

Five-Year Experience with Dupilumab in Children and Adolescents with Severe Asthma: A 16-Case Series

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Abstract

Background: Severe pediatric asthma remains burdensome despite optimized inhaled therapy, and chronic oral corticosteroids (OCS) carry substantial harm during growth. Dupilumab targets IL-4R α to inhibit IL-4/IL-13 signaling central to type-2 inflammation. **Objective:** To describe five-year clinical, functional, and biological outcomes in a real-world pediatric cohort with severe type 2 asthma treated with add-on dupilumab. **Methods:** Ambispective, longitudinal case series of children/adolescents (6 - 17 years) initiating dupilumab between 2020-2025. Annual assessments included asthma control (ACT/c-ACT, ACQ-5), severe exacerbations (systemic corticosteroids ≥ 3 days, emergency care, or hospitalization), spirometry (FEV₁, FVC, FEV₁/FVC; GLI-2012), biomarkers (FeNO, blood eosinophils, total IgE), OCS use/dose, and safety. Analyses were primarily descriptive (medians [IQR], frequencies). **Results:** Sixteen patients were included (median age 12 years; 56% male; allergic/mixed T2 phenotypes common). At baseline, median ACT/c-ACT was 14, severe exacerbations 3/year, FEV₁ 72% predicted, FeNO 38 ppb, and 38% required daily OCS (10 mg prednisone-equivalent). After dupilumab initiation, control improved steadily (ACT/c-ACT 23 by 2025; ACQ-5 0.7), severe exacerbations fell to 1 in year 1 and 0 from 2023 onward, and FEV₁ rose to 92% predicted by 2025, with reduced bronchodilator reversibility. FeNO declined to 13 ppb, with downward

trends in eosinophils and IgE. All patients discontinued maintenance OCS by year 3. Safety was favorable (mild injection-site reactions, transient eosinophilia, occasional conjunctivitis; no treatment-limiting events). **Conclusions:** In real-world pediatric practice, dupilumab was associated with sustained improvements in asthma control, exacerbation suppression, physiological recovery of lung function, biomarker modulation, and complete OCS withdrawal over five years, with a reassuring safety profile. These data complement pediatric trial evidence and support earlier, sustained biologic therapy in appropriately selected children.

Keywords

Dupilumab, Severe Pediatric Asthma, Type 2 Inflammation, Ambispective Multicenter Case Series, Colombia, Longitudinal Outcomes

1. Introduction

Asthma is among the most common chronic diseases in childhood and adolescence, and a subset of patients suffer from severe asthma that remains uncontrolled despite high-dose inhaled therapies and systemic corticosteroids [1]. In pediatric populations, the use of long-term systemic corticosteroids raises serious concerns due to their adverse effects on growth, bone density, adrenal suppression, and overall development [2] [3]. Hence, there is an unmet need for biologic therapies that provide effective control while minimizing systemic side effects.

Dupilumab is a monoclonal antibody that blocks the interleukin-4 receptor α (IL-4R α), thereby inhibiting both IL-4 and IL-13 signaling pathways, which are central in type 2 (T2) inflammation [4]. In adults, dupilumab has demonstrated reductions in exacerbation rates, improvements in lung function, and decreases in biomarkers such as FeNO and IgE [5] [6]. Evidence in children is more limited but promising: in recent trials involving children aged 6 - 11 years with type 2 asthma, dupilumab significantly reduced severe exacerbations and improved lung function and asthma control versus placebo [7]. Moreover, a recent meta-analysis of pediatric and adolescent populations has suggested that dupilumab's safety profile is comparable to that in adults, with conjunctivitis being among the more frequent adverse events [8].

However, most published data on dupilumab come from randomized controlled trials or real-world cohorts in North America and Europe [9]. Studies from Latin America, and particularly Colombia, remain scarce or lacking. For instance, a post hoc subanalysis of the LIBERTY ASTHMA QUEST trial assessed Latin American participants and found that dupilumab reduced exacerbation rates by ~52.7% and improved pre-bronchodilator FEV₁ in that subgroup [10]. Still, real-world, long-term pediatric series in the region are practically nonexistent.

