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Alimentary Tract

Dupilumab for paediatric eosinophilic esophagitis: a multicentre real-world study

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ABSTRACT

Background: Real-world paediatric data on dupilumab for eosinophilic esophagitis are scarce.
Aims: To assess the effectiveness and safety of dupilumab in children and adolescents with eosinophilic esophagitis in routine clinical practice.
Methods: This retrospective multicentre study included patients younger than 18 years treated with dupilumab in 13 Spanish centres between May 2022 and February 2025. Histological, clinical, patient-reported, endoscopic and safety outcomes were assessed at baseline and follow-up endoscopies.
Results: Fifty-one patients were included; median age at dupilumab initiation was 13.7 years (IQR, 12.3–15.0). Most had previously received proton pump inhibitors (88.2%), swallowed topical corticosteroids (84.3%) and elimination diets (70.6%). Histological remission occurred in 30/45 patients (66.7%) at first follow-up and 15/19 (78.9%) at final follow-up. Deep histological remission occurred in 55.6% and 63.2%, respectively. Mean peak eosinophil counts decreased from 67 to 8.5 eosinophils/high-power field ($p < 0.001$). Symptom scores decreased by >60%, asymptomatic patients increased from 17.6% to 78.9%, and mean endoscopic score decreased from 3.2 to 0.9. Adverse events occurred in 18/51 patients (35.3%), all mild.
Conclusion: Dupilumab was effective and well tolerated, with sustained histological, clinical and endoscopic improvement.

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1. Introduction

Eosinophilic esophagitis (EoE) is a chronic immune-mediated disease characterised by eosinophil-predominant esophageal inflammation and symptoms of esophageal dysfunction. In childhood, the clinical presentation is heterogeneous and may include dysphagia, food impaction, vomiting, abdominal pain, feeding difficulties and impaired quality of life [1,2].

Current treatment options include proton pump inhibitors (PPI), swallowed topical corticosteroids and dietary elimination. Although these strategies are effective for many patients, a relevant subgroup has persistent symptoms or histological activity, relapses after de-escalation, or experiences substantial treatment burden from long-term medication or restrictive diets [3–6].

Dupilumab is a monoclonal antibody targeting the interleukin-4 receptor alpha subunit, thereby inhibiting interleukin-4 and interleukin-13 signalling. This mechanism directly addresses type 2 inflammation, a central pathway in eosinophilic esophagitis. Randomised trials have demonstrated efficacy in adults, adolescents and children, but multicentre paediatric real-world data remain limited [7,8].

The aim of this study was to evaluate the effectiveness and safety of dupilumab in children and adolescents with eosinophilic esophagitis managed in routine clinical practice across Spanish centres.

2. Materials and methods

2.1. Study design and population

This national, multicentre, retrospective observational study included paediatric patients with EoE treated with dupilumab between May 2022 and February 2025 in 13 Spanish hospitals.

Inclusion criteria were age younger than 18 years, diagnosis of EoE according to international consensus criteria [1], dupilumab treatment, and at least one follow-up upper endoscopy with histological assessment. Dupilumab was prescribed either for refractory EoE or for a concomitant atopic indication in patients with EoE.

Data were collected at baseline before dupilumab initiation, at the first follow-up endoscopy, and at the last available follow-up endoscopy. Variables included demographics, atopic comorbidities, anthropometric parameters, symptoms, Pediatric Eosinophilic Esophagitis Symptom Score version 2.0 (PEESS v2.0), endoscopic findings using the Endoscopic Reference Score (EREFS), histology, previous and concomitant EoE treatments, dupilumab dose and interval, and adverse events.

Table 1
Baseline characteristics of the study population.

