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ORIGINAL RESEARCH

Economic Evaluation of Mepolizumab as Add-on Therapy to Standard Care in Severe Eosinophilic Asthma: A Cost-Effectiveness Analysis in Colombia

Jefferson Antonio Buendia[1], Ranniery Acuna-Cordero[2], Carlos E Rodriguez-Martinez[3,4]

[1]Department of Pharmacology and Toxicology, School of Medicine, Research Group in Pharmacology and Toxicology (INFARTO), Universidad de Antioquia, Medellín, Colombia; [2]Departamento de Neumologia Pediatrica, Hospital Militar Central, Departamento de Pediatria, Facultad de Medicina, Universidad Militar Nueva Granada, Bogota, Colombia; [3]Department of Pediatrics, School of Medicine, Universidad Nacional de Colombia, Bogota, Colombia; [4]Department of Pediatric Pulmonology, School of Medicine, Universidad El Bosque, Bogota, Colombia

Correspondence: Carlos E Rodriguez-Martinez, Universidad Nacional de Colombia, Avenida Calle 127 No. 20-78, Bogotá, Colombia, Tel/Fax +57 1 2595520, Email carerodriguezmar@unal.edu.co

Background: Mepolizumab, an IL-5 receptor antagonist, is a targeted therapy approved for treating severe eosinophilic persistent asthma. While it offers significant clinical benefits in reducing exacerbations and improving quality of life, its high cost raises concerns about its affordability and overall value in resource-constrained settings. This study evaluates the cost-effectiveness of adding mepolizumab to standard care (SoC) compared to SoC alone in adolescents and adults with severe, uncontrolled eosinophilic asthma in Colombia.

Methods: We used a Markov model with a societal perspective and a lifetime horizon to estimate costs and quality-adjusted life years (QALYs). Parameters were derived from local data and existing literature. Both deterministic and probabilistic sensitivity analyses were performed to test the model's robustness. Cost-effectiveness was assessed using a willingness-to-pay threshold of US$5,130.

Results: Mepolizumab demonstrated an additional 0.31 QALYs per patient compared to standard of care (SoC), with an incremental cost-effectiveness ratio (ICER) of US$25,210 per QALY gained. Sensitivity analyses showed that the price of mepolizumab was the key driver of cost-effectiveness. Over a 5-year horizon, adding mepolizumab to SoC would have a significant budgetary impact. These findings highlight the need to balance clinical benefit with affordability in resource-limited settings.

Conclusion: Although mepolizumab improves patients' quality of life, it is not considered cost-effective in Colombia under the conditions of this study. The results provide valuable information for policymakers to consider when refining local clinical practice guidelines.

Keywords: asthma, cost-effectiveness, health economics, mepolizumab

Introduction

There are different endotypes of asthma, such as atopic and non-atopic asthma.[1] Elevated levels of specific IgE and eosinophils are often found in the blood and airways of patients with severe asthma.[2] The current standard of care (SoC) for these individuals typically includes daily use of inhaled corticosteroids (ICS), long-acting beta-agonists (LABAs), and other potential controller and reliever medications.[3] Clinical trials and real-world studies have shown that the addition of mepolizumab to SoC can lead to fewer asthma exacerbations, reduced reliance on oral corticosteroids (OCS), and improved quality of life in patients with severe uncontrolled asthma and eosinophilia compared to SoC alone.[4,5]

Asthma is a significant public health problem in Colombia, with a prevalence of approximately 10% of the general population. Of these, it is estimated that 5–10% suffer from severe asthma, representing tens of thousands of patients who may require advanced therapies such as mepolizumab.[6] Severe asthma places a significant burden on the Colombian healthcare system, leading to higher rates of emergency room visits, hospitalizations, and lost productivity.[7] Studies have

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shown that the direct medical costs of asthma in Colombia are predominantly driven by medication use (79% of total costs), highlighting the economic impact of managing this chronic disease.[7]

