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Disease Progression and Outcomes of Pregnancies in Women With Eosinophilic Esophagitis

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3 **Title:** Disease Progression and Outcomes of Pregnancies in Women With Eosinophilic  
4 Esophagitis

5 Short title: Eosinophilic esophagitis and pregnancy

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20 **Abbreviations:**

21 EoE: Eosinophilic esophagitis

22 Eos/hpf: Eosinophils per high power field

23 PPI: Proton pump inhibitors

24 Th1/2: T-helper cell ½

25

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44 **Abstract:**

45 **Background & Aims:** Eosinophilic esophagitis (EoE) most often affects young patients of  
46 reproductive age, yet little is known about its effects during pregnancy. We examined the  
47 course of EoE during pregnancy, outcomes of pregnancies, and patient concerns related to  
48 pregnancy and EoE.

49

50 **Methods:** We sent a survey that queried demographic and disease-specific characteristics as  
51 well as pregnancy-related topics to all 151 female patients treated at 2 EoE centers in  
52 Switzerland. We analyzed cross-sectional survey data.

53

54 **Results:** Of 72 patients that returned the survey, we identified 20 patients that had at least 1  
55 pregnancy and analyzed the data on 34 pregnancies. During pregnancy, improvement of  
56 dysphagia was reported in 56% (19/34) of all pregnancies, whereas deterioration was reported  
57 in 20% (7/34) of all pregnancies. After delivery, dysphagia returned to the pre-pregnancy  
58 level in 68% (13/19) of all pregnancies for patients with improvement of dysphagia and 57%  
59 (4/7) of all pregnancies for patients with deterioration of dysphagia during pregnancy.  
60 Esophagogastroduodenoscopy during pregnancy was required in less than 10% (3/34) of all  
61 pregnancies. Pregnancy-related complications occurred in 12% of pregnancies (4/34). The  
62 leading patient-reported concerns were fear of heritability (40% of patients, 8/20) and  
63 concerns of that use of medication would harm the fetus (30% of patients, 6/20).

64

65 **Conclusions:** Pregnancy affects the course of EoE, with improvement of symptoms reported  
66 in most patients. Dysphagia returned to the pre-pregnancy level following delivery. EoE has  
67 likely no negative effects on outcomes of pregnancies.

68

69 **KEY WORDS:** esophagus, prenatal, neonate, chronic inflammatory disease

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## 71 **Introduction**

72 Eosinophilic Esophagitis (EoE) is a chronic immune-mediated disease of the esophagus  
73 characterized clinically by symptoms of esophageal dysfunction and histologically by an  
74 eosinophil predominant inflammation.<sup>1</sup> Because the peak incidence of this disease is among  
75 those between 20 and 30 years of age, female patients are often diagnosed and live with this  
76 condition during their reproductive age.<sup>1</sup>

77 Since EoE has a Th2-type inflammatory pattern<sup>2</sup> and may be considered as “asthma or  
78 atopic dermatitis of the esophagus”, its disease course during pregnancy might follow the one-  
79 third rule: disease ameliorates in a third of patients, disease deteriorates in a third of patients,  
80 and disease remain unchanged in a third of patients as in asthma<sup>3</sup>; or that the disease might  
81 deteriorate in the majority of patients as in atopic dermatitis.<sup>4</sup> It is generally considered that  
82 these allergic and autoimmune diseases course alterations during pregnancy occur as a result  
83 of down-regulation of Th1 cells and the up-regulation of Th2 cells,<sup>5,6</sup> as high concentrations  
84 of Th1- and Th17-type cytokines may have deleterious effects on outcome of pregnancy.<sup>7,8</sup>  
85 In general, patients with chronic diseases may have unique challenges and concerns during  
86 pregnancy.<sup>9</sup> From EoE patients’ perspective, it is important to know whether this condition  
87 has any consequences for a planned pregnancy.

88 To date, the data on pregnancy in EoE are extremely limited, with a single case series of  
89 four pregnant women in EoE published by Burk *et al.*<sup>10</sup> The aim of this study was three-fold:  
90 to investigate the clinical course of EoE during pregnancy, to analyze the outcome of the  
91 pregnancies in patients with EoE, and to explore the disease-specific concerns female EoE  
92 patients might have had before pregnancies.