Characteristic	Value
Male sex	36/51 (70.6)
Age at EoE diagnosis, years, median (IQR)	8.9 (5.8–12.1)
Age at dupilumab initiation, years, median (IQR)	13.7 (12.3–15.0)
Any atopic comorbidity	41/51 (80.4)
Food allergy	30/51 (58.8)
Rhinoconjunctivitis	24/51 (47.1)
Asthma	21/51 (41.2)
Atopic dermatitis	18/51 (35.3)
Family history of EoE	10/51 (19.6)
Dysphagia	24/51 (47.1)
Abdominal pain	23/51 (45.1)
Heartburn	16/51 (31.4)
Vomiting	14/51 (27.5)
Food impaction	7/51 (13.7)
Normal baseline endoscopy	4/51 (7.8)
Localised endoscopic involvement	14/51 (27.5)
Diffuse endoscopic involvement	33/51 (64.7)
Inflammatory phenotype	35/51 (68.6)
Mixed inflammatory/fibrostenotic phenotype	11/51 (21.6)
Fibrostenotic phenotype	1/51 (2.0)
Baseline EREFS, median (IQR)	3 (2–4)
Peak eosinophil count, eos/hpf, median (IQR)	60 (37–100)
Basal cell hyperplasia	26/37 (70.3)
Superficial epithelial alteration	28/45 (62.2)
Dyskeratosis	4/12 (33.3)
Lamina propria fibrosis	3/17 (17.6)
Previous PPI therapy	45/51 (88.2)
Previous swallowed topical corticosteroids	43/51 (84.3)
Previous elimination diet	36/51 (70.6)
Previous combination therapy	23/51 (45.1)

Note: Values are n (%) unless otherwise indicated. Percentages were calculated using the available denominator for each variable.
Abbreviations: EoE, eosinophilic esophagitis; IQR, interquartile range; EREFS, Endoscopic Reference Score; eos/hpf, eosinophils per high-power field; PPI, proton pump inhibitor.

2.2. Outcomes

The primary outcome was histological remission, defined as a peak eosinophil count below 15 eosinophils per high-power field (eos/hpf) in all esophageal biopsy samples obtained at follow-up endoscopy. Deep histological remission was defined as 5 or fewer eos/hpf. Clinical status was categorised according to symptoms reported by patients or their parents as asymptomatic, mild symptoms, or moderate/severe symptoms. In the subgroup with available questionnaires, symptom burden was assessed using the PEESS v2.0 version 2.0 [9]. Endoscopic response was assessed by change in total Endoscopic Reference Score (EREFS) and by change in the extent of esophageal involvement [10]. Safety was assessed by recorded adverse events, seriousness and treatment discontinuation.

2.3. Data collection and ethics

Study data were anonymised locally and entered into Research Electronic Data Capture (REDCap) hosted at the Spanish Society of Paediatric Gastroenterology, Hepatology and Nutrition, with support from the AEG REDCap unit [11]. The study was approved by the Research Ethics Committee of Aragón (CEICA) on 4 December 2024 (EOM24/057; Acta 22/2024). The requirement for informed consent was waived because of the retrospective design. The study conformed to the ethical guidelines of the Declaration of Helsinki.

2.4. Statistical analysis

Continuous variables were summarised as mean with standard deviation (SD) or median with interquartile range (IQR), as appropriate, and categorical variables as number and percentage. Ninety-five per cent confidence intervals (CI) for proportions were calculated using the Wilson score method. Longitudinal categorical variables were analysed using Cochran's Q test with McNemar post hoc comparisons and false discovery rate adjustment. Longitudinal continuous variables were analysed using repeated-measures analysis of variance or the Friedman test, as appropriate. Cross-sectional associations were assessed using the chi-square test or Fisher's exact test. A two-sided alpha level of 0.05 was considered statistically significant. All statistical analyses were performed using jamovi, version 2.5 (The jamovi project, Sydney, Australia).

3. Results

3.1. Patient characteristics and treatment exposure

A total of 51 paediatric patients with confirmed EoE were included. Dupilumab was prescribed for refractory EoE in 45 patients

