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Exploratory analysis of the economically justifiable price of reslizumab for asthma severe in Colombia

Jefferson Antonio Buendía[1,2*] and Andres Felipe Zuluaga[1,3]

Abstract

Introduction Asthma severe imposes important economic burden for health systems, especially with the incorporation of new drugs. Recently, reslizumab has been approved to prevent exacerbations in patients with eosinophilic asthma. This study evaluates the price at which reslizumab would be considered economically justified for patients with severe asthma in Colombia.

Materials and methods A model was developed using the microsimulation to estimate the quality-adjusted costs and life years of two interventions: reslizumab versus not applying standard treatment without reslizumab. This analysis was made during a time horizon of 50 year and from a third payer perspective.

Results Based on thresholds of U$4828, U$ 5128, and U$19 992 per QALY evaluated in this study, we established economically justifiable drug acquisition prices at each WTP were U$ 106, U$ 165, and U$ 349 per dose of reslizumab. Reslizumab not was cost-effective using a WTP of U$4828, U$ 5128 and U$19 992 per QALY.

Conclusion The economically justifiable cost for reslizumab in Colombia is between U106 to U$349per dose, depending on the WTP used to decide its implementation. This result should encourage more studies in the region that optimize decision-making processes when incorporating this drug into the health plans of each country.

Keywords Reslizumab, Asthma, Colombia, Cost, Price

Introduction

Severe asthma represents a significant global health challenge, affecting millions of individuals worldwide, with a marked impact in Latin America and Colombia. Globally, asthma affects approximately 262 million people and caused 455 000 deaths, and severe asthma accounts for a substantial proportion of these cases, leading to high morbidity and mortality rates [1, 2]. In Latin America, the prevalence of asthma varies widely, but estimates suggest that up to 22% of the population may be affected, with severe asthma constituting about 5–10% of these cases [3, 4]. The burden of severe asthma is exacerbated by factors such as environmental pollutants, limited access to healthcare services, and inadequate disease management,

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highlighting the need for effective treatment options and health policies to mitigate this public health issue.

Reslizumab, a humanized interleukin-5 antagonist monoclonal antibody, received its approval from the U.S. Food and Drug Administration (FDA) in March 2016 and subsequently from the European Medicines Agency (EMA) for use in specific groups of asthma patients [5, 6]. Its primary mechanism of action involves targeting and inhibiting interleukin-5 (IL-5), a key cytokine responsible for the growth, differentiation, recruitment, activation, and survival of eosinophils [7]. By blocking IL-5 from binding to its receptor on the surface of eosinophils, reslizumab effectively reduces eosinophil levels in the blood, thereby decreasing the frequency of asthma exacerbations in patients with eosinophilic phenotype asthma [7]. The evidence supporting the effectiveness and safety of reslizumab comes from several phase III clinical trials, which demonstrated significant improvements in lung function, asthma control, and quality of life in patients, along with a manageable safety profile [8]. These trials have been pivotal in establishing reslizumab as a valuable treatment option for patients with severe eosinophilic asthma who have a history of exacerbations despite receiving standard care (high dose fluticasone/Long-acting beta-agonists (LABAs combination).

The integration of pharmaceuticals presents economic challenges for healthcare systems, primarily attributable to the substantial initial expenditure associated with newly introduced drugs during their initial phases. This issue is particularly acute in developing nations, where there exists a differential willingness to pay for years of life gained or adjusted for quality of life [9]. An erroneous governmental decision to integrate a pharmaceutical product lacking cost-effectiveness may result in the misallocation of resources away from addressing other pathologies. Consequently, this could lead to an escalation in the burden of disease and associated costs due to a flawed political determination [10]. Therefore, it is necessary to have health economic studies before incorporating new technologies that provide evidence and allow a symmetrical negotiation with the manufacturers of new drugs. This study evaluates the price at which reslizumab would be considered economically justified for patients with severe asthma in Colombia.

Materials and methods

Model structure

Our study was developed using microsimulation modelling. Microsimulation modelling is a method that simulate individual-level data, allowing patient characteristics and patient history events to affect future values -such as probabilities, costs and utilities [11]. This model estimated the quality-adjusted life years and costs of two interventions: reslizumab in combination with standard care versus standard care alone (without reslizumab). The comparator was standard care, defined as high-dose inhaled corticosteroids (ICS) plus a long-acting beta-agonist (LABA), as reflected in the majority (82%) of patients in the phase III trials [12]. The information for this modelling came from results of randomized controlled trials where this intervention was studied [12]. The population included participants had moderate to severe asthma, defined as requiring medium-dose ICS. In addition, they had inadequate symptom control, with an ACQ of 1.5 or more, history of at least one exacerbation in the preceding 12 months, blood eosinophil count of 400 cells or more per uL.