Therefore, we present a five-year, 16-case pediatric series of children and adolescents with severe T2 asthma treated with dupilumab in Colombia (2020-

2025). The aim is to describe the longitudinal trajectories of clinical control (ACT/c-ACT, ACQ-5), exacerbations, lung function, biomarkers (FeNO, eosinophils, IgE), oral corticosteroid dependence, and safety, in order to expand the evidence base in Latin American pediatric populations.

2. Materials and Methods

2.1. Study Design and Setting

This is an ambispective, multicenter, observational case series including pediatric patients (<18 years) with a confirmed diagnosis of severe eosinophilic asthma who initiated dupilumab therapy between January 2020 and December 2025 in specialized allergy and pulmonology centers across Colombia. Participating centers were tertiary-level hospitals and referral clinics with expertise in pediatric severe asthma management, covering diverse geographic regions (Caribbean, Andean, and Pacific). The design was chosen to emulate real-world conditions, capturing longitudinal clinical outcomes beyond the controlled environment of randomized clinical trials.

We included children and adolescents aged 6 - 17 years with: 1) physician-confirmed severe asthma according to GINA 2020-2025 definitions, 2) persistent uncontrolled symptoms despite high-dose inhaled corticosteroids (ICS) plus long-acting β_2 -agonists (LABA), with or without additional controllers, and 3) initiation of dupilumab as add-on therapy. Patients were required to have at least 12 months of documented baseline clinical history and at least one follow-up assessment after treatment initiation.

Patients were classified into allergic, mixed eosinophilic-allergic, and non-allergic eosinophilic phenotypes according to baseline clinical and biomarker profiles: the allergic phenotype was defined by the presence of sensitization to aeroallergens on skin prick testing or serum specific IgE; the mixed eosinophilic-allergic phenotype combined allergen sensitization with peripheral eosinophilia ≥ 300 cells/ μ L and/or FeNO ≥ 25 ppb; and the non-allergic eosinophilic phenotype included patients without allergen sensitization but with eosinophilia ≥ 300 cells/ μ L or FeNO ≥ 25 ppb, consistent with predominant type 2 inflammation.

Exclusion criteria included: 1) diagnosis of other chronic respiratory diseases (e.g., cystic fibrosis, primary ciliary dyskinesia, bronchiectasis, or COPD overlap), 2) immunodeficiency syndromes, 3) concomitant biologic therapy other than dupilumab, or 4) treatment discontinuation before completing 6 months of therapy for reasons unrelated to efficacy or safety.

2.2. Data Collection and Follow-Up

Clinical data were systematically retrieved from electronic medical records using a standardized electronic case report form (eCRF). Baseline information included demographics, age of asthma onset, atopic comorbidities, pharmacological therapy, and biomarkers (blood eosinophil count [BEC], fractional exhaled nitric oxide [FeNO], total serum IgE). Follow-up visits were scheduled at 3, 6, 12, 24, 36, 48,

and 60 months after dupilumab initiation, with ± 1 month flexibility to account for multihealthcare access limitations common in the Colombian health system.

The index date was defined as the first dupilumab administration. The observation period extended from 12 months before the index date until the last available follow-up. Missing data and outliers were verified through double review and consensus with treating physicians.

2.3. Outcomes

The primary outcome of this series was the annualized rate of severe asthma exacerbations, defined as episodes requiring systemic corticosteroids, emergency visits, or hospitalization. Exacerbation frequency was assessed retrospectively for the year prior to dupilumab initiation and prospectively during follow-up, enabling a direct comparison of pre- and post-treatment rates.

Secondary outcomes included multiple domains of disease control. Asthma control was measured with age-appropriate validated tools (c-ACT for children <12 years, ACT for adolescents, and ACQ-5), while lung function was evaluated through spirometry according to ATS/ERS standards, focusing on FEV₁, FVC, FEV₁/FVC, PEF, and post-bronchodilator reversibility.

Type 2 inflammation biomarkers—FeNO, blood eosinophil counts, and total serum IgE—were monitored longitudinally to capture the biological effects of IL-4/IL-13 blockade. Given the clinical importance of steroid-sparing strategies in pediatrics, oral corticosteroid (OCS) use was tracked, recording both prevalence and daily dose. Finally, safety and tolerability were assessed, with systematic documentation of adverse events such as injection-site reactions, eosinophilia, and conjunctivitis.

