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Case report

Efficacy of dupilumab therapy in three children with refractory eosinophilic esophagitis: Case study

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ABSTRACT

Eosinophilic esophagitis (EoE) is an inflammatory chronic disease of esophagus, that contributes to symptoms of esophagus dysfunction. Recommended treatment strategies to obtain EoE resolution range from elimination diets, through proton pump inhibitors, to topical corticosteroids. In 2023 European Medicines Agency firstly approved the use of dupilumab, which currently is recommended for children from 1 year of age and weighing 15 kg, who cannot take conventional treatment or for whom the therapy is insufficient. We present cases of refractory to conventional therapies patients for whom dupilumab led to endoscopic, histologic and finally clinical remission.

KEYWORDS

children, treatment, eosinophilic esophagitis, dupilumab

INTRODUCTION

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease of the esophagus characterized by esophageal dysfunction, including dysphagia and food impaction, which may lead to feeding difficulties and failure to thrive. The diagnosis of EoE requires clinical symptoms consistent with swallowing disorders and histological evidence of >15 eosinophils in one high-power microscopy field (eos/HPF) in esophageal mucosa specimens [1]. Recommended treatment strategies to obtain EoE resolution include elimination diets, proton pump inhibitors (PPIs), and topical corticosteroids (tCS) [2,3]. However, due to inadequate response, intolerance, or adverse events in some patients, the European Medicines Agency (EMA) approved dupilumab in 2023 for children aged ≥1 year weighing ≥15 kg, who cannot take conventional treatment or for whom the therapy is insufficient [4,5].

Here we present three cases of pediatric patients with refractory EoE in whom dupilumab successfully induced clinical, histologic, and endoscopic remission.

CASE REPORTS

Patient 1

A 10-year-old male with autism, obesity (body mass index [BMI] = 37.8 kg/m^2), atopic dermatitis and asthma was admitted to our Gastroenterology and Hepatology Tertiary Care Centre for a diagnostic evaluation of celiac disease due to a six-month history of recurrent abdominal pain, bloating, and diarrhoea. The patient also complained of nausea, vomiting, acid regurgitation, frequent food impactions and dysphagia. Esophagogastroduodenoscopy (EGD) revealed longitudinal furrowing in the esophagus. Due to lack of pathological changes in the duodenum and negative serological test results celiac disease was excluded. The diagnosis of EoE was established

based on the histopathological finding of 30 eos/HPF in esophageal biopsy specimens. Initial treatment strategy involved a six-food elimination diet (SFED) showed poor compliance. Follow-up EGD after 3 months of treatment revealed a longitudinal furrowing and mild trachealization in the distal region of the esophagus. Consequently, therapy was transitioned to pantoprazole 40 mg twice a day. During therapy, the patient reported a subjective worsening with a recurrence of abdominal pain, diarrhoea and food impaction. Due to the lack of endoscopic remission and patient's worsening condition after PPI therapy, topical budesonide 1 mg twice daily was initiated. Even though two-month tCS treatment led to a significant reduction in previous symptoms, therapy related occurrence of diarrhoea was reported. What is more, EGD demonstrated longitudinal furrows in the distal third of the esophagus accompanied by fibrinous exudate above the gastroesophageal junction (E0, R0, Ex1, F1, S0). Eosinophilic infiltration in obtained biopsies reached up to 35 eos/HPF. Following the failure of conventional therapies and intolerance to topical steroids, the patient was qualified for biological therapy with dupilumab. Control endoscopy after 6 month of treatment shows only subtle linear furrowing and mucosal granularity in the distal esophagus (EREFS: E0, R0, Ex0, F1, S0) with full histopathological remission in all biopsies.