Study treatment and comparator

The intervention studied consisted of reslizumab administered intravenously at a dosage of 3 mg/kg once every four weeks, given alongside the usual standard care regimen. Standard care, acting as the comparator, was specified as treatment with a high-dose inhaled corticosteroid (ICS) combined with a long-acting beta-agonist (LABA). In the clinical trials considered (NCT01287039; NCT01285323), patients received ICS doses described as "fluticasone equivalents," indicating high-dose ICS therapy. Furthermore, most trial participants (approximately 82%) were concurrently treated with LABA. Therefore, the comparator (standard care) was characterized as high-dose fluticasone in combination with LABA [12]. The standard of care (i.e. the comparator) was defined as a high-dose fluticasone/LABA combination. The mean ICS dose administered to patients enrolled in the RCTs was reported as "fluticasone equivalents" and corresponded to a "high dose" of ICS. In addition, most patients (82%) enrolled in the RCTs also received LABA. Thus, we defined standard of care as a high dose fluticasone/LABA combination [12].

Our model has four health states, see Fig. 1:

I. Controlled asthma: patient with ACQ score less than 1.5 not currently experiencing an exacerbation,
II. OCS burst: exacerbation with requirement of burst of OCS for at least three consecutive days.
III. ER visit: patient with ACQ score equal or higher than 1.5 and currently experiencing an exacerbation with emergency department visit,
IV. Hospitalization: patient with ACQ score equal or higher than 1.5 and currently experiencing an exacerbation with hospitalization.
V. Asthma death related.

Our microsimulation runs different individuals from 50 years old through the model via a random walk using Monte Carlo Simulation. Each patient will run through the model until death or until reaching the termination