## 93 **Methods**

94 We conducted a cross-sectional questionnaire-based study in all female EoE patients treated  
95 at EoE Clinics in Olten and Zurich, Switzerland. Diagnosis of EoE was established based on  
96 the following criteria: clinically, based on presence of symptoms of esophageal dysfunction  
97 and histologically, based on esophageal peak eosinophilia of  $\geq 15$  eosinophils per high-power  
98 field (eos/hpf) in at least one biopsy specimen of the esophagus.<sup>11</sup> Other conditions leading to  
99 esophageal eosinophilia were excluded. We developed a German language-based survey that  
100 queries the number of pregnancies, pregnancy complications (premature birth, miscarriage,  
101 gestational diabetes, high blood pressure, or other complications), mode of delivery, EoE-  
102 specific pregnancy-related concerns (fear of heritability, fear of harming the unborn due to  
103 medication use, fear of EoE negatively impacting the course of pregnancy, fear of EoE  
104 deterioration, or other concerns), the presence of EoE symptoms including dysphagia during  
105 pregnancy and following delivery as well as change in EoE symptom severity (improvement  
106 or deterioration) in percent (10-30%, 31-50%, 51-70%, 71-100%) following the delivery  
107 compared to symptom severity during pregnancy, any EoE-related complication during  
108 pregnancy, the need of esophagogastroduodenoscopy during pregnancy, and the medication  
109 use and dose during pregnancy. Demographic and disease-specific data, such as age at the  
110 time of study enrollment, age at first manifestation and diagnosis of EoE, concurrent allergic  
111 diseases, and history of bolus impaction were also collected. The survey was sent and  
112 returned by post.

113 All statistical analyses were performed using the GraphPad Prism 5.0 (GraphPad Software,  
114 Inc., Sand Diego, CA). Quantitative data distribution was analyzed using Normal-QQ-Plots.  
115 Results of quantitative data are presented either as median plus interquartile ranges (for data  
116 with non-Gaussian distribution) or mean  $\pm$  SD and range (for normally distributed data).  
117 Categorical data were summarized as the percentage of the group total. For quantitative data,

118 differences in distribution between two groups were evaluated using either the Wilcoxon-  
119 Mann-Whitney rank test (for data with non-Gaussian distribution) or the Student's t-test (for  
120 normally-distributed data). For categorical outcomes, differences in observed frequencies  
121 between groups were compared using the chi-squared test, or using the exact Fisher test for  
122 groups with a small number of observations ( $n < 20$ ).

123 The study was approved by the local ethics committee (No. EKNZ 2015-388).

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## 124 **RESULTS**

125 One hundred and fifty one female patients are treated in EoE clinics in Olten and Zurich,  
126 Switzerland. These patients were invited to participate in this study and were send paper-  
127 based survey. Seventy-two patients (48%) returned the survey and were included in this  
128 study. Of 72 enrolled patients, 20 patients had at least one pregnancy after EoE diagnosis. Six  
129 patients (30%) had one pregnancy, whereas 14 patients (70%) had two pregnancies (total of  
130 34 pregnancies) (Figure 1). One patient was pregnant at the time of the survey completion.  
131 The demographic and disease-specific characteristics are shown in Table 1.

132 The course of the dysphagia during pregnancy and after delivery is shown in Figure 2.  
133 Most patients experienced improvement in dysphagia during their pregnancies (56%), a  
134 quarter of patients observed no change in dysphagia, and a fifth experienced worsening of  
135 dysphagia. In patients reporting an improvement of dysphagia, more than half experienced an  
136 improvement by 71-100%, whereas in patients with a deterioration, the majority had only a  
137 deterioration of less than 30%.

138 After delivery, the severity of dysphagia returned to the pre-pregnancy state in the majority  
139 of patients. The median duration of improvement or deterioration in dysphagia severity during  
140 pregnancy was 3.0 months (IQR 0) or 6.0 months (IQR 1 month), respectively. After  
141 pregnancy, an improvement in dysphagia severity occurred after a median of 3.1 month (IQR  
142 3.8 month), whilst a deterioration in dysphagia severity occurred after a median of 2.0 month  
143 (IQR 5.8 month). During pregnancy, three patients (9%) experienced EoE-related  
144 complications requiring esophagogastroduodenoscopy: bolus impactions (n=2), and herpes  
145 simplex esophagitis (n=1).