2.4. Statistical Analysis

Given the design of a case series with a small sample size, the statistical approach was primarily descriptive and exploratory. Continuous variables were summarized as median and interquartile range (IQR) when distributions were skewed, and as mean with standard deviation when approximately normal. Categorical variables were expressed as absolute and relative frequencies. Longitudinal changes were reported as both absolute and relative differences compared with baseline values, allowing interpretation of clinical relevance beyond statistical significance.

To illustrate the consistency of findings, exploratory paired tests were applied: the Wilcoxon signed-rank test for continuous variables and McNemar's test for paired categorical outcomes. However, these comparisons were considered exploratory only, without adjustment for multiple testing, and p-values were interpreted cautiously as indicative rather than confirmatory. Greater emphasis was placed on effect sizes and clinically meaningful thresholds, such as the proportion of patients achieving ACT/c-ACT ≥ 20 , withdrawal of OCS, or complete absence of exacerbations during follow-up.

Exacerbation rates were annualized by dividing the number of events by the

observation period (in months) and standardizing to 12 months. For lung function and biomarker data, trajectories across years were presented graphically to highlight temporal trends. All analyses were conducted using R software (v. 4.4.0, R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Baseline Characteristics

A total of 16 pediatric patients with severe asthma were included, with a median age at dupilumab initiation of 12 years (IQR 9 - 15); 9 (56%) were male. The majority presented with an allergic phenotype (62%), followed by mixed eosinophilic-allergic (25%) and non-allergic eosinophilic asthma (13%) (**Table 1**). Atopic comorbidities were highly prevalent: allergic rhinitis was reported in 75% of cases and atopic dermatitis in 44%.

Table 1. Values are presented as median (interquartile range) or frequency (percentage). FEV₁: forced expiratory volume in 1 second; FVC: forced vital capacity; BD: bronchodilator; FeNO: fractional exhaled nitric oxide; IgE: immunoglobulin E; OCS: oral corticosteroids; ICS: inhaled corticosteroids; LABA: long-acting β_2 -agonist; LAMA: long-acting muscarinic antagonist; LTRA: leukotriene receptor antagonist.

Characteristic	Overall (n = 16)
Age at dupilumab initiation, years	12 (9 - 15)
Male sex, n (%)	9 (56)
Asthma phenotype, n (%)	
- Allergic	10 (62)
- Mixed eosinophilic-allergic	4 (25)
- Non-allergic eosinophilic	2 (13)
Atopic comorbidities, n (%)	
- Allergic rhinitis	12 (75)
- Atopic dermatitis	7 (44)
- Food allergy	3 (19)
Baseline lung function	
- FEV ₁ % predicted	72 (64 - 79)
- FEV ₁ /FVC ratio	0.74 (0.69 - 0.77)
- Post-BD FEV ₁ change, mL	320 (220 - 420)
- Post-BD FEV ₁ change, %	14 (11 - 17)
Biomarkers	
- FeNO, ppb	38 (28 - 52)

Continued

- Blood eosinophils, cells/ μ L	410 (300 - 590)
- Blood eosinophils, %	5.6 (4.1 - 7.2)
- Total IgE, IU/mL	420 (190 - 780)
Corticosteroid exposure	
- Maintenance OCS use, n (%)	6 (38)
- Daily OCS dose, mg prednisone-eq	10 (7.5 - 12.5)
Concomitant inhaled therapy, n (%)	
- High-dose ICS/LABA	16 (100)
- Additional controller (LAMA/LTRA)	8 (50)

Baseline lung function reflected significant impairment, with median pre-bronchodilator FEV1 at 72% of predicted (IQR 64 - 79) and FEV1/FVC ratio of 0.74 (IQR 0.69 - 0.77). The reversibility test showed a median post-bronchodilator increase of 320 mL (IQR 220 - 420), corresponding to a 14% improvement. Median FeNO was elevated at 38 ppb (IQR 28 - 52), while blood eosinophil counts were 410 cells/ μ L (IQR 300 - 590). Total IgE levels were markedly heterogeneous, with a median of 420 IU/mL (IQR 190 - 780).

Systemic corticosteroid exposure was frequent: 6 patients (38%) required daily oral corticosteroids at baseline, with a median dose equivalent to 10 mg of prednisone/day. All patients were receiving high-dose ICS/LABA combinations, and 8 (50%) were on additional controllers (LAMA or LTRA). These findings confirm the high severity and uncontrolled status of the cohort at treatment initiation (**Table 1**).