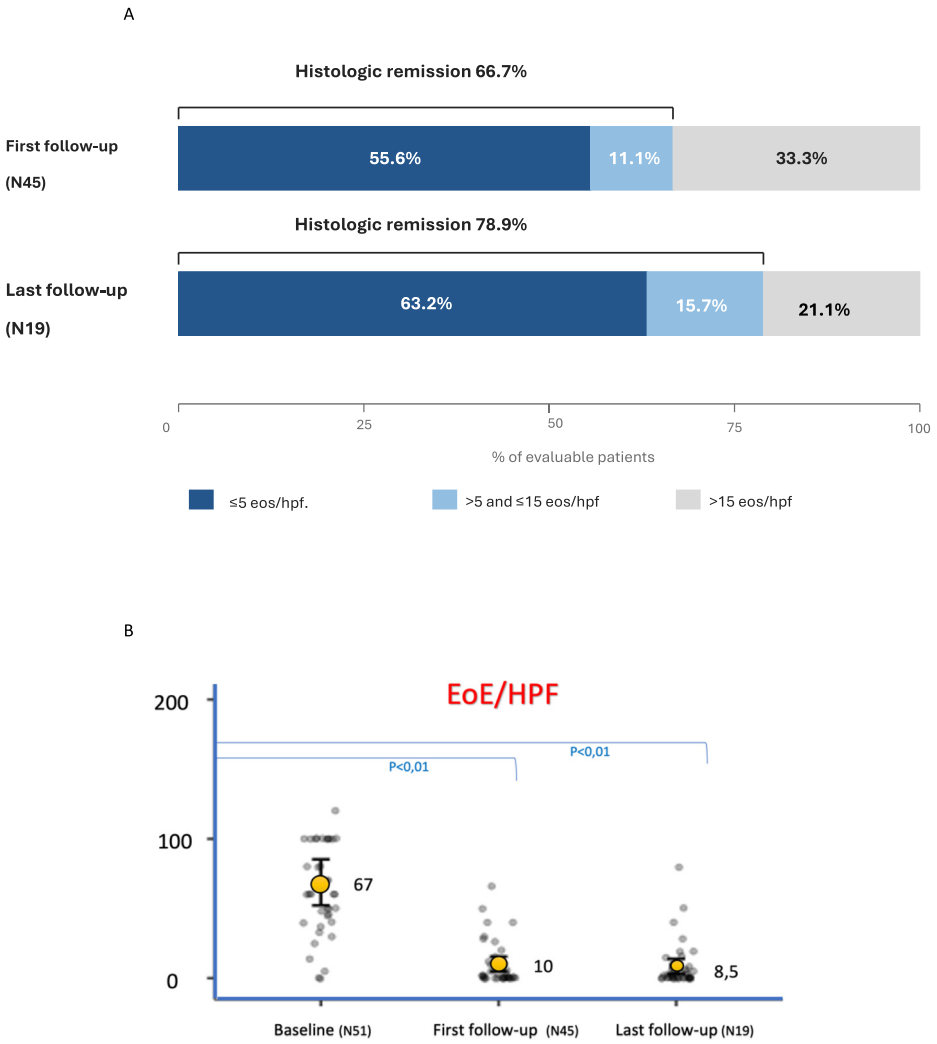

Fig. 1. Histological response to dupilumab at first and last follow-up endoscopy. Panel A shows the proportion of patients achieving histological remission, defined as fewer than 15 eosinophils per high-power field, and deep histological remission, defined as 5 or fewer eosinophils per high-power field. Panel B shows the change in peak eosinophil count per high-power field.

(88.2%) and for concomitant atopic disease in 6 (11.8%), including atopic dermatitis in 4 and allergic asthma in 2. Baseline characteristics are shown in Table 1.

The cohort was predominantly male (70.6%). Median age at EoE diagnosis was 8.9 years (IQR, 5.8–12.1), and median age at dupilumab initiation was 13.7 years (IQR, 12.3–15.0). Forty-one patients (80.4%) had at least one atopic comorbidity. Dysphagia, abdominal pain and food impaction were present in 47.1%, 45.1% and 13.7% of patients, respectively.

At baseline endoscopy, 4 patients (7.8%) had normal findings, 33 (64.7%) had diffuse involvement and 14 (27.5%) had localised involvement. Most patients had an inflammatory phenotype (68.6%), whereas 21.6% had a mixed inflammatory and fibrostenotic phenotype and 1 patient (2.0%) had an isolated fibrostenotic phenotype [10]. Baseline median peak eosinophil count was 60 eos/hpf (IQR, 37–100).

All patients had previously received at least one standard therapy: PPIs in 45 (88.2%), swallowed topical corticosteroids in 43 (84.3%) and elimination diets in 36 (70.6%). Prior combination therapy had been used in 23 patients (45.1%). Dupilumab regimens were 200 mg weekly in 3 patients, 200 mg every 2 weeks in 7, 300 mg weekly in 30 and 300 mg every 2 weeks in 11, according to weight and clinical indication. Forty-five patients underwent first follow-up endoscopy at a median of 22 weeks (IQR, 17.0–27.7). At the time of database closure, 19 patients had reached a sufficiently long treatment duration to undergo a second follow-up endoscopy, performed at a median of 56 weeks (IQR, 49.3–76.6). The remaining patients had not yet reached the time point for a second endoscopic assessment.