Despite the proven clinical benefits of mepolizumab, its high cost compared to inhaled corticosteroids (ICS) or long-acting beta-agonists (LABAs) poses a significant challenge, particularly in Colombia, where the drug was approved in 2016 for the treatment of severe eosinophilic asthma.[4] Socio-economic disparities and high out-of-pocket health expenditures limit access to advanced therapies, with an estimated 25% of Colombians experiencing catastrophic health expenditures annually. This highlights the urgent need for cost-effective interventions that optimize health outcomes while addressing the constraints of limited healthcare resources.[7–9]

This study evaluates the cost-effectiveness of combining mepolizumab with SoC versus SoC alone in adolescents and adults with severe, uncontrolled asthma characterized by eosinophilia. By addressing the economic implications, this study aims to provide evidence to guide local health policy and resource allocation.

Methods

Model Structure

We used a Markov simulation model to evaluate the costs and outcomes associated with mepolizumab in addition to standard of care (SoC) versus SoC alone. This model was based on a cohort of patients with the following characteristics: age 12 years or older, severe asthma, high blood eosinophil count (≥150/μL at screening or ≥300/μL within the past year), and at least two exacerbations in the past year despite ongoing treatment with high-dose inhaled corticosteroids (ICS). A review of MEDLINE (via PubMed, January 2019), Embase (via Ovid, January 2019), and CENTRAL (via The Cochrane Library, January 2019) identified three relevant Phase III randomized clinical trials (RCTs) comparing mepolizumab with SoC for uncontrolled severe eosinophilic asthma.[5,10–12] These RCTs excluded former smokers with a smoking history of ten pack-years or more, patients with concurrent respiratory disease, those who had received omalizumab within the last 130 days, and also patients with severe or clinically significant cardiovascular disease or other eosinophilic diseases. In the 32-week follow-up to the MENSA trial[5] and the SIRIUS and MUSCA trials,[11,12] 100 mg of mepolizumab was administered subcutaneously every four weeks. Patients with SoC in these trials were prescribed ICS plus LABA, montelukast, and tiotropium at doses and therapeutic schedules comparable to those recommended internationally by GINA 2024 in patients with severe asthma Step 5.[3]

The model defined four distinct and mutually exclusive health states: "symptom-free or asthma-controlled", "asthma exacerbation", "asthma-related mortality", and "all-cause mortality", reflecting the economic impact of each state. The "asthma exacerbation" condition was further categorized into three levels based on severity: OCS exacerbation, emergency department visit, and hospitalization. The model assumed that "asthma-related mortality" could only occur after an asthma exacerbation, while "all-cause mortality" could occur from any health state (Figure 1). The model adopted a societal perspective with a cycle length of 4 weeks, a lifetime horizon, a half-cycle correction, and an annual discount rate of 5%.

Clinical Data

We obtained the relative risk of mepolizumab, utilities, and transition probabilities without local data from existing economic evaluations[8,9] (Table 1). Because of this limitation, these parameters were subjected to probabilistic sensitivity analysis (PSA), as recommended for such evaluations.[13] We used life tables from the Colombian National Administration of Statistics (DANE) for 2016–2020 to estimate hospitalization rates, exacerbations, and all-cause mortality.[6,14,15] An annual discontinuation rate of 5% for mepolizumab was applied in the base case, with rates ranging from 0% to 10% tested in sensitivity analyses, following Colombian guidelines for health economic evaluations.[14] Cost-effectiveness was assessed using a willingness-to-pay (WTP) threshold of $5,180.[14]

Cost Analysis

Both direct and indirect costs were included in the analyses to provide a comprehensive economic impact assessment.[16] Cost estimates for each health state were derived from a Colombian study that reported direct and indirect costs for 20,410 asthma patients of varying severity.[6] Indirect costs related to lost productivity of parents were estimated using the