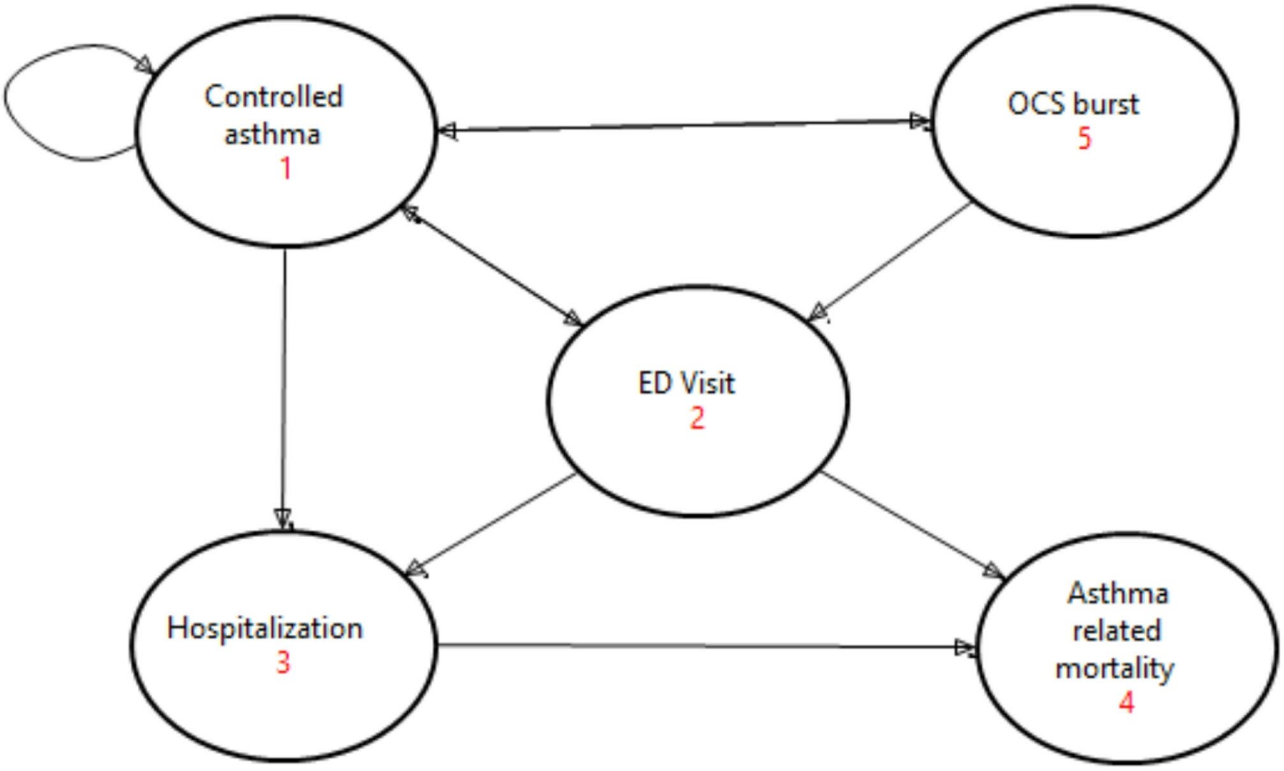

Fig. 1 Markov state model

condition for the model in our case time horizon limit. The time horizon was set to 50 years to reflect a lifetime horizon. The model cycle length was 28-days to align with the reslizumab treatment cycles and to adequately capture asthma-related events. In a Microsimulation model, each patient can have his own set of characteristics. To introduce heterogeneity into the model we assign patient characteristics by creating distributions that are sampled for each patient as he/she enters the model. The sampling rate was set to resample per individual trial which lets us to generate a new sampled start age for every person entering the model. Our model also included a response assessment at 26 weeks where patients may discontinue due to lack of adequate treatment response [13]. Patients who do not respond, reslizumab will be discontinued, and transition probabilities of no reslizumab will be applied. In two 52 week RCTs, reslizumab add-on therapy exhibited a similar overall safety profile compared to placebo. Our model did not consider the impact of adverse events related to reslizumab or standard of care [12].

Source of information

To estimate the expected quality-adjusted costs and life years for each intervention, information was extracted from the literature, Table 1. This table shows all parameters used in the estimations with the values used in the deterministic and probabilistic analysis as is detail below. The transition probabilities were extracted from a study conducted in a Colombian asthma patients [14]. The directs costs associated with severe asthma in Colombian asthma patients were extracted from local cost-disease study [15, 16]. The relative risk was extracted from a recent meta-analysis that evaluated the effectiveness of Reslizumab for the treatment of severe asthma [17]. Utilities and disutilities were extracted from a systematic review utilities for asthma [18]. Since relative risks utilities and disutility were extracted from literature not generated in the Colombian population, they were subjected to sensitivity analysis according to international recommendations [19]. A discounts rate of 0.05 were applied to costs and benefits following the national recommendations for health technology assessment in Colombia [20]. All costs were expressed in 2023 US dollars (USD), adjusted using the U.S. Consumer Price Index.

Estimating the economically justifiable price of reslizumab

Following the methodology published by Luttjeboer and Buendia [23, 24], the economically justifiable price (EJP) is defined as the price that reslizumab must have in the model not to exceed the Willingness to pay (WTP). In the absence of an updated and officially defined value in Colombia of WTP, the EJP was estimated by threshold analysis between the reslizumab cost and the three different WTPs published for Colombia: U$4828 per QALY

Table 1 Data input summary

Variable	Deterministic analysis		Probabilistic analysis			Reference
	Value	Range	distributión	Parameters		
Probability from controlled to ED visit	0.1971	±25%	beta	α = 12,19	β = 42,35	[14]
Probability from controlled to Hospitalization	0.0345	±25%	beta	α = 11,09	β = 27,37	
Probability from ED visit to Hospitalization	0.07	0.06–0.60	beta	α = 13,30	β = 70,77	
Probability from OCS burst to Hospitalization	0.34	0.06–0.60	beta	α = 13,30	β = 70,77	[16]
Probability from controlled to OCS	0.29	0.06–0.60	beta	α = 13,30	β = 70,77	
Probability of asthma-related death	0.007	±25%	beta	α = 15,90	β = 2704	[21]
Utility of controlled	0.74	±25%	beta	α = 6751	β = 1,557,046	[18]
Utility of ED visit	0.59	±25%	beta	α = 14,01	β = 63,77	
Utility of Hospitalization	0.64	±25%	beta	α = 15,02	β = 62,54	
Utility of OCS	0.54	±25%	beta	α = 13,06	β = 62,77	
Annual cost per patients on controlled state (US$)	2107	±25%	gamma	α = 18	λ = 0,067	[15]
Cost per episode of ED visti (US$)	324	±25%	gamma	α = 16	λ = 0,2424	
Cost per episode of Hospitalization (US$)	853	±25%	gamma	α = 25	λ = 5	
Relative risk of reslizumab		0.07–0.47	log-normal	μ=-1,38	ds = 0,327	[22]
Discontinuation rate at 26 week	0.09	±25%	beta	α = 11.45	λ = 61.52	[13]

according to Pichon-Riviere estimate in 2023 [25], U$ 5128 by QALY according to the estimate of Espinosa et al. in 2021 [26] and up to three times the GDP-per capita or U$19,992 per QALY suggested by the national agency for health technology assessment in Colombia in 2014 [20].

To evaluate the impact of uncertainty on each of the parameters incorporated in the model, deterministic sensitivity analysis was performed in which the incremental cost-effectiveness ratio of the model was estimated by changing each parameter within a pre-established range, see Table 1. To explore the impact of parameter uncertainty, we conducted a probabilistic sensitivity analysis using 10,000 Monte Carlo simulations. Model inputs were sampled from predefined distributions: beta (transition probabilities, utilities), gamma (costs), and log-normal (relative risks). For each simulation, incremental costs and QALYs were computed, and results were presented as cost-effectiveness acceptability curves (CEACs) to assess the likelihood of cost-effectiveness across varying WTP thresholds. The sampling rate was set by individual test resampling, which implies that a new value of each parameter was generated at the beginning of each sample for each patient entering the model. This way, 10,000 individual microsimulations were programmed to obtain each intervention's costs and quality-adjusted life years. A result is obtained with a measure of variability that reflects the possible clinical heterogeneity and uncertainty in each parameter. The acquisition prices of US$106, US$165, and US$349 per dose were obtained through iterative threshold analysis. At each WTP level, the model was rerun with varying prices until the ICER matched the specified threshold. These values were calculated algorithmically within the TreeAge software.

