

Brief Report

Orodispersible Budesonide Tablets in Pediatric Patients with Eosinophilic Esophagitis—A Viennese Experience

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Abstract

Background: Orodispersible budesonide tablets (OBTs, Jorveza) are approved by the EMA as a therapy option in eosinophilic esophagitis (EoE) in adults. However, data on their use in pediatric patients remain limited and no approved pediatric OBT formulation is currently available in Europe. Therefore, real-world data on off-label use of OBTs in children is needed. **Methods:** We retrospectively analyzed data on the off-label use of OBTs in eight children (five girls) at a median age of 10.5 years (ranging from 5 to 14). Clinical, histological and safety outcomes were assessed descriptively. **Results:** Treatment with OBTs was associated with clinical improvement and a reduction in eosinophil counts. Specifically, the median eosinophil count decreased from 38.5 (ranging from 20 to 100) to 0 (ranging from 0 to 20) eosinophils per high-power field. Histological remission, defined as <15 eosinophils per high-power field, was achieved in six of eight patients (75%). Clinical remission was reached in seven of eight patients (87.5%). No severe side effects could be detected. **Conclusions:** OBTs showed promising clinical and histological responses in this small retrospective pediatric case series. However, larger prospective studies are required before efficacy and safety can be established. Further clinical studies are needed to assess whether OBTs could become an approved pediatric therapy.

Keywords: pediatric; eosinophilic esophagitis; therapy; budesonide

1. Introduction

Eosinophilic esophagitis (EoE) is defined as an immune-mediated chronic inflammatory disease that affects the esophagus and is frequently associated with other atopic diseases, such as IgE-mediated food allergy, allergic rhinitis, asthma and atopic dermatitis [1]. EoE is not primarily driven by IgE-mediated inflammation; however, Th2-lymphocytes are postulated as a mediator [2]. The Th2-lymphocyte pathway is potentially activated as a response to dietary food and aeroallergen presentation in the esophageal tissue and sends signals such as thymic stromal lymphopoietin and interleukin-33, and induces allergic cytokines such as Il-5- or Il-13, which leads to the recruitment of eosinophil cells and mast cells [3].

Histopathologic diagnostic criteria are defined by ≥ 15 eosinophils per high-power field (standardized to a field size of 0.27 mm²) in esophageal tissue and the exclusion of other disorders with similar presentation [4,5]. The incidence of EoE in children was



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reported to be 6.6 cases/100,000 persons each year. Despite various definitions of EoE, rising incidence and prevalence rates are detected globally. Besides its increasing frequency, it has relevant public health implications, especially in the pediatric population. Children require long-term-treatment, concomitant endoscopy monitoring and dietary restrictions, oftentimes leading to psychosocial burden and limitations in social participation [6,7]. In pediatrics, clinical presentations are typically age-dependent, and symptoms differ in younger children and adolescents [8]. Infants and toddlers are more likely to present with symptoms such as failure to thrive, vomiting or feeding difficulties. Older children or adults more commonly present with abdominal pain, dysphagia, food impaction, chest pain, heartburn or anorexia [9,10].

For immune modulation, corticosteroids, especially budesonide as immunosuppressive local therapy, are widely used [11]. In adults, orodispersible budesonide in tablet form (Jorveza) was recently approved by the EMA and Australia for EoE due to its safety and efficacy in inducing and maintaining remission. Currently, there is no approved therapy for EoE in pediatric patients in Europe, resulting in either off-label use of Jorveza or self-made-formulations of budesonide suspensions. Swallowed topical corticosteroids in the form of self-made-formulations have been previously studied in pediatric EoE, but evidence regarding the off-label use of commercially manufactured OBTs in pediatric EoE remains limited [7].

The aim of this study was to report our single-center experience in the usage of OBTs in a case series of pediatric patients with EoE.

2. Results

Between January 2020 and December 2024, we diagnosed EoE in 23 children: 17 patients underwent endoscopy for EoE-specific symptoms (dysphagia, failure to thrive, GERD, nausea, abdominal pain), and six children had symptoms potentially compatible with EoE. However, endoscopy was primarily performed due to other clinical indications rather than suspected EoE. Of these 23, 15 were managed and followed outside our center and were therefore excluded from outcome analyses, leaving eight children for in-house longitudinal evaluation.