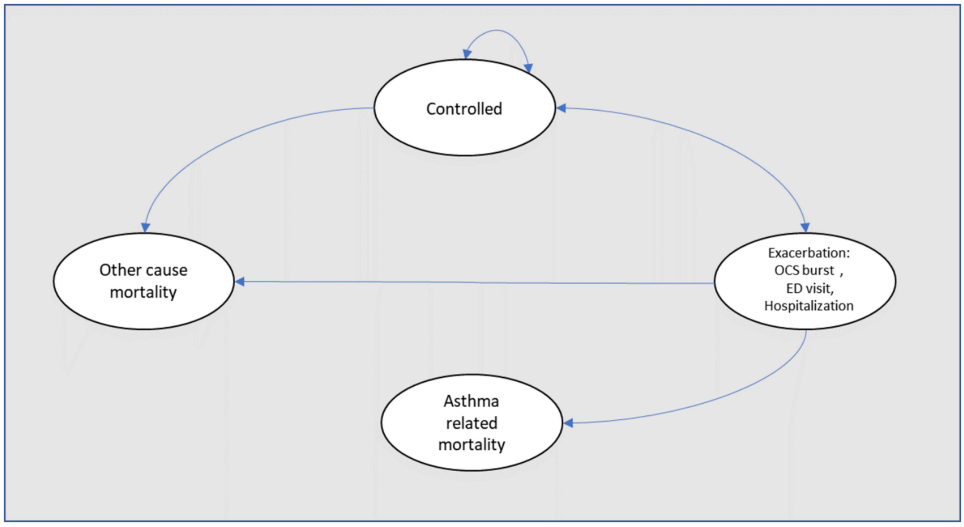

Figure 1 Markov model. OCS Burst is defined as relatively major symptoms during the week and the need to use oral corticosteroids to control symptoms.
Abbreviation: ED visit, The patient requested treatment with systemic corticosteroids.

human capital method, assuming a minimum wage income for all formal or informal work. The opportunity cost of lost productivity, excluding transportation costs, was based on the 2020 minimum wage (US$230 per month).[15,17]

Costs associated with serious adverse events were not included because clinical trials did not show significant differences between the drug and placebo groups. The unit cost of mepolizumab was obtained from the Drug Price Information System (SISMED, 2022) maintained by the Colombian Ministry of Health and Social Protection, which provides representative drug prices for the country.[15] All costs were reported in Colombian pesos (COP) and converted to US dollars (US$) using an exchange rate of 1 US$ = 3,000 COP.[18]

Table 1 Base Case Analysis

Variable	Base case	Valor High*	Valor Low**	Reference
Cost US$				
Cost Mepolizumab (per 4 week cycle)	$855	$ 1095	$ 850	[13]
Cost controlled (annual)	$ 2244	$ 3000	$ 1000	
Cost OCS burst (per episode)	$ 195	$ 300	$ 100	
Cost ED visit (per episode)	$ 228	$ 300	$ 100	
Cost hospitalization (per episode)	$ 4635	$ 6000	$ 3000	
Utilities (annual)				
Asthma on SOC	0.794	0.9	0.6	[6]
Asthma on mepolizumab and SOC	0.802	0.9	0.6	
Utility decrement				
Exacerbations requiring OCS burst	0.1	0.2	0.1	[6]
Exacerbations requiring ED visit	0.15	0.3	0.1	
Exacerbations requiring hospitalization	0.2	0.1	0.3	
Mepolizumab effect				
Relative risk on exacerbation rate	0.49	0.66	0.38	[10]
Relative risk on hospitalization	0.3	0.71	0.13	
Exacerbation				
Exacerbation rate	1.1	1	4	[13]
# Hospitalization annual	2.6	1	5	

Notes: * upper range evaluated in the sensitivity analysis. ** lower range evaluated in the sensitivity analysis.

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Sensitivity Analyses

Deterministic sensitivity analysis was performed using one-way threshold analysis and tornado plots, with all parameters (costs, benefits, relative risks, and transition probabilities) evaluated within plausible ranges (±25% of baseline values or 95% confidence intervals, where available). In addition, a PSA was performed using a second-order Monte Carlo simulation with 10,000 iterations. This involved assigning uncertainty distributions (beta distribution for relative risks and utilities, Dirichlet distribution for multinomial data related to transition probabilities, and gamma distribution for costs) and sampling random values from each distribution. All analyses were performed using Microsoft Excel®.