3.2. Asthma Control and Exacerbations

Marked improvement in asthma control was observed from the first year of dupilumab therapy. Median ACT/c-ACT scores increased from 14 at baseline to 19 in 2021 and stabilized above 22 from 2023 onwards, while ACQ-5 scores decreased from 2.5 to 0.7 across follow-up, surpassing thresholds for well-controlled asthma (**Table 2**).

The annualized rate of severe exacerbations showed a dramatic decline. From a baseline median of three exacerbations per patient-year, the rate decreased to one during the first year and reached zero from 2023 through 2025. No hospitalizations or emergency visits for asthma were recorded beyond the second year, highlighting the sustained suppression of acute disease episodes.

3.3. Lung Function Trajectories

Progressive and consistent improvements in pulmonary function paralleled clinical gains. Median FEV1 improved from 72% predicted at baseline to 82% in

2021 and 92% in 2025. The FEV₁/FVC ratio normalized over time, rising from 0.74 to 0.82, while bronchodilator reversibility diminished from 14% to 6%, suggesting reduced airway hyperreactivity. FVC and PEF also increased steadily, indicating broader recovery of ventilatory capacity.

Table 2. Values are presented as median (interquartile range) or frequency (percentage). ACT: Asthma Control Test; ACQ-5: Asthma Control Questionnaire-5; FEV₁: forced expiratory volume in 1 second; FVC: forced vital capacity; BD: bronchodilator; FeNO: fractional exhaled nitric oxide; IgE: immunoglobulin E; OCS: oral corticosteroids.

Parameter	Baseline 2020	2021	2022	2023	2024	2025
Asthma control						
ACT/c-ACT score	14 (12 - 16)	19 (17 - 21)	21 (20 - 23)	22 (21 - 23)	22 (21 - 24)	23 (22 - 24)
ACQ-5 score	2.5 (2.2 - 2.9)	1.5 (1.2 - 1.8)	1.1 (0.9 - 1.4)	0.9 (0.7 - 1.2)	0.8 (0.6 - 1.0)	0.7 (0.5 - 0.9)
Severe exacerbations, n/year	3 (2 - 4)	1 (0 - 2)	0 (0 - 1)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
Lung function						
FEV ₁ % predicted	72 (64 - 79)	82 (76 - 87)	87 (82 - 92)	89 (84 - 94)	91 (86 - 95)	92 (88 - 96)
FVC % predicted	80 (74 - 86)	86 (80 - 90)	89 (84 - 93)	91 (87 - 95)	92 (88 - 96)	93 (89 - 97)
FEV ₁ /FVC ratio	0.74 (0.69 - 0.77)	0.78 (0.74 - 0.80)	0.80 (0.76 - 0.82)	0.81 (0.77 - 0.83)	0.82 (0.78 - 0.84)	0.82 (0.78 - 0.84)
PEF, L/s	3.2 (2.8 - 3.7)	3.8 (3.3 - 4.2)	4.0 (3.6 - 4.4)	4.1 (3.7 - 4.5)	4.2 (3.8 - 4.6)	4.3 (3.9 - 4.7)
Post-BD FEV ₁ change, %	14 (11 - 17)	11 (8 - 14)	9 (6 - 12)	8 (5 - 10)	7 (5 - 9)	6 (4 - 8)
Biomarkers						
FeNO, ppb	38 (28 - 52)	22 (16 - 28)	18 (12 - 24)	15 (10 - 20)	14 (10 - 18)	13 (9 - 17)
Blood eosinophils, cells/ μ L	410 (300 - 590)	380 (260 - 500)	360 (240 - 480)	340 (230 - 460)	320 (210 - 440)	310 (200 - 420)
Total IgE, IU/mL	420 (190 - 780)	400 (170 - 720)	370 (160 - 680)	350 (150 - 640)	340 (140 - 600)	330 (130 - 580)
Oral corticosteroids (OCS)						
Patients on maintenance OCS, n (%)	6 (38)	3 (19)	1 (6)	0 (0)	0 (0)	0 (0)
Daily OCS dose, mg prednisone-eq	10 (7.5 - 12.5)	5 (0 - 7.5)	0 (0 - 5)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Biomarkers of type 2 inflammation

Biological markers demonstrated durable modulation of type 2 inflammation. FeNO levels declined progressively from 38 ppb at baseline to 13 ppb in 2025, corresponding to a reduction of approximately 65%. Peripheral blood eosinophil counts decreased gradually over follow-up, from 410 to 310 cells/ μ L, while total IgE levels trended downward, supporting the systemic effect of IL-4/IL-13 pathway inhibition.