Therapy with OBTs was started in these eight children, five female (62.5%) and three male (37.5%). Their median age of diagnosis of EoE was 10.5 years, ranging between 5 and 14 years (Table 1). Four children presented with major symptoms typical for EoE. The primary indications for endoscopy in the other four patients with symptoms potentially compatible with EoE were biliary atresia (after Kasai's procedure), ulcerative colitis, celiac disease, and being post-liver-transplantation for metabolic disease, each in one patient (Table 1). For classification, GERD (as mentioned under symptoms) was defined as heartburn/retrosteral burning, acid regurgitation, or chest/epigastric pain, as recorded in the clinical notes. In younger children, feeding refusal, irritability with feeds, or back-arching documented as reflux-related by the clinician were counted as GERD symptoms.

A history of allergies was reported in three patients and one patient had a history of atopic dermatitis. All patients had additional proton-pump-inhibitor therapy (esomeprazole) at a dose of 1 mg/kg/day, and six patients underwent a prior trial therapy with a six-food-exclusion diet. The mean follow-up time in our patient cohort was 3.0 ± 1.5 years (Table 1).

Table 1. Demographic and clinical characteristics of the studied case series.

Patient	Gender	Age of Manifestation (Years)	Age of Initial OBT Intake (Years)	Follow-Up Duration (Years)	Allergy History	Symptoms Pre-OBTs
ID 1	f	7	14	4.8	no	GERD
ID 2	m	9	10	2.6	no	GERD
ID 3	f	10	14	4.4	yes	GERD
ID 4	f	2	5	2.1	no	GERD
ID 5	m	6	6	4.4	yes	GERD *
ID 6	m	11	11	0.9	yes	Diarrhea #
ID 7	f	11	12	3.6	no	GERD +
ID 8	f	5	6	1.3	no	Abdominal pain –

OBTs: orodispersible budesonide tablets. Primary diagnosis: * biliary atresia, # ulcerative colitis, + post-liver-transplantation, – celiac disease.

Orodispersible Budesonide Tablets (Jorveza)

Therapy with OBTs was started at a median age of 10.5 years, ranging between 5 and 14 years (Table 1). Patients under 11 years were started on Jorveza® (Dr. Falk Pharma GmbH, Freiburg, Germany) with 1 mg tablets once daily, while patients above 11 years on Jorveza® received 1 mg tablets twice daily for 8 to 12 weeks. After 8–12 weeks of treatment with OBTs (depending on endoscopy availability and patient scheduling) endoscopic reassessment was performed and OBTs were either continued or stopped depending on the therapy response, according to the current guidelines at the time [12].

Histological remission was achieved in six of eight patients. As shown in Table 2, peak eosinophil counts were 42.4 (± 24.3) cells per high-power field before and 6.1 (± 8.7) per high-power field after initial therapy with OBTs, resulting in a marked reduction. Adverse effects were screened by chart review and physical examination with a focus on oral candidiasis. To screen for potential adrenal suppression, we additionally reviewed longitudinal growth data before, during and after therapy. No clinically apparent adverse effects (such as oral candidiasis or growth delay) were identified during follow-up. However, biochemical assessment of adrenal function was not performed.

Table 2. Demographic and clinical characteristics of the studied case series.

Patient	Peak Eosinophil Count Pre-OBTs	Peak Eosinophil Count Post-(1st) OBTs	Treatment Cycles of Budesonide Dosage *	Therapy Escalation to Biologicals
ID 1	30	17	2	no
ID 2	20	0	2	no
ID 3	40	0	2	no
ID 4	40	12	2	yes
ID 5	40	20	3	no
ID 6	37	0	1	no
ID 7	32	0	1	no
ID 8	100	0	1	no

OBTs: orodispersible budesonide tablets; * 1 mg/day in children <11 years and 2 mg/day in children ≥ 11 years and adolescents.

In all eight children, longitudinal data on serial height measurements was available. Across the cohort, the median overall height velocity was 4.2 cm/year, ranging from 0.2 to 8.0 cm/year. Among younger children still experiencing active linear growth during follow-

up, overall height velocity ranged from 5.2 to 8.0 cm/year. Lower height velocities were mainly observed in older children and adolescents, several of whom were approaching or had reached their final height during the observation period. No consistent progressive growth deceleration pattern could be identified in the available data.