To estimate the budget impact of mepolizumab over a 5-year period from the perspective of the Colombian National Health System, a Microsoft Excel® macro-enabled workbook was developed. This workbook calculated the incremental budget impact by subtracting the cost of mepolizumab plus SoC from the cost of conventional SoC therapy. The target population consisted of patients with severe eosinophilic asthma as defined by the GINA level five guidelines in Colombia.[3] The estimated population size was approximately 227,524 patients,[19] 63% of whom had eosinophilic asthma.[20] An annual growth rate of 1.5% was assumed based on national averages from 2015 to 2019.[14] In the base case, a 20% uptake rate of mepolizumab plus SoC was projected, increasing by 20% each subsequent year, following Colombian guidelines for budget impact analysis studies.[6] All analyses were conducted in Microsoft Excel.

Results

Base Case Analysis

In the base case analysis, mepolizumab was associated with higher costs and more quality-adjusted life years (QALYs) than the standard of care (SoC). In the Markov cohort simulation, patients receiving mepolizumab had a lower risk of exacerbations than those receiving SoC. Specifically, the median probability of exacerbation-free was estimated to be 0.52 for mepolizumab and 0.40 for SoC. In addition, patients on mepolizumab had longer quality-adjusted survival. The model projected a gain of 0.31 QALYs per patient per year with mepolizumab compared to SoC. However, the annual cost per patient was higher with mepolizumab, with a difference of US$7,916 in total discounted costs per person-year compared to SoC (Table 2). The incremental cost-effectiveness ratio (ICER) was calculated to be US$25,210.

Sensitivity Analyses

A one-way sensitivity analysis was performed to determine which variables significantly affected the ICER. This analysis showed that the unit price of mepolizumab had the most significant impact on the ICER (Figure 2). The threshold analysis suggested that if the price of mepolizumab fell below US$329, the combination of mepolizumab plus SoC would become a dominant strategy. In the probabilistic sensitivity analysis (PSA), variables such as costs, benefits and relative risks (RRs) were varied based on predefined statistical distributions, resulting in 10,000 simulated outcomes as shown in the cost-effectiveness plane (Figure 3). Of these simulations, 24% fell into quadrant 4 (higher cost, fewer QALYs), while 76% fell into quadrant 1 (higher cost, more QALYs). The 95% confidence intervals (CIs) for cost per patient were US $1,527 to US$1,538 for SoC and US$9,364 to US$9,532 for SoC plus mepolizumab. The 95% CIs for QALYs per patient were 5.8 to 5.9 for SoC and 6.1 to 6.2 for mepolizumab. The cost-effectiveness acceptability curve indicated that mepolizumab would be considered cost-effective more than 50% of the time if the willingness to pay exceeded US $27,000 (Figure 4).

Table 2 Cost- Effectiveness of Mepolizumab Plus SOC vs SOC

Strategy	Cost (US$)	Difference (US$)	QUALYs	Difference	NMB	ICER (US$)
Mepolizumab plus SOC	9,448		6.2		23,280	25,210
SOC	1,533	7,916	5.9	0.31	29,536	

Abbreviations: SOC, Standard of care; NMB, Net monetary benefit.

