2022

BSG/ BSPGHAN Guidelines

Together we *know more.*
Together we *do more.*

KEoEPING UP TO DATE WITH THE LATEST GUIDELINES

British Society of Gastroenterology/British Society of Paediatric Gastroenterology, Hepatology and Nutrition consensus on the diagnosis and management of eosinophilic oesophagitis in adults[1]

Eosinophilic oesophagitis (EoE) is an increasingly common cause of dysphagia, as well as one of the most prevalent oesophageal diseases with a significant impact on physical health and quality of life.[1]

Given EoE is a disease that most physicians are not familiar with, it comes as no surprise that there is considerable variability in its investigation and treatment across the UK.[2,3]

With recent advancements in managing the condition, the BSG has recently published guidelines providing a practical and evidence-based guide to diagnosing and managing EoE.[1]

Specifically, the aims were to:[1]

Introduce
new diagnostic criteria and promote consistency in pathology reporting

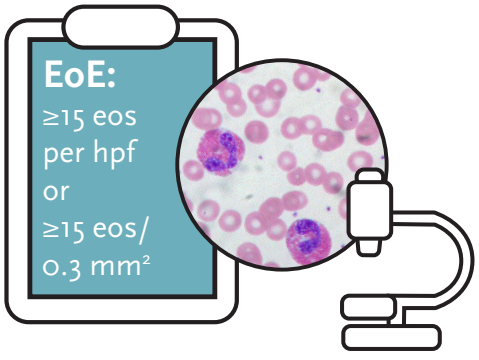
Review and standardise
the diagnosis, treatment and follow-up of patients

Summarise
the optimal management, identify knowledge gaps and set out research priorities

Definition[1]

EoE is an oesophageal disease characterised by symptoms related to oesophageal dysfunction and eosinophil predominant mucosal inflammation.

Since most laboratories are moving to digital optical microscopy, the definition of EoE has been expanded in the current guidelines.



You can read the BSG/BSPGHAN guidelines in their entirety by scanning this QR code

Prescribing information can be found on the back cover

Clinical presentation and diagnosis[1]

Elective setting

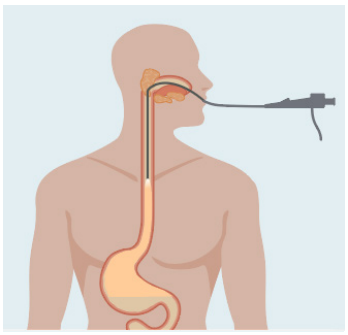
In adults, dysphagia is strongly associated with a diagnosis of eosinophilic oesophagitis

Symptoms suggestive of EoE

- Does the patient have a feeling of food sticking in the chest after swallowing?
- Do they modify how they eat, for example, drinking a lot of fluid to wash food down?
- Are they often the last to finish at mealtimes, chewing their food very thoroughly?
- Do they avoid eating certain foods, worried that they may get stuck completely?
- Have they had self-resolving food bolus obstructions?

While symptoms point to EoE, it can only be confirmed histologically

- Refer patients for a diagnostic OGD
- ≥6 biopsies should be taken from different anatomical sites in the oesophagus
- EoE is diagnosed if the peak eosinophil count is ≥15 /0.3 mm^2
- For an accurate diagnosis, PPIs should be withdrawn for ≥3 weeks prior to biopsy