For descriptive purposes, patients' disease courses were clustered post hoc into three different groups. These categories were not prespecified and do not represent validated clinical response definitions. Patients 6, 7 and 8 were "primary responders" to OBT treatment, reaching remission without further recurrence. Patients 1, 2, 3 and 5 were classified as "maintenance-therapy-required", requiring additional cycle(s) or continued treatment with OBTs after initial endoscopy until reaching remission. Patient 4 was a "non-responder" who had recurrent relapses despite multiple cycles due to structuring disease and had to be switched to further therapy with Dupilimumab. Our escalation beyond topical corticosteroids was guided by a composite of endoscopic findings (such as strictures), ongoing clinical symptoms and histologic activity. Patient 4 was switched to Dupilimumab due to notably endoscopic worsening (strictures), irrespective of eosinophil count trends.

Regarding combination therapy, no patient was on a concurrent six-food-elimination diet during index budesonide induction, and no other therapies such as biologicals were used during budesonide treatment.

3. Discussion

In this study, off-label use of orodispersible budesonide tablets (Jorveza) resulted in clinical improvement to complete absence of symptoms in seven out of eight patients, and in reduced eosinophil count in six out of eight pediatric patients with EoE without major adverse effects.

These findings are broadly consistent with adult studies showing that orodispersible budesonide tablets can reduce symptoms and induce histological and clinical remission in patients with EoE. However, results from adult populations should be interpreted cautiously when extrapolated to children. About 75% of adult patients receiving OBTs reached persistent remission compared to less than 5% of patients in the placebo group [13]. About 60% of adult patients achieved remission within 6 weeks [14,15]. In adults, symptoms reoccurred in 1/5 patients after OBT therapy [14,16]. Although half of the children in our cohort developed histologic relapses, none of them experienced clinical symptoms after initial induction therapy. In our case series only one patient was clinically resistant to OBT therapy and was subsequently switched to Dupilimumab as escalation therapy [17,18]. With regard to safety, we found no adverse events in this study, in good agreement with the less than 10% incidence of fungal infections (the most frequently reported side effect) in adult studies of OBTs in EoE [19].

Current data in the adult population shows a better quality of life and reduced dysphagia symptoms, as well as the induction of histologic and endoscopic remission [20]. Recent adult studies also showed a superiority of OBTs in comparison to oral suspensions of budesonide [21,22]. However, there is currently no available pediatric data on OBTs, as pediatric studies on budesonide have exclusively investigated oral viscous suspensions [7,23].

In rare diseases, such as EoE, the pharmaceutical industry is less likely to invest in developing treatments, particularly for the pediatric population [24]. Therefore, despite the significant clinical and financial burden of EoE, only a few clinical trials have been conducted, and there is currently only one pediatric medication approved (the oral suspension EOHILIA in the US) [25]. Nevertheless, children need effective and safe medications to treat often severely debilitating EoE. Approval by the EMA reflects an evaluation of a

medicine's quality, safety and efficacy within the approved indication. Therefore, OBTs may represent an alternative formulation but they require further pediatric evaluation.

However, uncontrolled off-label use impedes the creation of reliable evidence and may expose children to increased risks, as dosage recommendations for OBTs are extrapolated from adult experience without evidence on pediatric efficacy and harm [26]. The compilation of observational data with objective outcomes (such as the histological effects reported in our single-center study) represents a feasible alternative for evidence generation. Ultimately, the integration of this data into meta-analyses might allow so-called "bibliographic applications" in rare diseases that cover the clinical aspects of the drug relevant for market authorization "<https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng>" (accessed on 9 March 2025)".

Limitations

The small sample size of eight pediatric patients as a highly selected tertiary-care population represents a major limitation of this study and precludes robust inferential statistical analysis. It is susceptible to selection bias because longitudinal follow-up data were available for only 8 of 23 patients due to follow-up taking place at their referring institutions. Consequently, comparisons between included and excluded patients were not possible. Secondly, the cohort was clinically heterogeneous, including concomitant PPI use, prior six-food-elimination diet trials and several relevant comorbidities (including patients with biliary atresia, ulcerative colitis and those who were post-liver-transplantation), which may influence clinical and histological outcomes. The underlying comorbidities reflect the complexity of patients managed at a tertiary referral center. However, all patients fulfilled the diagnostic criteria for eosinophilic esophagitis and received the same treatment protocol; therefore, they were analyzed as a single exploratory cohort. Due to the small sample size, subgroup analyses according to comorbidities were not feasible. Therefore, the potential influence of individual comorbidities cannot be determined and findings should be interpreted with appropriate caution. Third, regarding safety outcomes, we monitored for oral candidiasis and screened for adrenal suppression via growth data, but did not perform biochemical testing (e.g., morning cortisol/ACTH stimulation).