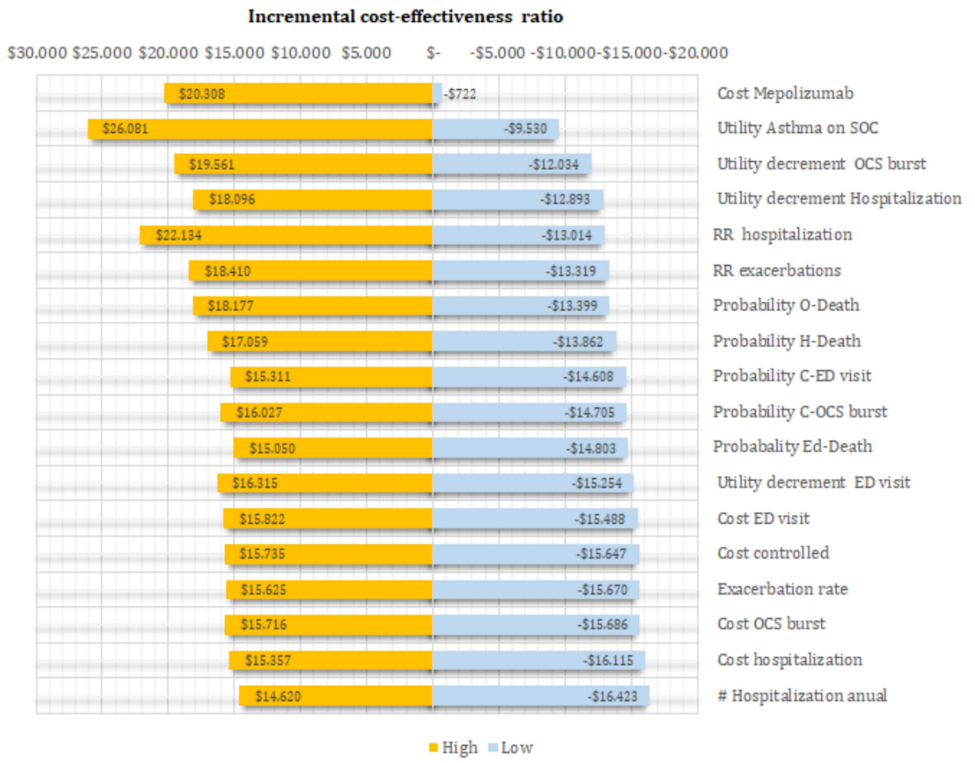

Figure 2 Tornado diagram. OCS Burst is defined as relatively major symptoms during the week that require the use of oral corticosteroids to control.
Abbreviations: SoC, Standard of care; ED visit, The patient requested treatment with systemic corticosteroids; Probability O-Death, Probability of death from OCS burst; Probability C-ED, Probability of ED visit from controlled; Probability ED-Death, Probability of death from ED visit; RR, Relative risk.

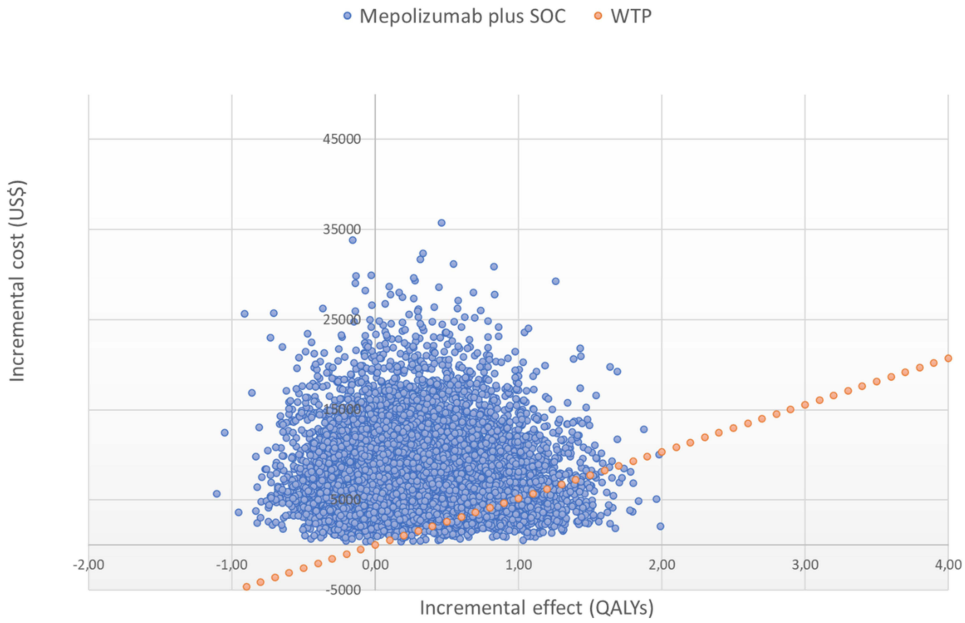

Figure 3 Cost-effectiveness plane.