Results

Threshold analysis of economically justifiable price for reslizumab

Reslizumab not was cost-effective using a WTP of U$4828, U$ 5128 and U$19 992 per QALY. Based on thresholds of U$4828, U$ 5128, and U$19 992 per QALY evaluated in this study, we established economically justifiable drug acquisition prices at each WTP were U$ 106, U$ 165, and U$ 349 per dose of reslizumab, Figs. 2, 3 and 4.

The Fig. 2 show that if the cost con reslizumab is higher than U$ 165 the ICER will be higher than WTP of US$ 5180, making reslizumab not cost effective using this WTP as a decision rule. The Fig. 3 show that if the cost con reslizumab is higher than U$ 106 the ICER will be higher than WTP of US$ 4828, making reslizumab not cost effective using this WTP as a decision rule. The Fig. 4 show that if the cost con reslizumab is higher than U$ 349 the ICER will be higher than WTP of US$ 19 992, making reslizumab not cost effective using this WTP as a decision rule.

The depicted bar graph offers an analysis of the budgetary impact attributable to varying pricing structures for reslizumab dosages over a quintennial timeframe. Each bar represents cost savings, indicated by the negative values on the y-axis, which is segmented into US$ 10,000,000 decrements. Sequentially labeled from Year 1 through Year 5, the x-axis facilitates temporal tracking of fiscal impacts. Notably, the data suggest an inverse relationship between the price per dose and the corresponding budgetary effect: as the price per dose of reslizumab increases, the resultant cost savings decrease. This graphical representation serves as a vital tool for elucidating the financial consequences of pharmaceutical pricing decisions, demonstrating that strategic pricing of

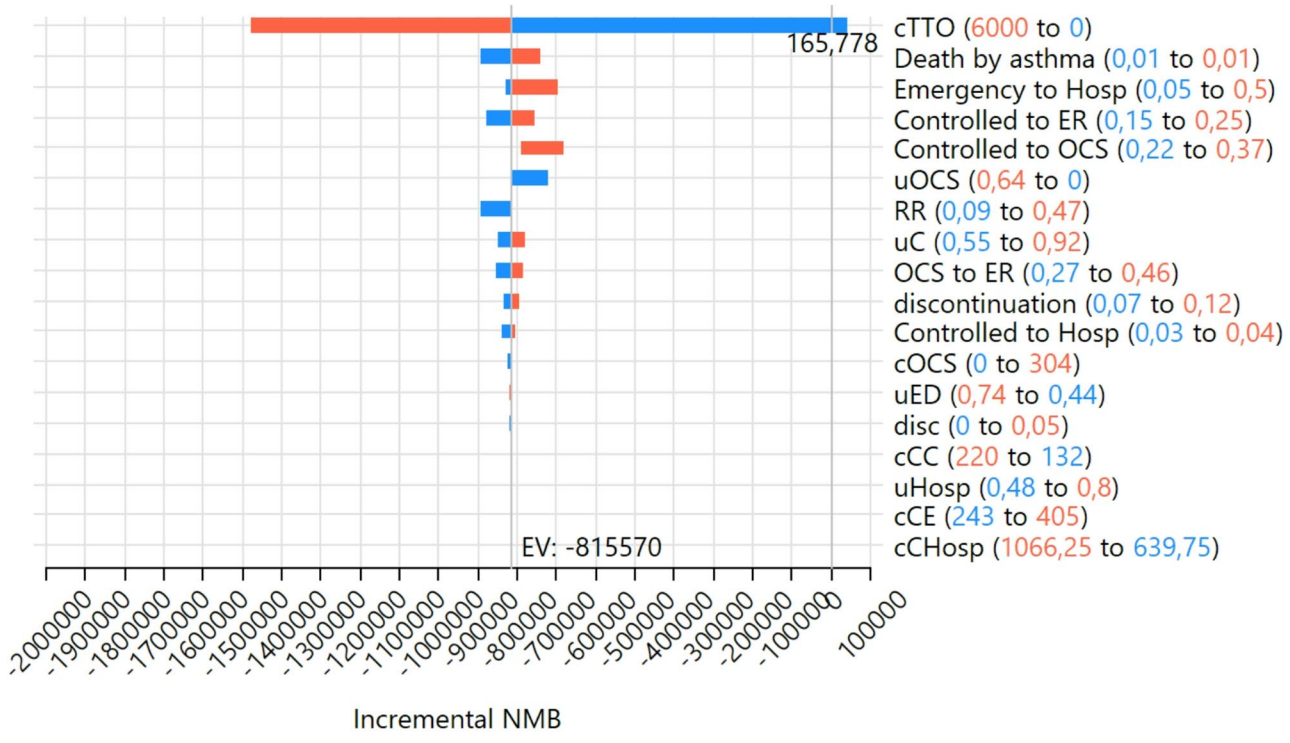

Fig. 2 Tornado diagram: ICER No reslizumab vs. reslizumab (WTP:5180)