4. Materials and Methods

4.1. Population

At the outpatient clinic of the Division of Pediatric Nephrology and Gastroenterology, Medical University of Vienna, a retrospective chart review was performed to identify all children and adolescents with histologically proven diagnosis of EoE who were started on OBT therapy. Histopathological diagnosis of EoE was defined as ≥ 15 eosinophils per high-power field in esophageal tissue in 6 biopsies in 3 different locations (distal esophagus, middle and proximal esophagus) by the histopathology department of our institution as part of routine clinical care. Clinical symptoms were retrospectively extracted from routine clinical documentation and subsequently classified using a predefined symptom score (Pediatric Eosinophilic Esophagitis Symptom Scores) [27]. Clinical remission was defined as the absence of documented EoE-related symptoms during follow-up.

Histological relapse or persistent EoE was defined as ≥ 15 eosinophils per high-power field in esophageal tissue in the follow-up endoscopies, and therefore histological remission was defined as < 15 eosinophils per high-power field. Overall, relapse was considered present if histologic criteria were met.

Patients were excluded when only the index endoscopy was performed at our hospital, since our center serves as a tertiary pediatric endoscopy unit and receives referrals from

other hospitals in Vienna, with patients returning to their referring institution for further treatment and follow-up.

In these patients, the following demographics and clinical variables were collected: gender, age of disease manifestation, additional diagnoses, history of allergy or atopic dermatitis and prior therapies such as exclusion diet or proton-pump-inhibitor therapy, symptoms and endoscopic results at onset of disease and during further course, therapy start date, dose and times of OBTs, adherence to recommended therapies and need for escalation to further therapies.

Parameters on efficacy and adverse effects of OBTs were independently double-checked by 2 authors (B.B.-F., R.E.). Therapy response was assessed by clinical symptoms; relapse—yes or no; and eosinophil cell count in biopsy material. Data regarding adverse events was assessed by general data review, focusing on physical examination regarding oral candidiasis and growth percentiles.

We reviewed growth charts, and interval-specific and overall height velocity (between appointments and overall over available observation period) were calculated for each child with available serial height measurements. It was defined as the annualized change in height between two measurements ($\text{height velocity} = \Delta \text{height in cm} / \Delta \text{time in years}$).

4.2. Statistics

Statistical analysis and graphical illustration was performed using IBM SPSS V.24.0.0.0 2016 (SPSS, Inc., Chicago, IL, USA). No formal inferential statistical testing was performed. Data is presented descriptively.

Categorical data was summarized using absolute and relative frequencies. Continuous data was summarized using median and range, or mean and standard deviation (SD), as appropriate.

4.3. Ethics

Our local ethics committee at the Medical University of Vienna approved this study on 19 February 2025 (EK-NR: 2398/2024). The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in a prior approval by the institution's human research committee. All authors mentioned had access to the study data, and reviewed and approved the final manuscript. The need for written informed consent for data collection and analysis was waived due to the retrospective design of the study.

5. Conclusions

In conclusion, we report that the treatment of children with EoE with orodispersible budesonide tablets (Jorveza) suggests potential efficacy and acceptable short-term safety in a small Viennese pediatric cohort. Further systematic studies with a higher number of patients are necessary to compare the use of orodispersible budesonide tablets with a placebo and/or other off-label drugs used to treat EoE in pediatric populations.

Author Contributions: R.E. and C.A. designed the study; R.E., C.A. and B.B.-F. performed the research and analyzed the data; R.E. wrote the paper; J.P., C.A., B.B.-F., A.H. and W.-D.H. reviewed and edited it. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and was approved by the ethics committee of the Medical University of Vienna on 19 February 2025 (EK-NR: 2398/2024).

Informed Consent Statement: The requirement for written informed consent was waived due to the retrospective nature of the study and the use of anonymized/de-identified data.

Data Availability Statement: The data used and analyzed in this study are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

OBT Orodispersible budesonide tablets

EoE Eosinophilic Esophagitis

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