Budget Impact Analysis

The base case budget impact analysis estimated a 5-year cost of US$3,202,312,043 for mepolizumab plus SoC compared to US$540,442,570 for SoC alone. This suggests an additional financial burden of US$2,661,869,473 on the Colombian

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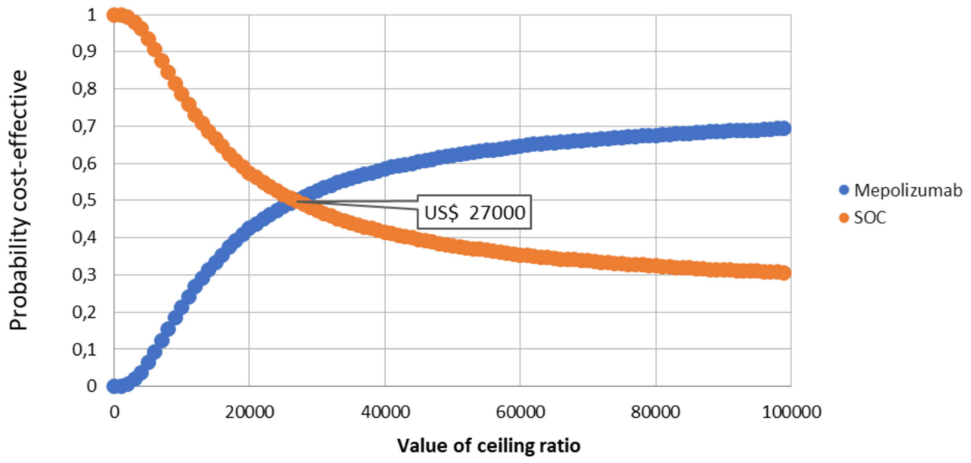

Figure 4 Acceptability curve.

National Health System if mepolizumab plus SoC were adopted as the standard of care for adolescents and adults with severe uncontrolled asthma and an eosinophilic phenotype.

Discussion

Asthma remains the most common non-infectious respiratory disease worldwide.[20,21] Advances in understanding the pathogenesis of asthma have led to the development of new biological treatments over the past two decades, including mepolizumab. Clinical trials and real-world studies have consistently shown that mepolizumab reduces asthma exacerbations, improves lung function, and significantly improves patients' quality of life.[4,5] However, such therapies have led to increased healthcare costs, particularly for biologic therapies, which are often considered high-cost even in affluent countries.

The economic impact is even more pronounced in low- and middle-income countries, such as Colombia, where health resources are limited. Our study's hypothetical scenario suggests that mepolizumab is not cost-effective in Colombia, and these findings may be relevant to other middle-income countries. Our results are consistent with economic analyses from high-income countries, such as the United States and Singapore, where mepolizumab was also found to be not cost-effective.[8,9] While these results do not undermine the significant clinical benefits of mepolizumab, they highlight the need for new health policies to ensure more equitable access to new, high-cost therapies.

Rising drug prices are a growing concern, widening the gap between innovative healthcare technologies and their potential benefits. Mepolizumab, along with other newer biologic therapies (eg, omalizumab, benralizumab, dupilumab), is significantly more expensive than traditional asthma medications. This disparity is particularly acute in low-income countries where drug prices are high relative to average income levels. Despite the hope these therapies offer to patients who struggle to manage their asthma with conventional treatments, their cost remains a significant barrier to widespread access.