3.4. Oral Corticosteroid Use

The corticosteroid-sparing effect of dupilumab was particularly relevant in this

pediatric cohort. At baseline, 6 patients required daily OCS (median 10 mg prednisone-equivalent). By the first year, only 3 remained on OCS, and by the third year, all had discontinued systemic corticosteroids. This effect eliminated chronic steroid exposure and its associated risks, including impaired growth, metabolic complications, and bone fragility.

3.5. Safety and Tolerability

Dupilumab was well tolerated throughout the five-year observation period (**Table 3**). Mild injection-site reactions, transient eosinophilia, and conjunctivitis occurred during the first two years but resolved spontaneously without treatment interruption. Mild upper respiratory tract infections were reported intermittently, consistent with background pediatric frequency. No treatment discontinuations or serious adverse events attributable to dupilumab were documented during follow-up.

Table 3. Values are presented as frequency (percentage). Adverse events were mild to moderate, transient, and self-limited. No treatment discontinuations or serious adverse events attributable to dupilumab were observed during follow-up.

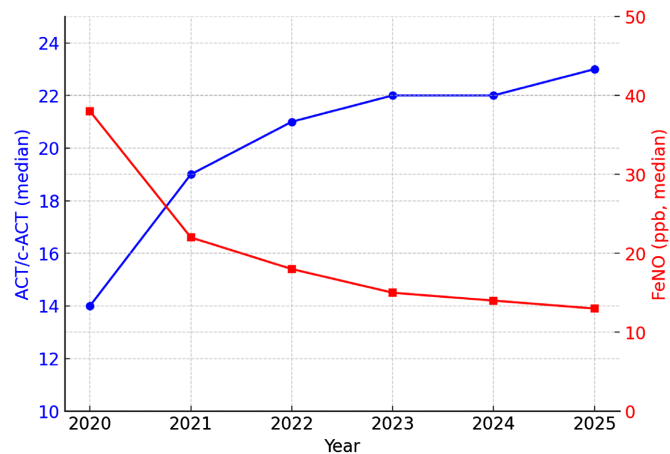
Adverse event	2020	2021	2022	2023	2024	2025
Injection-site reactions, n (%)	3 (19)	2 (13)	1 (6)	1 (6)	0 (0)	0 (0)
Transient eosinophilia, n (%)	2 (13)	1 (6)	1 (6)	0 (0)	0 (0)	0 (0)
Conjunctivitis, n (%)	2 (13)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Mild upper respiratory infections, n (%)	4 (25)	3 (19)	3 (19)	2 (13)	2 (13)	2 (13)
Treatment discontinuation, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Serious adverse events related to dupilumab, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

4. Discussion

In this real-world pediatric cohort with severe type-2 asthma, add-on dupilumab was associated with rapid and durable multidomain benefit: early gains in symptom control consolidating into sustained well-controlled status by year 3; a step-wise fall in severe exacerbations culminating in complete suppression from 2023 onward; progressive normalization of lung function (FEV1%pred and FEV1/FVC) with reduced bronchodilator reversibility; down-trending type-2 biomarkers (FeNO, eosinophils, IgE); and a clinically meaningful steroid-sparing effect—full discontinuation of maintenance OCS by year 3—with favorable long-term tolerability (**Tables 1-3; Figures 1-3**). These convergent trajectories suggest not only symptomatic control but also attenuation of airway hyperresponsiveness over time, a desirable target in growing lungs [11] [12].