146 Pregnancy-specific characteristics are shown in Table 2. Complications occurred in four  
147 (12%) of the pregnancies including one miscarriage. At the time point of data analysis, one  
148 patient was still pregnant.

149 In 14 pregnancies (41%), patients did not take any EoE-specific medications. Of the  
150 remaining pregnancies, swallowed topical corticosteroids (STC), proton-pump inhibitors  
151 (PPI), and elimination diet were used in 13 (39%), nine (26%), and two pregnancies (6%),  
152 respectively. The rate of EoE-related complications requiring esophagogastroduodenoscopy  
153 in patients treated with EoE-specific modalities (2/20, 10%) and that in patients that did not  
154 undergo treatment (1/14, 7.1%) did not appear to differ ( $P = ns$ ). Furthermore, the rate of  
155 pregnancy-related complications in patients (who finished their pregnancy) treated with EoE-  
156 specific therapies (1/20, 5.0%) and that in patients without treatment (3/13, 23.1%) did not  
157 appear to differ ( $P = ns$ ).

158 The major concerns reported by patients with prior pregnancy were fear of child inheriting  
159 EoE (40%), and fear of harming the child due to EoE medication use (30%). Only a minority  
160 of patients were concerned about a negative effect of pregnancy on EoE course or vice versa.  
161 Half of the patients (50%) reported no concerns at all (Table 2).

162

**163 DISCUSSION**

164 Eosinophilic esophagitis (EoE) has an increasing prevalence and frequently affects  
165 individuals of child-bearing age. Whilst the study on contribution of genetic and  
166 environmental factors to EoE heritability have recently been carried out,<sup>12</sup> the studies on  
167 impact of a pregnancy on esophageal inflammation and clinical disease course as well as  
168 outcome of pregnancies in EoE patients are scarce. In this survey-based study, we describe  
169 the case series of 20 EoE patients that experienced 34 pregnancies. Our main findings are as  
170 follows: 1) more than half of the EoE patients experienced symptom improvement during  
171 pregnancy; 2) the rate of pregnancy-related complications was low; and 3) major concerns  
172 reported by patients were fear of child inheriting EoE and harming the unborn child due to  
173 EoE medication use.

174 Given that during pregnancy clinical worsening of several autoimmune diseases, such as  
175 asthma and atopic dermatitis, was demonstrated in several studies<sup>3, 4</sup>, we learned with interest  
176 that more than half of the patients (56%) reported a marked improvement in their dysphagia,  
177 whereas only a minority (20%) of patients experienced deterioration of dysphagia severity.  
178 Our data pave way for prospective studies closely examining the alterations in EoE course  
179 during pregnancy as well as mechanistic work aimed to explore whether the pregnancy results  
180 in changes in levels of expression of various cytokines compared to pre/post-pregnancy state.

181 Chronic inflammation might have a negative impact on the outcome of pregnancies, either  
182 as a consequence of the disease activity itself or due to side effects of the treatment. In EoE,  
183 the risks of an uncontrolled disease activity as well as side effects of corticosteroids and  
184 potential nutritional deficits in those adhering to dietary regimens are all grounds for concern  
185 for healthcare professionals taking care of EoE patients. This was not the major concern for  
186 our EoE patients, as only one of the twenty patients feared that EoE might negatively impact  
187 the course of pregnancy. Our data show that the course of the pregnancies and deliveries were  
188 uneventful in almost 90% of all cases. A miscarriage occurred in one patient (3%). Since the

189 miscarriage rate in high-income countries is approximately 10% in young women, it appears  
190 that the prevalence of miscarriage in EoE patients is similar to that observed in the general  
191 population.<sup>13</sup> In addition, the incidence of premature birth (3%) and the rate of placental  
192 abruption (3%) in our study population is similar to that in other northern European countries  
193 (premature birth is observed in approximately 5% of patients, whilst placental abruption is  
194 observed in approximately 1% of patients).<sup>14,15</sup> In summary, we did not document a negative  
195 impact of the underlying EoE on the course and the outcome of the pregnancies.