3.2. Histological outcomes

At baseline, 6 of 51 patients (11.8%) were already in histological remission and received dupilumab for another atopic indication. Among the 45 patients with active histological disease who underwent the first follow-up endoscopy, 30 achieved histological remission (66.7%; 95% CI, 52.1–78.6), of whom 25 met the more stringent criterion for deep histological remission (55.6%; 95% CI, 41.2–69.1). At the last follow-up endoscopy, 15 of 19 patients achieved histological remission (78.9%; 95% CI, 56.7–91.5), of whom 12 achieved deep histological remission (63.2%; 95% CI, 41.0–80.9) (Fig. 1A). Mean peak eosinophil count decreased from 67 (SD, 51) at baseline to 10 at first follow-up and 8.5 (SD, 16.5) at last follow-up ($p < 0.001$) (Fig. 1B). Significant reductions were also observed in basal cell hyperplasia, superficial epithelial alter-

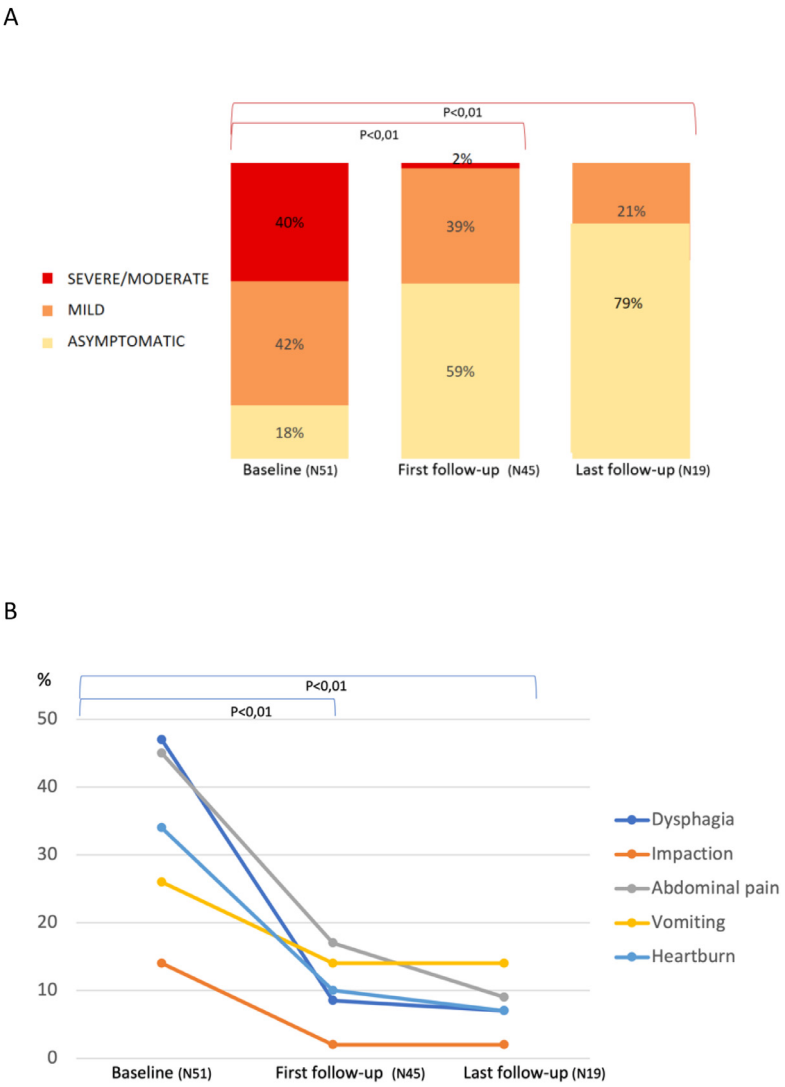

Fig. 2. Clinical response to dupilumab. Panel A shows the change in overall symptom severity from baseline to first and final follow-up. Panel B shows symptom-specific improvement after dupilumab treatment.

ations and dyskeratosis. None of the three patients with baseline lamina propria fibrosis had fibrosis at first follow-up.