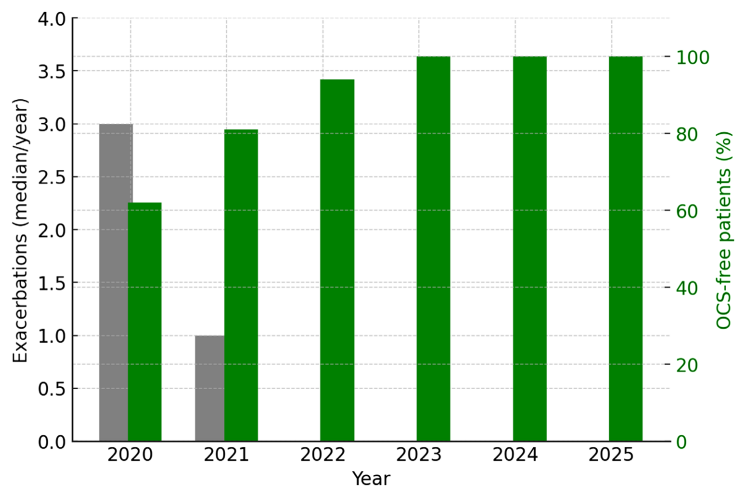
Our findings mirror and extend pediatric RCT signals. The VOYAGE program demonstrated significant improvements in control and lung function in children 6 - 11 years with type-2 asthma; subsequent analyses confirmed early and persistent FEV1 gains across biomarker strata and sustained control/HRQoL improvements (**Figure 1, Table 2, Table 3**). The pediatric open-label extension EXCUR-

SION reported durable reductions in exacerbations and stable safety beyond the blinded period. In older populations, TRAVERSE documented long-term durability up to ~3 years with a safety profile consistent with registrational trials (12), and a continuation analysis reinforced multi-year safety [13]. Notably, our complete OCS withdrawal and absence of severe exacerbations from year 3 are directionally concordant with extension programs that emphasize maintenance of effect under continuous therapy (Figure 2, Figure 3) [14].



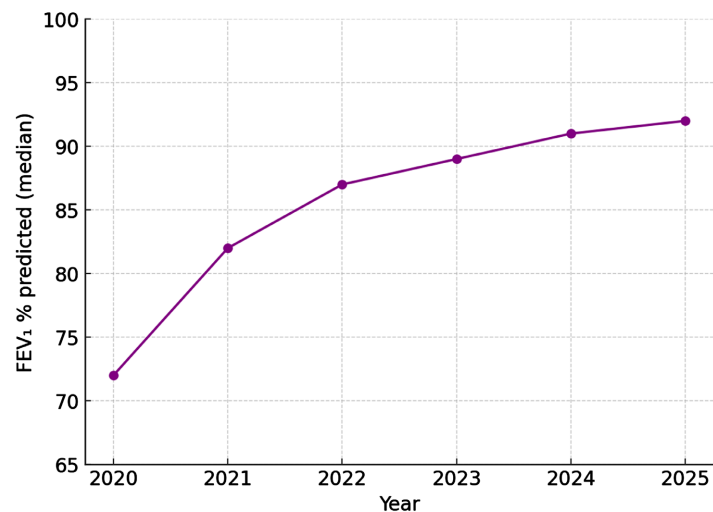
Yearly medians for asthma control (ACT for ≥ 12 years; c-ACT for < 12 years) and fractional exhaled nitric oxide (FeNO, ppb) in the pediatric cohort (n = 16). Points and lines depict medians by calendar year; FeNO measured using standardized analyzers at each visit. Progressive improvement in control paralleled a sustained decline in FeNO, consistent with attenuation of type-2 airway inflammation. See also (Table 2).

Figure 1. Trajectories of ACT/c-ACT and FeNO (2020-2025).



Dual-axis bar chart showing the median number of severe exacerbations per patient-year (left axis) and the percentage of patients free of maintenance oral corticosteroids (OCS) (right axis). Severe exacerbations were defined as those requiring systemic corticosteroids ≥ 3 days, emergency care, or hospitalization. The cohort shows a stepwise reduction in exacerbations with complete suppression from 2023 onward, alongside universal OCS independence by year 3. See also (Table 2).

Figure 2. Severe exacerbations and OCS-free patients (2020-2025).



Yearly medians of pre-bronchodilator FEV₁ expressed as percent predicted using GLI-2012 pediatric equations. The trajectory documents progressive restoration toward normal lung function across the five-year follow-up. Bronchodilator reversibility decreased in parallel (see [Table 2](#)), suggesting attenuation of airway hyperresponsiveness.

Figure 3. Longitudinal trajectory of FEV₁ % predicted (2020-2025).