196 Almost one third of patients had concerns that their medication could have a negative  
197 impact on the outcome of the pregnancy. The only approved medication for treatment of EoE  
198 are swallowed topical corticosteroids (STC), which have a favorable safety profile and  
199 represent the first-line treatment in non-pregnant patients.<sup>16,17,18</sup> Topically-acting  
200 corticosteroids can be safely administered during pregnancy in patients with skin diseases and  
201 asthma.<sup>19,20</sup> However, one must keep in mind that STC are metabolized differently depending  
202 on the mode of application. In our study, three pregnancy-related complications occurred in  
203 patients that did not undergo any treatment (3/13; 21.3%), and one complication (1/20; 5.0%)  
204 occurred in the group undergoing treatment. The one complication in a patient treated with  
205 STC was a herpes esophagitis. However, that was supposed to be unrelated to the medication  
206 and more a surrogate marker for an uncontrolled EoE. In summary, the rate of pregnancy-  
207 related complications was not higher in patients adhering an anti-inflammatory treatment with  
208 STC during pregnancy when compared to that in patients taking no medications for EoE  
209 management.

210 Mode of delivery is an important topic for expectant mothers regardless of whether they  
211 have a chronic disease or not. In Switzerland, caesarean section rate of 33% is one of the  
212 highest worldwide.<sup>14</sup> Our analysis demonstrated that more than 40% of our EoE patients had a  
213 caesarean section. As such, the rate of caesarean section in our population is consistent with  
214 nation-wide rates.

215 Parents affected by chronic diseases often fear of transmitting the disease to their children.  
216 Our data show that almost half of the EoE patients were concerned that the offspring might  
217 inherit the disease. This fear is justified, as the risk for first-degree relatives to be affected  
218 with EoE is about 2.3%.<sup>12</sup> However, the environmental exposures increase the rate of EoE  
219 development to a much greater extent than genetic background.<sup>12</sup> Furthermore, the risk for  
220 transmitting EoE from father to the offspring is at least twice as likely as that from mother to  
221 the offspring. Therefore, we have no reasons to discourage female EoE patients from having  
222 children based on the increased risk of disease inheritance alone.

223 Our study has several limitations. Relatively small number of patients was examined.  
224 However, since the prevalence of EoE is three-fold lower in female than in male patients<sup>1</sup>, it  
225 is difficult to study female patients that are of childbearing age and experienced pregnancy.  
226 Despite the low number, our study represents the largest number of pregnant EoE patients  
227 ever examined. Given the retrospective nature of the study, symptoms were assessed using a  
228 non-validated instrument. We did not collect the age when the women experienced  
229 pregnancy. However, the mean age in our population was not much higher than the mean age  
230 of having children in average population in Switzerland (32 years). In addition, given that  
231 only three patients underwent esophagogastroduodenoscopy for emergency reasons, we could  
232 not examine the relationship between symptom severity and biologic findings. Nevertheless,  
233 given the clinical need and almost complete absence of literature on course of pregnancy in  
234 patients with EoE, these data might be useful for management of these patients.

235 Based on our analysis and on practical experience, we provide the following four  
236 clinical suggestions: 1.) Female EoE patients considering pregnancy should be informed that  
237 to date no increased maternal and fetal risk was observed in pregnant EoE patients on and off  
238 EoE-specific medication; 2.) In patients having inactive disease at the beginning of a  
239 pregnancy, a cessation of the treatment may be considered, provided that the patients undergo

240 regular monitoring of EoE during pregnancy; 3.) In patients with active disease at the  
241 beginning of the pregnancy the treatment should be continued and 4). After delivery, patients  
242 having had an improvement in symptoms during pregnancy must be advised to pay attention  
243 to a worsening of symptoms.

244 In conclusion, our analysis indicates that clinical course of EoE appears to be  
245 favorable in pregnancy. Use of EoE-specific medications during pregnancy appears to be safe,  
246 as we could not detect a higher rate of pregnancy-related complications in patients having an  
247 EoE-specific therapy.

248

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253 There is no conflict of interest for the work under consideration for publication.