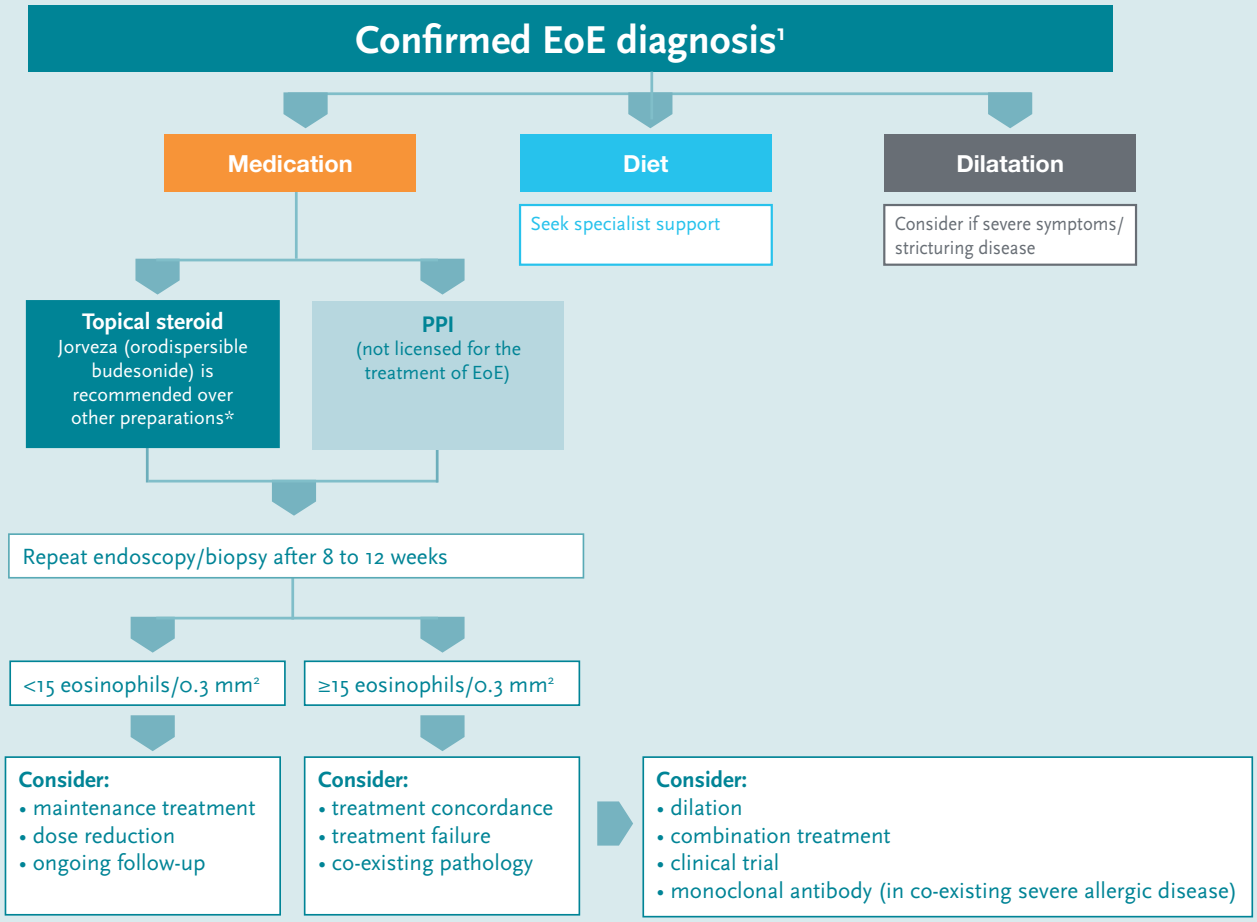


Emergency setting

In adults, food bolus obstruction is strongly associated with a diagnosis of eosinophilic oesophagitis

- Strongly consider EoE in all adult patients with an FBO
- Make an urgent referral to gastroenterology for a therapeutic OGD
- Take ≥6 biopsies at two levels at the index endoscopy
- Book the patient for an endoscopy/outpatient review if the FBO resolves spontaneously

Treatment



*Data from the Jorveza phase III induction study suggest prolongation of Jorveza therapy to 12 weeks is beneficial to bring more patients into clinico-histologic remission[4]

The BSG recommend Jorveza (orodispersible budesonide) over other steroid formulations for both the induction and maintenance of remission in adults with EoE[1]

Recommended Jorveza dosing

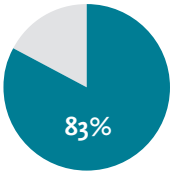
Induction	Maintenance
1 mg bd	0.5 or 1 mg bd

85% of Jorveza 1 mg bd patients achieved clinical and histological remission within 12 weeks; over the course of 3 years, Jorveza 0.5 mg bd maintained disease control in the majority of patients[4,5]

Patients completing the double-blind, 48-week Jorveza study could continue with an open-label extension for a further 96 weeks[5]

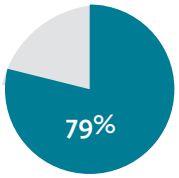
Efficacy maintained at the end of up to 3 years Jorveza treatment:[5]

Clinical remission
(EEsAI-Pro ≤20)