Patient 2

A 15-year-old boy with autism spectrum disorders was admitted to our department due to dysphagia, food impaction episodes and poor weight gain. Patient gave a history of difficulties in swallowing and food selectivity since an early age. He remains under allergology follow-up for multiple IgE-mediated food allergies. The patient presented with an asthenic physique, poorly developed subcutaneous tissue and underweight (BMI = 15.72 kg/m^2, below the 5th percentile for age). Diagnostic evaluation, including gastroscopy and histopathological analysis, confirmed the diagnosis of EoE with >50 eos/HPF and the presence of two circular strictures. The primary therapeutic approach consisted of an elemental diet combined with pantoprazole 40 mg twice daily and oral budesonide 1 mg twice daily. Follow-up upper endoscopy after 2 months of treatment demonstrated linear furrows in the distal portion of the esophagus but no strictures were observed. Remission of the disease was further confirmed by the histopathological findings from oligobiopsy (4 eos/HPF). Because of the patient's marked clinical improvement, budesonide dosage was decreased to 1 mg once daily and SFED was recommended. Over the following year, the patient experienced a food impaction episode. Follow-up gastroscopy revealed a rigid, circumferential stricture impassable by endoscope, alongside diffuse trachealization and epithelial peeling. Despite escalating budesonide to 1 mg twice daily and pantoprazole 40 mg twice daily, no clinical or histological improvement was noted. Consequently, an 8-week course of oral

prednisolone was initiated. Finally, given the persistence of strictures despite systemic steroid use, the patient was qualified for dupilumab therapy. Significant clinical progress was observed during therapy. Although follow-up endoscopy revealed persistent structural changes, including longitudinal trachealization, generalized esophageal stiffness, and a rigid circumferential narrowing (EREFS: E0, R3, Ed0, F0, S1) histopathological analysis confirmed the resolution of eosinophilic infiltration.

Patient 3

A 12-year-old male was urgently referred to our clinic for an extended diagnostic evaluation of hematemesis. What is more, the patient's history included allergy to house dust mites, abdominal pain, accompanied by non-bilious vomiting, which subsequently became bile-stained and contained traces of fresh blood one week prior to admission. However, physical examination revealed no abnormalities. Urgent gastroscopy revealed small, white, punctate deposits in the middle and distal esophagus. Moreover, a gastric ulcer, approximately 1 cm in diameter and covered with a fibrinous coating, was also described. Histopathological examination of the esophageal samples was non-diagnostic, thus fungal infection could not be excluded. Based on the endoscopic findings, high-dose of omeprazole was prescribed. The definitive diagnosis of EoE was reached after follow-up gastroscopy revealed persistent abnormalities and >50 eos/HPF. Management began with omeprazole and a SFED excluding major food allergens. As first-line therapy failed to induce remission, tCS therapy with budesonide was initiated. Four months later, a normal endoscopic appearance was obtained, and no eosinophilic infiltration was detected. It was decided to continuate topical budesonide therapy at a maintenance dose. Nevertheless, the clinical course subsequently became steroid-dependent, as every attempt to lower the dose resulted in immediate disease recurrence. Consequently, therapy was intensified by reintroducing oral budesonide 1 mg twice a day with full remission after 6 months. However, maintaining therapeutic effect demanded longitudinal full-dose budesonide treatment, associated with recurrent stomatomycosis. Fluconazole therapy was initiated several times, leading to complete resolution of oral mucosal lesions. To address the steroid dependence and recurrent adverse effect (oral mycosis) the patient was considered for dupilumab therapy. After 6 month of treatment full clinical, endoscopic and histological remission was achieved.

A comparison of the patients' medical histories is presented in Table I.

Table I. Comparison of patients medical history

Characteristic	Patient 1 (10-year-old)	Patient 2 (15-year-old)	Patient 3 (12-year-old)
Comorbidities	non-celiac gluten intolerance, autism spectrum disorders, atopic dermatitis, asthma, obesity	food allergy, autism spectrum disorders	airborne allergy, gastric ulcer
Prior treatments	SFED, PPIs, tCS	elemental diet, PPIs, tCS, oral prednisolone	SFED, PPIs, tCS
Indication for dupilumab	PPIs and tCS intolerance	persistent esophageal strictures	adverse drug reaction (recurrent stomatomycosis after tCS)
Outcomes	clinical and histopathological remission	- persistent structural changes of esophagus with circumferential narrowing - resolution of eosinophilic infiltration in histopathological analysis - clinical improvement	clinical endoscopic and histological remission

SFED – six-food elimination diet; PPIs – proton pump inhibitors; tCS – topical corticosteroids

DISCUSSION

The estimated annual prevalence of EoE, which is an antigen-driven, Th2-mediated inflammatory disease of the esophagus, reaches approximately 5.1 cases per 100,000 children [6]. The primary induction therapy for pediatric EoE is based on three equally effective pillars, including PPIs, tCS, and empiric elimination diets [1]. Meta-analyses and systematic reviews indicate that histological remission rates in pediatric EoE are approximately 50.5% for PPIs, 60.6% for dietary elimination, and 68%–77% for tCS [1,7,8]. Prospective data indicate that approximately 30%–50% of pediatric patients remain refractory to a single initial treatment modality [1,7]. Failure to achieve a longitudinal clinico-histological response results in the necessity of therapeutic rotation, combination strategies, or treatment escalation [1,9,10]. According to guidelines, dupilumab is now an established second-line intervention for children over one year of age with first-line treatment failure or refractory course of the disease [1].

