection	2	41039	32000	1.2	28%
3	adalimumab	40mg	Injection	10	25000	16071	1.5	55%
4	anakinra	100mg	Injection	1	7000	7000	-	-
5	abatacept	250mg	Injection	1	30000	30000	-	-
6	rituximab	100mg	Injection	15	16000	5299	3.09	201%
		500mg	Injection	20	80000	30285	2.64	164%

3.1. Key Findings:

- **Etanercept 25 mg** showed the **highest variation (402%)**, indicating extreme price disparities.
- **Infliximab 100 mg** had the **lowest variation (28%)**, suggesting relatively stable pricing.

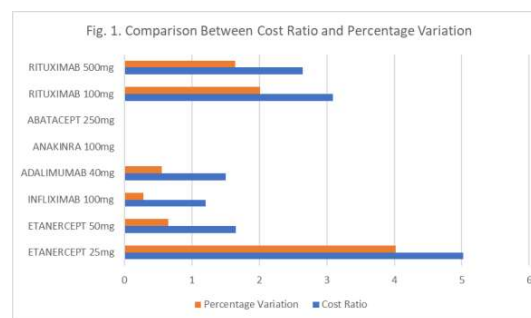


Fig.1 Comparison between Cost Ratio and Percentage Variation

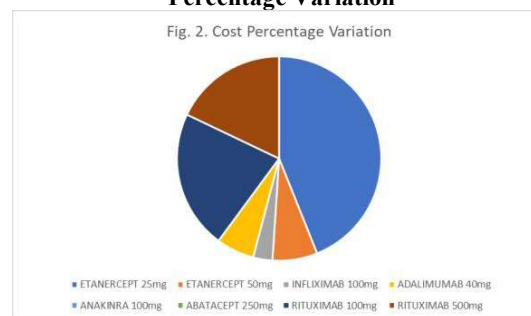


Fig. 2 Cost Percentage Variation

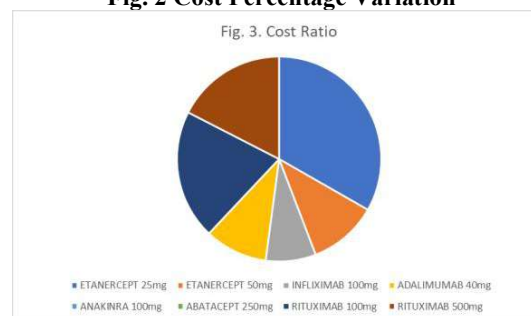


Fig. 3 Cost ratio

4. Discussion

According to the study, there are serious issues with medicine accessibility and cost in India's pharmaceutical industry. Extreme price differences were also noticeable; etanercept revealed a startling 402% cost gap between brands, underscoring the problems of market monopolies & insufficient price control for biologics. These results are consistent with other studies showing comparable trends, such as 1022% variation for pegfilgrastim [2] and 733% differences for antifungal drugs[6]. Further demonstrating how monopolistic practices lead to significant pricing differences across therapeutic categories, similar discrepancies were also observed in hypolipidemic medications [7].

There are serious clinical repercussions from the affordability crisis brought on by these

differences. Exorbitant expenses have been shown to be a direct cause of treatment cessation and worsening illness outcomes [8]. A systematic review by Ping-Hsuan Hsieh et al states that indirect cost like work disability due to rheumatoid arthritis is the major component of total cost. Apart from direct cost of the medicine all other indirect cost leads to poor compliance.[9] Quality of life of patients is improved by biosimilars but medicines appear not to be cost-effective due to their high incremental cost-effectiveness ratio (ICER) [10]. This emphasises how vital it is to promote biosimilar substitutes, a strategy backed by antiplatelet drug research [11]. Such price differences will keep preventing patients from accessing necessary treatments if nothing is done, especially for long-term illnesses like rheumatoid arthritis.

The study suggests a number of policy solutions to address these systemic problems. As previously suggested for antidiabetic drugs [12], implementing price limits through mechanisms like the Drugs Prices Control Order (DPCO) could aid in cost stabilisation. Furthermore, establishing tax breaks to encourage the development of biosimilars domestically-a tactic that has been effectively emulated for anxiety drugs [13] - may lead to more competition in the market and reduced costs. These steps could guarantee long-term medication availability while lessening the financial strain on patients. Contextualising the study's findings with earlier research makes them even more urgent. Significant differences have been reported between SSRIs (3477%) [4] and antidiabetic medications (3668%) [5], which together show pervasive pricing inconsistencies across drug classes. These stark differences point to structural problems with pharmaceutical pricing schemes, which call for regulatory changes to guarantee fair access to necessary medications.

4.1 Limitations

The study does, recognise some limitations, most notably its dependence on maximum retail price (MRP) data, which could not accurately represent current market prices. Furthermore, it doesn't evaluate explicitly how these pricing

differences affect patients' affordability and adherence to therapy in practical contexts. In order to enhance healthcare accessibility and better inform policy decisions, future research should examine the effects of drug pricing discrepancies at the patient level.

5. Conclusion

Based on this study, there are significant pricing differences across bDMARDs in India, especially for etanercept, which makes it difficult for RA patients to get medication. These results highlight the need for immediate legislative changes, such as more stringent DPCO pricing regulations, the promotion of biosimilars to boost competition, and subsidised treatment programs. Future studies should look at adherence trends and affordability effects in the real world to better inform clinical and policy decisions for chronic autoimmune disorders.

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Conflict of Interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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Ethical Information

Ethical clearance was obtained from the Institutional Ethical Committee before the start of this study.

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