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306

**307 Legends:**

308 Figure 1: Flow diagram.

309 Figure 2: Course of dysphagia during and after pregnancy.

310 Table 1: Demographic and disease-specific characteristics of the study population.

311 Table 2: Pregnancy-specific characteristics in patients with EoE.

312

Table 1

	Patients with pregnancy during EoE (n=20)	Patients without pregnancy post EoE diagnosis (n = 52)
Age, y, mean +- SD	39.2 +- 8.7	49.0 +-14.1
Age at first manifestation, y, mean +- SD	18.8 +- 7.1	31.3 +- 16.1
Age at diagnosis, y, mean +- SD	28.2 +- 8.4	39.6 +- 12.9
Diagnostic delay, y, mean +- SD	9.4 +- 9.4	10.1 +- 10.4
Concurrent allergic diseases, n (%)	14 (70)	37 (71)
Bolus impaction in past, n (%)	8 (40)	17 (33)
Desire to have children, n (%)	19 (95)	12 (23)
Number of pregnancies, n (%)		
1	6 (30)	4 *
2	14 (70)	0

Demographic and disease-specific characteristics of the study population

\* Pregnancy before EoE diagnosis

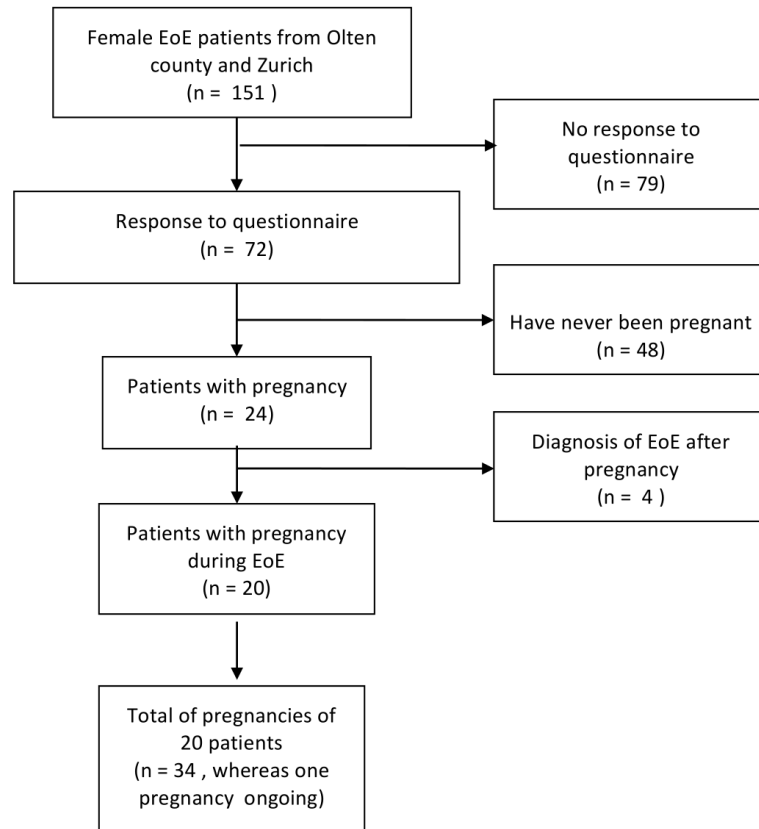


Table 2

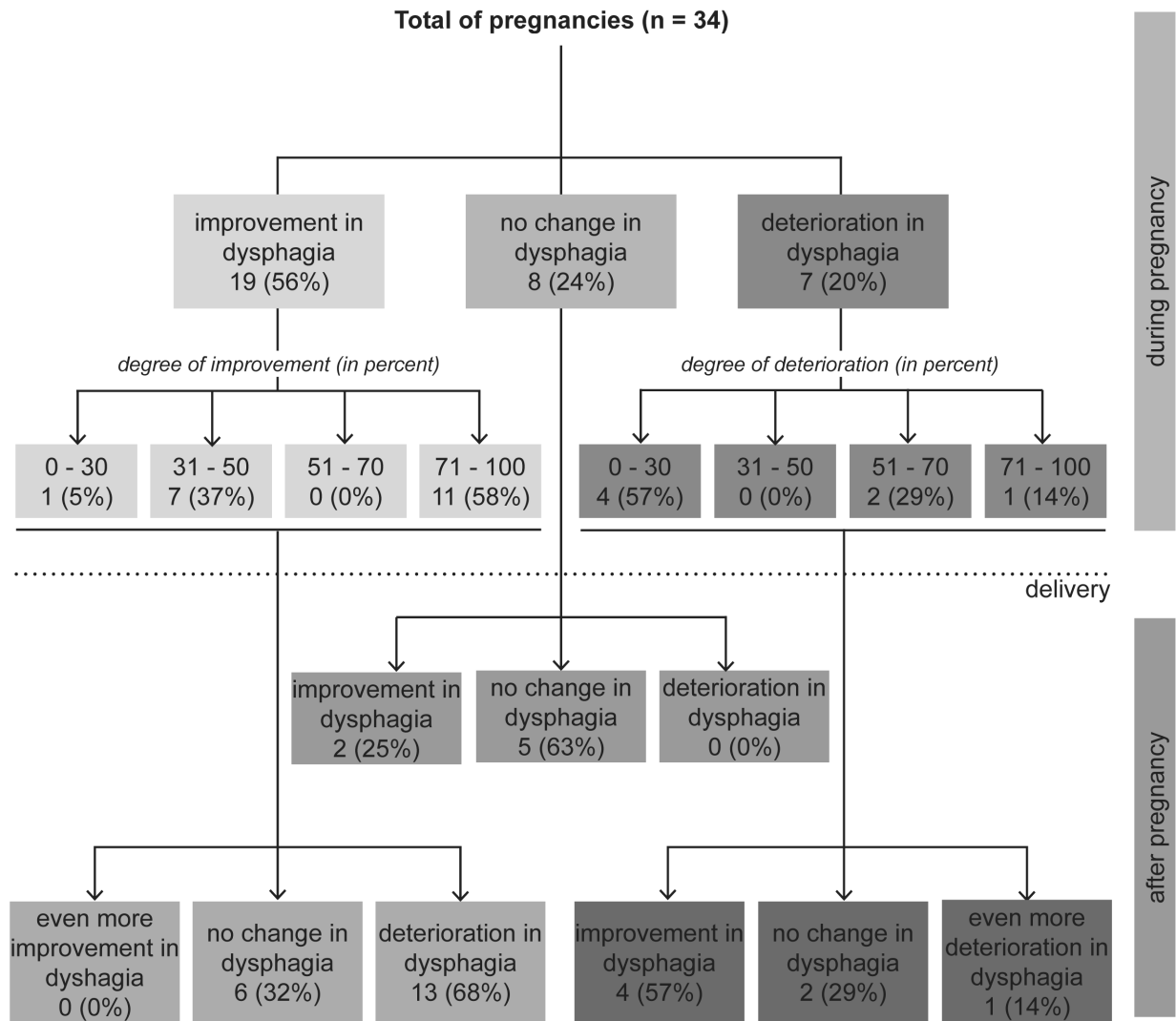
<b>Number of Patients having Concerns regarding Pregnancy (%)</b> (duplicates counted)	
None, n (%)	10/20 (50)
Heritability, n (%)	8/20 (40)
Fear of harming the child due to medication, n (%)	6/20 (30)