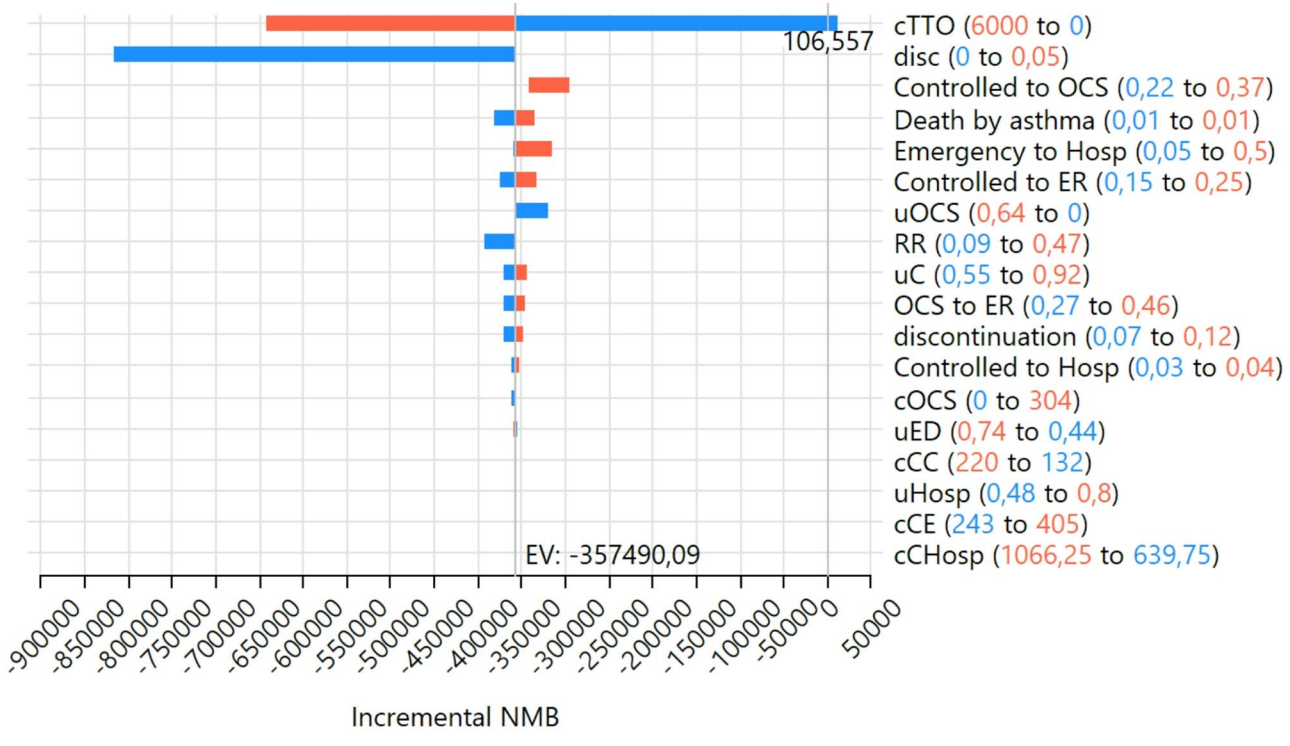

Fig. 3 Tornado diagram: ICER No reslizumab vs. reslizumab (WTP: 4828.00)