3.3. Clinical and patient-reported outcomes

Clinical status improved significantly during dupilumab treatment (Fig. 2A). The proportion of asymptomatic patients increased from 18% at baseline to 59% at first follow-up and 79% at last follow-up. Conversely, the proportion of patients with moderate or severe symptoms decreased from 40% at baseline to 2% at first follow-up and 0% at last follow-up. The distribution of symptom-severity categories differed significantly between baseline and both first and last follow-up assessments ($P < 0.01$). (Fig. 2A). Dysphagia decreased from 24/51 (47.1%) at baseline to 3/45 (6.7%) at first follow-up, food impaction from 7/51 (13.7%) to 1/45 (2.2%), and abdominal pain from 23/51 (45.1%) to 4/45 (8.9%) (Fig. 2B)

Symptom burden assessed by PEESS v2.0 version 2.0, available from children ($n = 18$) and parents ($n = 16$), decreased significantly from baseline to both follow-up assessments ($p < 0.01$), with a mean reduction exceeding 60% (Fig. 3). Improvement was consistent in patient- and parent-reported scores. No significant changes were observed in weight, height or body mass index during follow-up.

3.4. Endoscopic outcomes

Dupilumab was associated with significant endoscopic improvement. Mean total EREFS decreased from 3.2 (SD, 1.6) at baseline to 1.1 (SD, 1.2) at first follow-up and 0.9 (SD, 1.1) at final follow-up ($p < 0.01$ for both comparisons versus baseline; Fig. 4). Normal endoscopy was documented in 23 of 45 patients (51.1%) at first follow-up, and the extent of esophageal involvement decreased significantly over time.

Among nine patients with grade 1 rings at baseline, rings resolved in seven and persisted in one; one patient had no follow-up endoscopy. Among three patients with grade 2 rings, rings resolved in two and persisted in one. A baseline stenosis in one patient resolved after dupilumab.

3.5. Concomitant therapy and safety

Use of concomitant EoE treatment decreased after dupilumab initiation. At first follow-up, PPIs were maintained in 16 of 45 patients (35.6%), swallowed topical corticosteroids in 5 of 45 (11.1%) and dietary elimination therapy in 4 of 45 (8.9%). Only 2 patients (4.4%) received more than one concomitant treatment. At the second follow-up, PPIs were used in 6 of 19 patients (31.6%), swal-

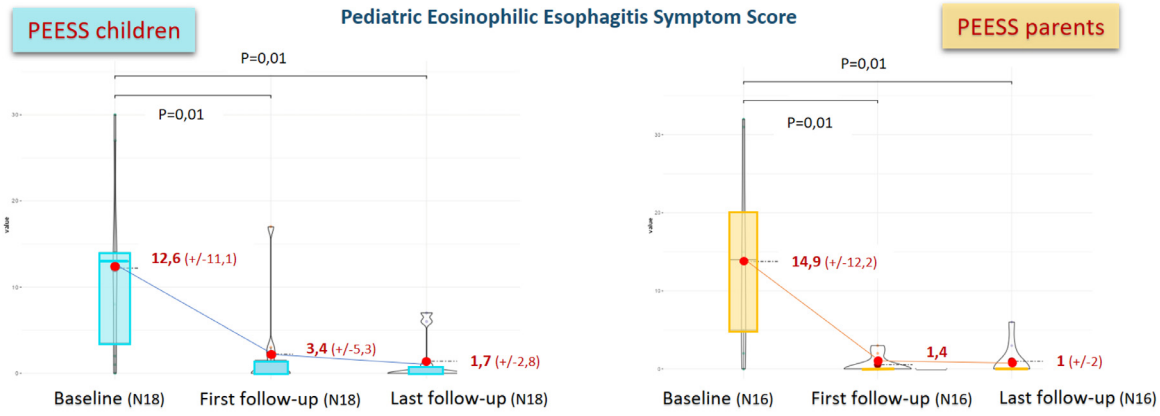

Fig. 3. Change in Pediatric Eosinophilic Esophagitis Symptom Score version 2.0. Mean scores reported by patients and parents decreased significantly from baseline to first and final follow-up.



Fig. 4. Endoscopic response to dupilumab. Panel A shows the change in total Endoscopic Reference Score over time. Panel B shows the change in the extent of esophageal involvement from baseline to first and last follow-up.

lowed topical corticosteroids in 3 of 19 (15.8%) and dietary therapy in 1 of 19 (5.3%).

Adverse events were reported in 18 of 51 patients (35.3%). The most frequent events were injection-site pain in 13 patients (25.5%) and injection-site reactions in 8 (15.7%). One patient developed a transient skin rash. No conjunctivitis, serious adverse events or clinically relevant laboratory abnormalities were recorded, and no adverse event led to treatment discontinuation.

4. Discussion

This multicentre Spanish study provides real-world evidence on dupilumab in children and adolescents with EoE. In a predominantly treatment-refractory cohort, dupilumab was associated with consistent improvement across histological, clinical, patient-reported and endoscopic domains, with a favourable safety profile and no treatment discontinuations.