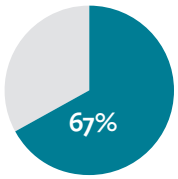
n=166

Deep histologic remission
(Peak eos in all biopsies: 0/hpf)



n=146

Total EREFS of 0
(Grade 0 for oedema, rings, exudate, furrows & stricture)



n=82

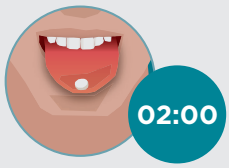
Patients' global satisfaction at the end of DB & OLE treatment (n=166)[1]

Extremely satisfied:	77.7%
Satisfied:	19.9%
Neither satisfied nor dissatisfied:	0.6%

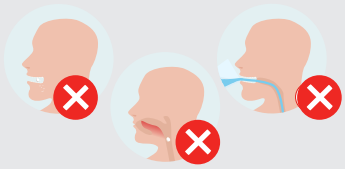
How to take Jorveza

Jorveza is placed on the tip of the tongue, then gently pressed against the roof of the mouth while it dissolves.

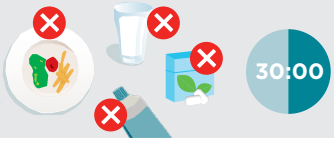
It should take about 2 minutes for the Jorveza tablet to dissolve completely.



Jorveza should not be chewed, or swallowed undissolved, or taken with liquid.



It's very important that patients give Jorveza time to work. So, at the very least, they should leave 30 minutes before eating, drinking, cleaning teeth or chewing gum.



It may help if patients take Jorveza after they have had breakfast and brushed their teeth in the morning and very last thing at night, just as they go to bed. That way Jorveza will stay in contact with the oesophagus for as long as possible.