In view of the upregulation of several Th2 cytokines, such as IL-4, IL-5 and IL-13, dupilumab, a human monoclonal antibody, that inhibits IL-4 and IL-13 signaling by blocking their receptors, is

considered a good treatment option for EoE [11,12]. This medication, first approved by the Food and Drug Administration (FDA) in 2017, is now recommended by the EMA for atopic dermatitis, asthma, chronic obstructive pulmonary disease chronic rhinosinusitis with nasal polyposis, prurigo nodularis and finally since 2023 EoE [4,13]. Initially, dupilumab was approved in May 2022 for children aged ≥12 years, but since it turned out to be beneficial, dupilumab may be considered in selected cases of children aged over 1 year and weighing at least 15 kg who have EoE refractory to conventional treatment [1]. According to guidance published in 2023, dupilumab may be considered in patients who exhibit failure to thrive, require recurrent systemic corticosteroids, have severe dietary restrictions, or present with esophageal strictures [14]. In view of the recommended dosage depending on the patient's body weight, dupilumab should be administered as 200 mg every other week for patients weighing 15 to 30 kg, 300 mg every other week for those weighing 30 to 40 kg, and 300 mg weekly for patients ≥40 kg of body weight [4].

The efficacy of dupilumab in EoE has been demonstrated in recent randomized controlled trials. Histologic remission was achieved respectively, in 58%–68% of patients on dupilumab in the study performed by Chehade et al. [15], and 74%–85% of patients receiving dupilumab in the study performed by Rothenberg et al. [16]. Both studies reported that higher-exposure dupilumab regimen was associated with superior therapeutic efficacy compared with the lower-exposure and placebo groups. The mean reduction in peak eosinophil counts from baseline approached 90%–96%, accompanied by concordant improvements in histologic grading, endoscopic reference scores, and patient-reported dysphagia outcomes. Despite being generally well tolerated among pediatric patients, dupilumab is documented to cause adverse events (AE). Reported side effects included hypersensitivity reactions, conjunctivitis and keratitis-related events, and eosinophilia [4]. On the other hand, the study performed by Hasosah et al. [17] reported only 9% of patients with conjunctivitis related to dupilumab injection, while in another study, the most common events were injection-site reactions (11%–14%) [15].

Real-life data on dupilumab therapy in pediatric EoE are still limited. In Poland, dupilumab is available only for children who have failed all traditional treatment options. In all cases presented in our article, remission was not sustained despite initial responses to diet, PPIs, or tCS. Furthermore, the clinical course of the disease was complicated by recurrent symptoms and poor medication tolerance.

As part of the pre-treatment assessment, we obtained stool cultures, and ova-and-parasite testing in view of the label-based recommendations to treat helminth infections prior to dupilumab initiation and local epidemiologic risk, and we also performed chest radiography to exclude

pulmonary pathology before commencing biologic therapy [13]. Following eligibility confirmation, the 300 mg of dupilumab was administered subcutaneously at our department, after which treatment was continued at home as 300 mg dupilumab s.c. once weekly. In all patients no history of food bolus impaction episodes, dysphagia or vomiting was given three months after dupilumab initiation. During the initial therapy, the patients' general condition, adverse events and laboratory parameters were assessed every 6 weeks. The therapy was well tolerated, with no significant adverse events observed. During the six-month follow-up period, clinical stability was maintained in all patients, with complete clinical remission achieved. Although follow-up endoscopy revealed varying degrees of mucosal recovery histopathological analysis confirmed the resolution of eosinophilic infiltration in all cases, meeting the criteria for full histologic remission. Notably, these findings underscore that histologic remission can be achieved even in the presence of residual structural changes.

Study limitations must be acknowledged, primarily the small sample size, the observational nature of the report, and the relatively brief follow-up period. Although these preliminary findings are promising, large-scale, long-term prospective studies in pediatric cohorts are warranted to establish the sustained efficacy and safety profile of dupilumab in this clinical setting.

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