<b>Fear of EoE negatively impacting the course of pregnancy, n (%)</b>	1/20 (5)
Fear of EoE deterioration, n (%)	1/20 (5)
<b>Number of Patients having Contact with Medical-Persons during Pregnancy because of EoE (%)</b>	
Gastroenterologist	5/20 (25)
Gynecologist	3/20 (15)
None	12/20 (60)
<b>Number of Pregnancies requiring Treatment for EoE during Pregnancy (%) (duplicates counted)</b>	
None	14/34 (41)
Steroids	13/34 (39)
PPI	9/34 (26)
Elimination Diet	2/34 (6)
<b>Number of Pregnancy-Complication (%)</b>	
<b>Total</b>	4/33 (12)
Miscarriage	1/33 (3)
Premature Birth	1/33 (3)
Placental Abruption	1/33 (3)
Unknown	1/33 (3)
<b>Mode of delivery (%)</b>	
Vaginal delivery	19/33 (58%)
Caesarean section	14/33 (42%)

Pregnancy-specific characteristics in patients with EoE

Figure 1



Flow diagram



## **What you need to know**

### **Need to Know**

Background: Eosinophilic esophagitis (EoE) most often affects young patients of reproductive age, yet little is known about its effects during pregnancy.

Findings: Pregnancy affects the course of EoE, with improvement of symptoms reported in most patients. Dysphagia returned to the pre-pregnancy level following delivery.

Implications for patient care: EoE has likely no negative effects on outcomes of pregnancies.