See an animation on how to take Jorveza here

Recommended dosing

Induction	Maintenance
1 mg bd	0.5 or 1 mg bd

Prescribing Information (refer to full SmPC before prescribing).
Presentations: Jorveza 1mg and 0.5mg orodispersible tablets containing 1mg or 0.5mg of budesonide. **Indications:** treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age). **Dosage:** Induction of remission: one 1mg tablet taken twice daily (morning and evening) after a meal and immediately after removal of the tablet from the blister pack. Usual duration of induction treatment is 6 weeks. Extend up to 12 weeks for non-responding patients. Maintenance of remission: 0.5mg twice daily or 1mg twice daily depending on clinical need. A maintenance dose of 1mg twice daily is recommended for patients with long-standing disease history and/or high extent of esophageal inflammation in the acute disease state. Duration of maintenance treatment - to be determined by the treating physician. Administration: tablet is placed on tip of tongue and pressed to top of mouth then swallowed slowly without liquid or food and without chewing or swallowing undisintegrated. May take 2 to 20 minutes to disintegrate and swallow completely. Wait at least 30 minutes before eating, drinking or performing oral hygiene. **Contra-indications:** hypersensitivity to budesonide or any ingredient of the tablets. **Warnings/ precautions:** infections - Suppression of inflammatory response and immune function increases susceptibility to infections and their severity which can be atypical or masked. Oral, oropharyngeal and esophageal candida infections occur at high frequency. Treat symptoms with topical or systemic anti-fungals. Jorveza treatment can continue. Chickenpox, herpes zoster and measles - can be more serious in patients treated with glucorticosteroids. Check vaccination status. Avoid exposure. Vaccines - avoid co-administration of live vaccines and glucocorticosteroids. The antibody response to other vaccines may be diminished. Special populations - monitor patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataract, family history of glaucoma. Systemic effects of glucocorticosteroids may occur, depending on duration of treatment, concomitant and previous glucocorticosteroid treatment and individual sensitivity. Patients with reduced liver function - an increased systemic availability of budesonide may be expected, with increased risk of adverse reactions. Patients with hepatic impairment should not be treated. Not recommended for use in patients with severe renal impairment. Angioedema - treatment should be stopped if signs of angioedema are observed. Visual disturbance - patients with blurred vision or other visual disturbances should be considered for referral to an ophthalmologist. Causes may include cataract, glaucoma or central serous chorioretinopathy resulting from corticosteroid use. Others - glucocorticosteroids may cause suppression of the hypothalamic–pituitary–adrenal (HPA) axis and reduce the stress response. When patients are subject to surgery or other stresses, supplementary systemic glucocorticosteroid treatment is therefore recommended. Concomitant treatment with ketoconazole or other CYP3A4 inhibitors should be avoided. Serological testing - adrenal function may be suppressed by budesonide so an ACTH stimulation test for diagnosing pituitary insufficiency might show false (low) results. Sodium - contains 52 mg of sodium per daily dose. **Interactions:** CYP3A4 inhibitors - concomitant treatment with ketoconazole or other potent CYP3A inhibitors including grapefruit juice should be avoided to reduce the risk of systemic side effects unless the benefit outweighs the risk. Such treatment should be monitored. Oestrogens, oral contraceptives - may elevate plasma concentrations and enhance effects of glucocorticosteroids. Concomitant intake of low dose combination oral contraceptives has not shown this effect. Cardiac glycosides - action of glycoside can be potentiated by potassium deficiency - a potential and known adverse reaction of glucocorticoids. Saluretics - potassium excretion can be enhanced and hypolalaemia aggravated. Use in pregnancy should be avoided unless there are compelling reasons for therapy. Breast-feeding - budesonide is excreted in human milk. The benefit of breast feeding for the child and the benefit of therapy for the woman should be assessed. Fertility - there are no data on the effect of budesonide on human fertility. **Undesirable effects:** fungal infections in the mouth, pharynx and the oesophagus were the most frequently observed adverse reactions in clinical studies. Long term treatment did not increase the rate. Adverse reactions and frequencies: Very common: esophageal candidiasis, oral and/or oropharyngeal candidiasis, Common: sleep disorder, headache, dysgeusia, dry eyes, gastroesophageal reflux disease, nausea, oral paraesthesia, dyspepsia, upper abdominal pain, dry mouth, glossodynia, tongue disorder, oral herpes, fatigue, blood cortisol decreased. Uncommon: nasopharyngitis, pharyngitis, angioedema, , anxiety, agitation, dizziness, , hypertension, cough, dry throat, oropharyngeal pain, abdominal pain, abdominal distension, , dysphagia, erosive gastritis, gastric ulcer, lip edema, gingival pain, rash, urticaria, sensation of foreign body, osteocalcin decreased, weight increased. . Other (class) effects with unknown frequency that may occur: increased risk of infection, Cushing's syndrome, adrenal suppression, growth retardation in children, hypokalaemia, hyperglycaemia, depression, irritability, euphoria, psychomotor hyperactivity, aggression, pseudotumor cerebri including papilloedema in adolescents, glaucoma, cataract (including subcapsular cataract), blurred vision, central serous chorioretinopathy (CSCR), increased risk of thrombosis, vasculitis (withdrawal syndrome after long-term therapy), duodenal ulcers, pancreatitis, constipation, allergic exanthema, petechiae, delayed wound healing, contact dermatitis, ecchymosis, muscle and joint pain, muscle weakness and twitching, osteoporosis, osteonecrosis, malaise. **Legal category:** POM. **Cost:** 1mg - pack of 90 - £323; 0.5mg - pack of 60 - £214.80. Not currently available in Ireland. **Product licence holder:** Dr. Falk Pharma GmbH. **Product licence number:** IE/NI: 1mg: EU/1/17/1254/004, 0.5mg: EU/1/17/1254/008. GB: 1mg: PLGB08637/0030; 0.5mg: PLGB08637/0032. **Date of preparation:** February 2023.

Further information is available on request.

Adverse events should be reported. In the UK visit www.mhra.gov.uk/yellowcard. In Ireland: https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form. Adverse events should also be reported to Dr Falk Pharma UK Ltd on pv@drfalkpharma.co.uk or 0044 (0)1628 536600.

References:
1. Dhar A *et al*. Gut 2022; doi: 10.1136/gutjnl-2022-327326.
2. Pham KE. J Gastrointestinal Dig System 2019; 9(3): 598.
3. Shillitoe B *et al*. Frontline Gastroenterol 2021; 13(3): 231-6.
4. Lucendo AJ *et al*. Gastroenterology 2019; 157:74-86.
5. Schlag C *et al*. Gastroenterology 2022; 162(7): S-213.

Abbreviations:
BSG: British Society of Gastroenterology
BSPGHAN: British Society of Paediatric Gastroenterology, Hepatology and Nutrition
DB: double-blind
EEsAI: EoE activity index
EoE: eosinophilic oesophagitis
eos: eosinophils
EREFS: endoscopic reference score
FBO: food bolus obstruction
hpf: high-power field
OGD: oesophagogastroduodenoscopy
PPI: proton pump inhibitor

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Dr Falk Pharma UK Ltd, Unit K, Bourne End Business Park,
Cores End Rd, Bourne End, SL8 5AS
Registered in England No: 2307698

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