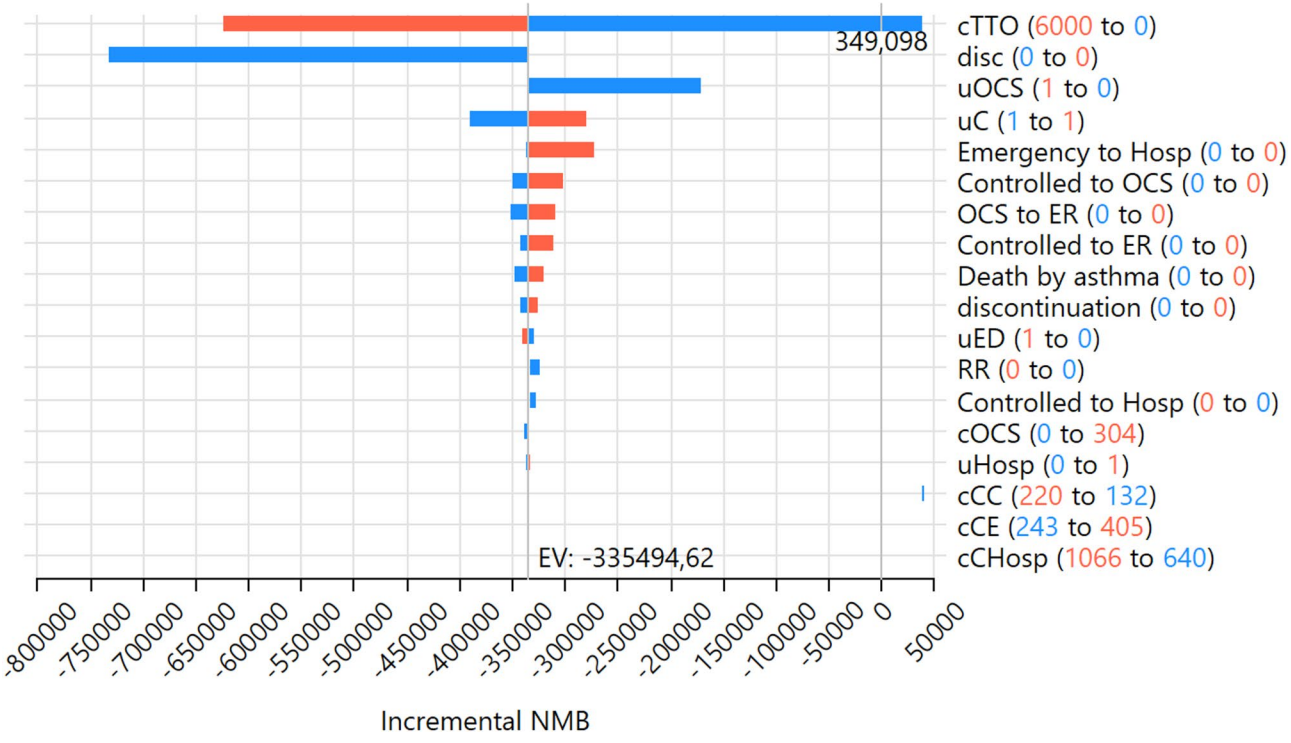

Fig. 4 Tornado diagram: ICER No reslizumab vs. reslizumab (WTP: 19 992)

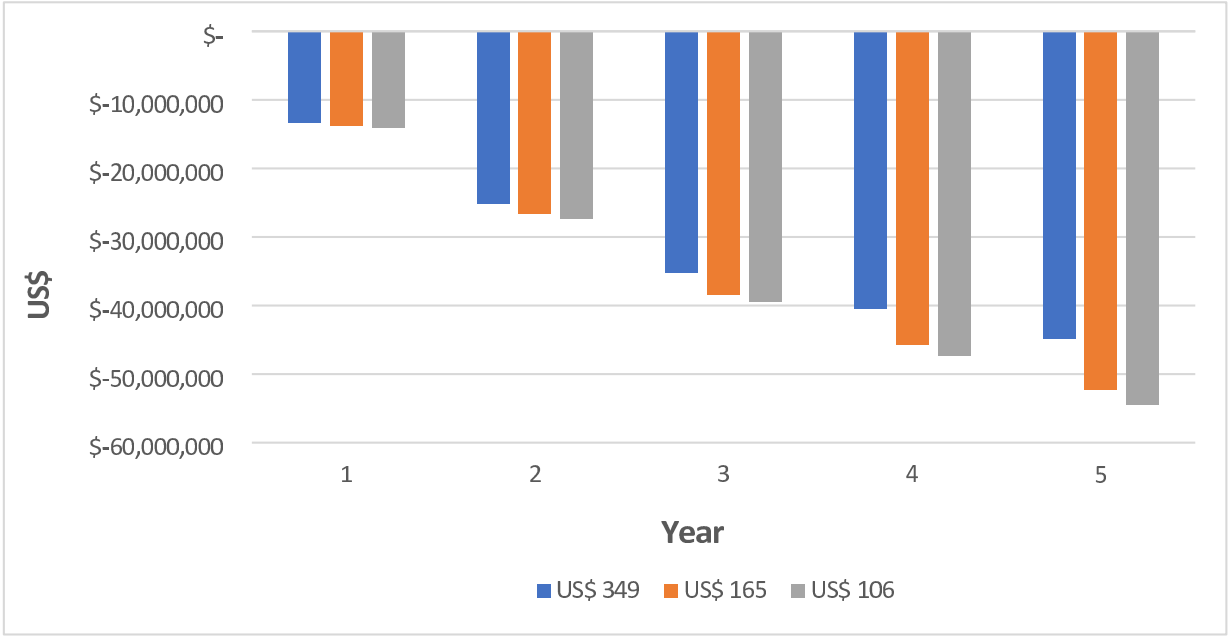

Fig. 5 Budget impact per year by price per dose of reslizumab

reslizumab can yield significant cost savings within a longitudinal healthcare budgetary context, Fig. 5.