The histological remission rate of 66.7% at a median of 22 weeks is clinically relevant given the refractory nature of the cohort and the high frequency of previous PPI, swallowed topical corticosteroid and dietary therapy exposure [12–19]. The higher remission rate observed at the final assessment should be interpreted cautiously because only 19 patients had reached a sufficiently long treatment duration to undergo a second follow-up endoscopy. Although the smaller denominator reflected differences in available follow-up rather than loss to follow-up or treatment discontinuation, it limits the precision of the long-term estimate; nevertheless, the finding is consistent with a potential cumulative treatment effect described in clinical trials and real-world studies [8,20–25]. These data support reassessment after adequate exposure before concluding treatment failure in otherwise stable patients.

Symptomatic improvement paralleled histological response. The proportion of asymptomatic patients increased substantially, and both dysphagia and food impaction decreased. The improvement in PEESS v2.0, reported by both children and parents, strengthens the clinical relevance of the findings because symptom assessment in paediatric EoE is often influenced by adaptive eating behaviours and parent-child reporting differences [9,19].

Endoscopic improvement was also marked, with reductions in EREFS and in the extent of esophageal involvement. Resolution of rings or stenosis in a small number of patients and disappearance of lamina propria fibrosis in three patients raise the hypothesis that interleukin-4 and interleukin-13 blockade may influence remodelling features. However, these observations are exploratory and limited by small denominators, variable biopsy sampling of the lamina propria and lack of protocolised dilation assessment. They should therefore be considered hypothesis-generating rather than evidence of disease modification [26–28].

An important practical finding was the reduction in concomitant EoE-directed therapy after dupilumab initiation. This potential treatment-sparing effect is relevant in children, in whom chronic swallowed corticosteroid therapy and restrictive diets may increase treatment burden, affect adherence and impair quality of life. Because treatment de-escalation was not protocolised, future prospective studies should define when and how background therapy can be safely withdrawn.

The safety profile was reassuring. Adverse events were mild and mainly injection-site related, with no conjunctivitis, serious adverse events, laboratory safety signal or treatment discontinuation. These findings are consistent with clinical trials and observational studies reporting generally favourable tolerability of dupilumab in EoE [8,12,18,20,29,30].

The main limitations are the retrospective design, absence of a control group, heterogeneity in dosing and concomitant treatments, variability in follow-up intervals, and incomplete longitudinal endoscopic data. These factors limit causal inference and may introduce selection and attrition bias. Strengths include the multicentre design, inclusion of a real-world paediatric population with high treatment burden, and comprehensive assessment of histological, clinical, patient-reported, endoscopic and safety outcomes.

In conclusion, dupilumab was effective and well tolerated in this multicentre real-world cohort of paediatric EoE, with sustained improvement across key disease domains. Larger prospective studies should define predictors of response, optimal duration before response assessment, treatment de-escalation strategies and the long-term impact on esophageal remodelling.

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Author contributions

Ruth García-Romero: conceptualization, methodology, investigation, formal analysis, data curation, writing - original draft, writing - review and editing. **Gloria Domínguez-Ortega:** conceptualization, methodology, investigation, data curation, writing - review and editing. **Beatriz Espín-Jaime:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Sonia Fernández-Fernández:** conceptualization, methodology, investigation, data curation, writing - review and editing. **Víctor Vila-Miravet:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Julia Gonzalo-Consuegra:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Iván Carabaño-Aguado:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Alejandro García-Diaz:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Ricardo Torres-Peral:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Jose Vicente Arcos:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Luis Grande-Herrero:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Cristina Rodríguez-Jiménez:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Laura Escartín-Madurga:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Begoña Perez Moneo:** investigation, resources, patient recruitment, data curation, writing - review and editing. **David Gil-Ortega:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Mariana Di Campli-Zaghlul:** investigation, resources, patient recruitment, data curation, writing - review and editing. **Daniel Bordonaba-Bosque:** Formal analysis, Methodology, Software, Data curation. **Carolina Gutiérrez-Junquera:** conceptualization, methodology, investigation, formal analysis, supervision, writing - original draft, writing - review and editing. All authors critically reviewed the manuscript and approved the final version for submission.

Ethics approval

The study was approved by the Research Ethics Committee of Aragón (CEICA) on 4 December 2024 (EOM24/057; Acta 22/2024). The requirement for informed consent was waived because of the retrospective design.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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