The results of our study can inform decision-making regarding mepolizumab and other biologics in Colombia and may serve as a reference for similar middle-income countries. In our analysis, the incremental cost-effectiveness ratio (ICER) was highly sensitive to the unit price of mepolizumab. If the price were reduced to less than US$329, mepolizumab could become a cost-effective option in Colombia. This figure could be a starting point for negotiations between government agencies and pharmaceutical companies to determine a feasible market price. Such information is crucial for policymakers. Colombia is a developing country with a mixed healthcare system and public and private funding sources. However, economic constraints, socioeconomic inequalities, and high out-of-pocket healthcare expenditures pose significant challenges to access to high-cost biologic therapies such as mepolizumab. Given the limited healthcare resources available, decision-makers must carefully evaluate the cost-effectiveness of new treatments to ensure optimal resource allocation. The novelty of our study is that it provides the first cost-effectiveness analysis of mepolizumab in Colombia, a middle-income country with limited healthcare budgets. Our findings can serve as

a valuable reference for other developing countries, particularly Latin America, facing similar economic and healthcare challenges. By assessing whether mepolizumab is a cost-effective option within a limited budget, our study supports evidence-based decision-making for local policymakers. In addition, these results may contribute to developing reimbursement policies and clinical guidelines in countries with comparable healthcare systems, thereby improving access to biologic therapies for severe eosinophilic asthma in resource-limited settings.

Our study incorporated the economic impact of exacerbations by modeling different levels of severity, including oral corticosteroid use, emergency department visits, and hospitalizations. The Markov model allowed us to estimate and compare the costs associated with these health outcomes for patients receiving mepolizumab + SoC versus SoC alone. Previous studies have shown that mepolizumab significantly reduces the risk of severe exacerbations, resulting in fewer hospitalizations and emergency department visits, major cost drivers in asthma management.[8,22]

Our findings are consistent with cost-effectiveness analyses conducted in other healthcare settings, including Singapore,[8] and Chile.[22] These studies have consistently shown that incorporating biologic therapies, such as mepolizumab, into asthma management strategies reduces exacerbation-related costs and improves patient outcomes. However, a more detailed direct cost comparison between exacerbation-related events and mortality risk in both groups would further strengthen our findings.

The study has limitations. Despite using cost data, utilities, transition probabilities, and relative risks from local and international sources in our sensitivity analyses, the ICER remained stable, confirming the robustness of our results. Our findings are specific to patients with severe asthma inadequately controlled on medium- to high-dose ICS plus LABAs and may not apply to patients on daily oral corticosteroids. Another limitation of our analysis is that we did not explicitly model the costs associated with intensive care unit (ICU) admissions or asthma-related mortality as separate cost categories. While mepolizumab has been shown to significantly reduce the risk of severe exacerbations and asthma-related death, our model focused primarily on exacerbation-related costs, such as oral corticosteroid use, emergency department visits, and hospitalizations. The exclusion of ICU costs and mortality as separate outcomes was due to data availability constraints and the need to maintain a manageable model structure within the scope of this economic evaluation. We believe that the three main strengths of this cost-effectiveness study are: first, the inclusion of not only direct costs but also indirect costs, allowing for a more comprehensive assessment of economic impact; second, the use of a lifetime time horizon for the analysis, allowing for a thorough assessment of long-term costs and outcomes; and third, the study was conducted in a middle-income country, where health care resources are typically more limited than in high-income countries, making the findings particularly relevant to similar settings.

In conclusion, although mepolizumab improves patients' quality of life, it is not cost-effective under current conditions in Colombia. This study provides valuable evidence to help policymakers and clinicians efficiently allocate limited resources to manage patients with severe eosinophilic persistent asthma. It also suggests that similar analyses should be conducted in other middle-income countries to validate these findings. Future studies could extend this analysis by including detailed cost estimates for ICU stays and asthma-related mortality, which would further strengthen the case for the cost-effectiveness of mepolizumab in real-world settings. In addition, examining these outcomes in broader healthcare systems beyond Colombia could provide valuable insights for other middle-income countries considering the inclusion of mepolizumab in their clinical guidelines.

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Disclosure

The authors report no conflicts of interest in this work.

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