Sensitivity analysis

The deterministic sensitivity analysis showed that the cost of reslizumab has the highest impact on the Incremental cost-effectiveness ratio (ICER) in Colombia in all thresholds analyzed, Figs. 2, 3 and 4. The probabilistic sensitivity analysis demonstrated that, at willingness-to-pay (WTP) thresholds of US$4828, US$5128, and US$19,992 per QALY, reslizumab was not the preferred option in the majority of simulations. Only when the WTP exceeded

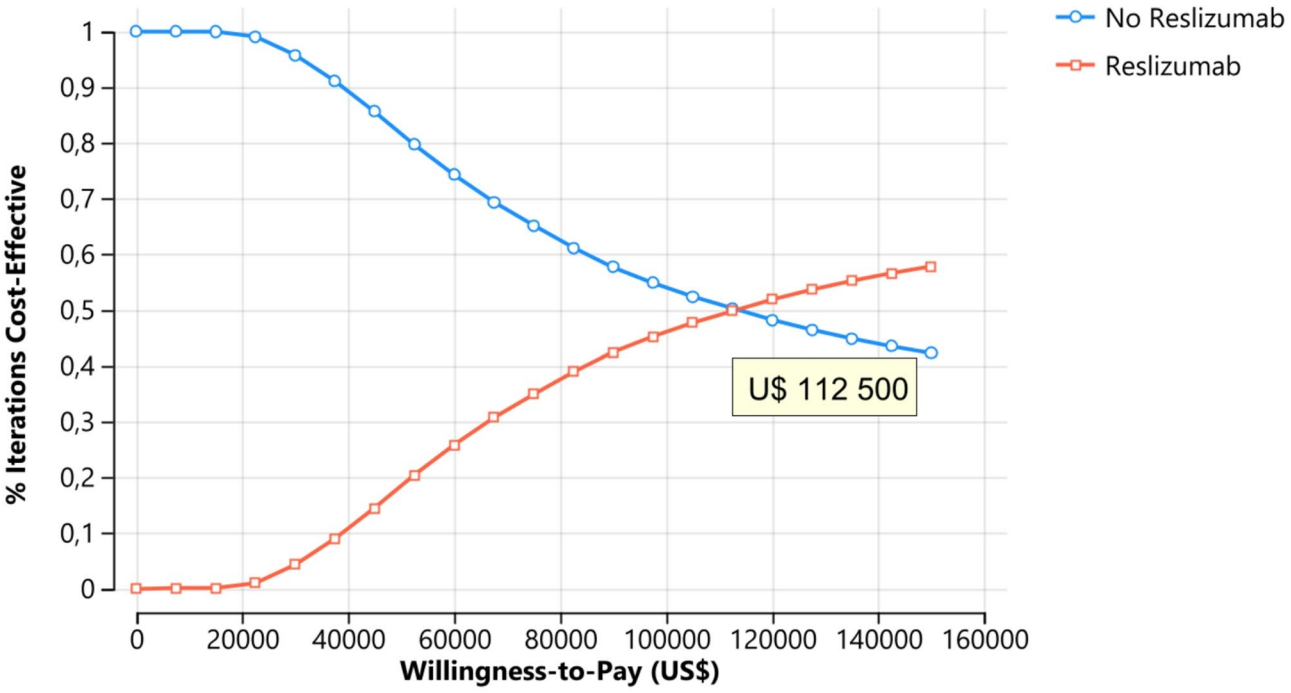

Fig. 6 CE acceptability curve

approximately **US$112,500 per QALY** did reslizumab become the optimal intervention in over 50% of the 10,000 simulations conducted (Fig. 6). This WTP value represents the point at which the net monetary benefit (NMB) of reslizumab surpasses that of the comparator, accounting for uncertainty across all model inputs. This finding underscores the high level of uncertainty and the need for significant price reduction to render reslizumab a cost-effective option under typical WTP thresholds in low- and middle-income countries like Colombia., Fig. 6.

Discussion

Our study shows that the economically justifiable cost for reslizumab in Colombia is between $165 and $349 per dose, depending on the WTP used. The aforementioned values represent the per-dose expenses necessary for this pharmaceutical to be deemed an economically viable option for adult patients suffering from severe asthma within the Colombian context. This data serves as a foundational basis for initiating negotiation dialogues between governmental bodies and pharmaceutical manufacturers [28–29]. It is anticipated that this information will facilitate the optimization of limited healthcare resources, thereby exerting a beneficial effect on public health outcomes.