Beyond RCTs, pediatric real-world data (RWD) remain scarce but are emerging. Observational series and registries increasingly show reduced exacerbation rates, improved spirometry, and biomarker modulation with dupilumab in routine care, including pediatric subgroups outside tightly controlled trial settings. A U.S. multi-database analysis found lower severe exacerbations and fewer systemic corticosteroid prescriptions with dupilumab versus comparators under routine practice, while pediatric RWD from Asia supports effectiveness and tolerability in children <12 years ([Table 2](#)). Our cohort adds 5-year longitudinal depth with systematic safety capture—including transient conjunctivitis and eosinophilia that resolved without discontinuation ([Table 3](#))—a level of follow-up that is uncommon in pediatric RWD.

Pediatric evidence from Latin America is limited, and access to biologics is heterogeneous. Regional analyses highlight unmet needs, variable control, and inequities in advanced therapy access, underscoring the value of local longitudinal data to inform policy and equity discussions. These results can help guide national and regional health policy decisions regarding inclusion of biologic therapies in pediatric asthma management programs, insurance coverage frameworks, and equitable access strategies within public health systems. Our 5-year outcomes—elimination of severe exacerbations, normalization of FEV₁ trajectories, and OCS independence—align with global efficacy while providing contextualized, region-specific evidence that may support earlier identification of type-2 pediatric phenotypes and timely biologic initiation ([Table 2](#), [Table 3](#); [Figure 2](#), [Figure 3](#)) [15].

The pediatric window—marked by somatic growth and lung maturation—offers a unique opportunity to modify long-term trajectories. Childhood asthma with impaired lung growth is linked to fixed airflow limitation and early COPD risk in

adulthood; conversely, sustained control during adolescence may preserve normal growth curves (Figure 3). The longitudinal improvement of FEV1%pred and reduction in reversibility seen here (Table 2) are consistent with this paradigm. In parallel, FeNO declines (Figure 1) track with suppression of IL-13–driven epithelial nitric oxide pathways and help integrate clinical and biological response in children (Table 2). Safety signals remained consistent with pediatric trials—mild conjunctivitis and transient eosinophilia early in treatment—without serious events (Table 3), an important reassurance in a population sensitive to ocular and growth-related adverse effects [15] [16].

Strengths include prolonged follow-up (5 years), multidomain ascertainment (symptoms, exacerbations, spirometry, FeNO, biomarkers), objective physiologic endpoints (FEV1%pred, FeNO), and systematic safety monitoring, mapped transparently to (Tables 1-3; Figures 1-3). Limitations include the case-series design without a concurrent control group and modest sample size ($n = 16$), precluding causal inference and detailed subgroup analyses. Given these constraints, analyses were primarily descriptive, prioritizing effect sizes and clinically relevant thresholds over confirmatory p -values—an approach aligned with real-world pediatric evidence generation and complementary to RCTs [17] [18].

5. Conclusion

In a real-world pediatric cohort with severe type-2 asthma, add-on dupilumab was associated with rapid and durable benefits across clinical, functional, and biological domains over five years. Asthma control improved to well-controlled ranges, severe exacerbations were eliminated from the third year onward, and lung function trajectories approached normalization, while FeNO and other type-2 biomarkers declined in parallel (Figures 1-3; Tables 1-3). The therapy enabled complete withdrawal of maintenance oral corticosteroids by year 3, a clinically meaningful steroid-sparing effect in children. Safety was favorable, with only mild, self-limited adverse events and no treatment-limiting toxicity. Although limited by the case-series design and modest sample size, these findings align with pivotal pediatric evidence and underscore the potential of dupilumab to modify disease trajectories when initiated and sustained during growth. Multicenter, region-specific real-world studies are warranted to confirm generalizability and to evaluate long-term outcomes relevant to quality of life and health-care utilization.

Data Availability Statement

The de-identified dataset underlying this article is available from the corresponding author upon reasonable request and subject to an approved data-sharing agreement to protect participant confidentiality.

Ethics Statement

The study adhered to the Declaration of Helsinki (2013) and institutional policies. Ethics approval was obtained from the Institutional Research Ethics Committee,

Instituto Neumológico de Córdoba. Given the ambispective design, the Committee granted a waiver of informed consent for the retrospective chart-review segment. For the prospective segment, written informed consent from parents/legal guardians and age-appropriate assent from minors were obtained.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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