Previous health economic evaluation has been previously to our research in developed countries. Han et al., assess the cost-utility of reslizumab for patients with severe eosinophilic asthma uncontrolled with high-dose inhaled corticosteroids and long-acting b2-agonists (ICS/LABAs) in Korea [30]. Using a Markov model with six health states and from societal perspective, found that reslizumab resulting in an incremental cost-effectiveness ratio of US$23,081 per QALY gained, being cost-effective in Korean patients based on the WTP WTP threshold of 1 gross domestic product (GDP) per capita in Korea (US$38,275 in 2017). Two cost-effectiveness analysis reports of reslizumab add on therapy for patients with severe eosinophilic asthma are publicly available through NICE and the Canadian Agency for Drugs and Technologies in Health (CADTH). Both agencies in Canada and United Kingdom concluded that reslizumab can be reimbursed to adult patients with severe eosinophilic asthma inadequately controlled with medium-to high dose ICS and an additional asthma controller (e.g. LABA) who have blood eosinophil levels higher than 400 cells and exacerbations in the preceding year [16, 31]. Previous health economic evaluations conducted in developed nations such as Korea, the United Kingdom, and Canada have demonstrated that reslizumab is cost-effective for treating patients with severe eosinophilic asthma uncontrolled by high doses of inhaled corticosteroids and long-acting beta-2 agonists (ICS/LABA). These countries exhibit significantly higher willingness-to-pay (WTP) thresholds for Quality-Adjusted Life Years (QALYs) compared to developing nations. The underlying issue in this scenario is that, whereas in countries with more robust economies the cost of reslizumab does not preclude its integration into healthcare systems due to the high WTP thresholds for QALYs, in developing countries, this cost

constitutes a significant barrier that restricts access to the treatment. Consequently, the price variable emerges as the primary modifiable factor to enhance access to such medications in nations facing more severe economic constraints. It is imperative to acknowledge that without a price adjustment strategy that considers the economic realities of developing countries, equitable access to innovative and effective treatments like reslizumab will remain a challenge. This underscores the necessity for differentiated pricing schemes that enable the inclusion of these essential therapies in the healthcare systems of resource-limited countries, thereby promoting broader access to advanced medical treatments. In our budget impact estimation underlines also the importance of drug pricing in the context of healthcare budgeting and implies that the adoption of reslizumab could be economically favourable at competitive pricing, offering potential cost savings over existing treatment options. These findings are pivotal for policymakers and healthcare providers in making informed decisions about the inclusion of new treatments like reslizumab in clinical practice.

The exploration of adopting a cost-effective approach necessitates a comprehensive assessment of Colombia's healthcare system. Negotiation strategies, including potential government dialogues and group purchasing agreements, should align with the country's economic constraints and reimbursement policies. Evaluating the practicability within the Colombian context requires recognition of the global variance in drug pricing and the disparate economic standings of countries. Proposing lower drug costs in Colombia calls for an examination of potential impacts on pricing negotiations in other regions. The advocacy for international collaboration and the review of analogous research in various countries may yield a more robust understanding of global pricing tactics.

The challenge of encouraging the pharmaceutical industry to reduce prices encompasses a range of complexities. It is essential to balance profit motives with sustainability, address concerns within the industry, and overcome barriers to market entry. Critical elements such as regulatory challenges, intellectual property rights, and the nuances of competitive markets play a crucial role in understanding the pharmaceutical sector's position. Proposals for establishing public-private partnerships and advocating for transparent pricing models present potential avenues to navigate these obstacles. In line with these efforts, recommendations include pushing for policy reforms, transparent pricing mechanisms, and global collaborations. Fostering an environment that balances industry profitability with global health goals may pave the way for persuading the pharmaceutical sector to adopt more equitable pricing practices.

These results demonstrate how threshold analysis and cost-effectiveness acceptability curves can inform drug pricing negotiations in settings with limited healthcare budgets. By linking WTP thresholds to economically justifiable pricing, policymakers can simulate price adjustments that align with societal willingness to pay. We recommend that future studies in other countries apply similar methodologies—combining deterministic and probabilistic sensitivity analysis—to establish context-specific pricing ceilings for high-cost therapies.

Our study has limitations. Transition probabilities and cost were extracted from Colombian hospital-based and not from population-based studies and this fact could overestimate or underestimate the number of cases. Also, relative risk and utilities were extracted from studies that did not include Colombian patients. However, variations in estimates of this variables within a plausible range of ±25% did not modify the results during sensitivity analysis.

In conclusion, the economically justifiable cost for reslizumab in Colombia is between $165 and $349 per dose, depending on the WTP used. This result should encourage more studies in the region that optimize decision-making processes when incorporating this drug into the health plans of each country.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-025-23205-1.

Supplementary Material 1

Author contributions

JAB. and AF. wrote the main manuscript text and AF prepared Figs. 1, 2 and 3. All authors reviewed the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent

This study was approved by the Institutional Review Board of University of Antioquia. The need for consent was waived by an IRB (2015–4690), following local regulations of resolution 8430/93, because this is a study which all information was extracted from the literature and do not use data from patients".

Consent for publication

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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