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

FOOD BOLUS OBSTRUCTION:

LET'S KEoEP REPEAT FBO OUT OF A&E

FBOs represent an increasingly common event in the everyday clinical practice of emergency physicians[1]

938 patients

with oesophageal food bolus impaction presented to a tertiary emergency unit in Wales between November 2018 and May 2021[2]

→ **1 FBO patient in the unit every day**

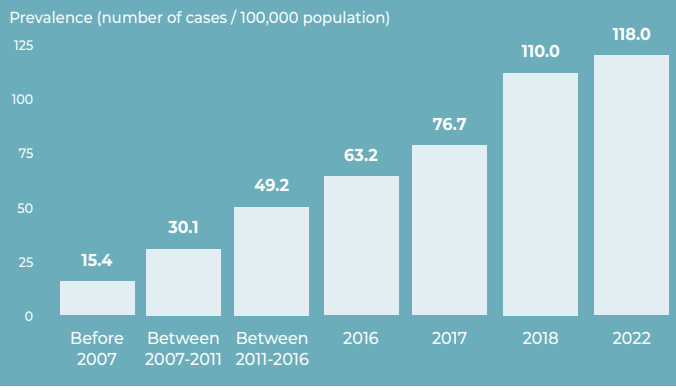
A quarter of patients with FBO may experience recurrent impaction[1]

Non-malignant FBOs are strongly associated with EoE[2] – a chronic, inflammatory condition in which eosinophils infiltrate the oesophageal epithelium. Signs and symptoms include:[3-5]

changes in oesophageal structure:
oesophageal rigidity, fibrostenotic features such as rings and ultimately strictures

changes in oesophageal function:
food feels like it is moving slowly/sticking in the chest after swallowing, food impaction

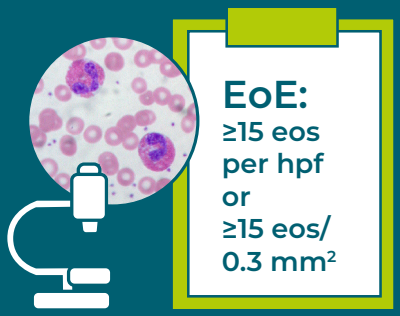
Once considered rare, EoE has rapidly increased in prevalence to become the second most common disease of the oesophagus, following GORD[6-10]



As EoE has become more common, so too has FBO[11]

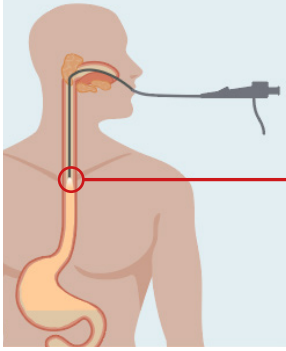
EoE ↑ FBO ↑

While symptoms such as swallowing difficulties point to EoE, it takes histology to confirm the diagnosis[12,13]



Recent British Society of Gastroenterology guidelines recommend:[13]

- Considering EoE in all adult patients with an FBO
- Making an urgent referral to gastroenterology for a therapeutic OGD
- Taking ≥6 biopsies from different anatomical sites in the oesophagus at the index endoscopy



At a UK university hospital, **38% of patients** newly diagnosed with EoE had received

up to **3 OGDs**

for prior episodes of food obstruction before their diagnosis[3]

Even if the episode is transient and self-resolving, FBO patients should be booked for an endoscopy and outpatient review[13]

of the patients presenting to the emergency department in Wales were sent home with no follow-up[2]

> **"Lack of appropriate follow-up for patients has been shown to be a predictor for recurrent food impactions[14]"**

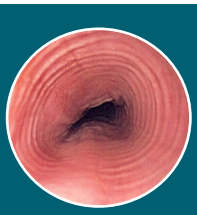
By focusing on appropriate patient diagnostic work-up after the first episode of impaction a proportion of FBO cases could be prevented, relieving pressure on A&E[1]

EoE can turn any meal into an emergency, with chronic oesophageal inflammation and progressive fibrosis obstructing the passage of food[15]

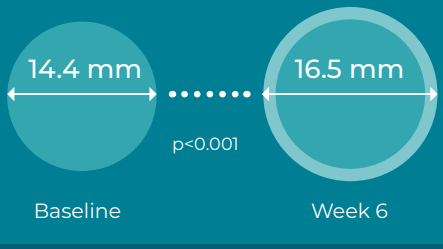
Jorveza (orodispersible budesonide) was specifically designed to treat EoE.[11] The only oral medicine with European regulatory approval for EoE, Jorveza treats both the symptoms of EoE and its defining histology[16]

At 6 weeks — Within weeks, oesophageal distensibility improved in 94% of Jorveza patients[17]

At 48 weeks — Prolonged treatment with Jorveza can delay and even revert fibrotic remodelling[18]



Mean oesophageal diameter on Jorveza[17]



Patients with fixed rings (% change from baseline at week 48)[18]

Jorveza 2 mg daily	-19%*	From 38.2% to 30.9%
Jorveza 1 mg daily	-14%*	From 42.6% to 36.8%
Placebo	+58%	From 38.2% to 60.3%

*p≤0.01 vs placebo

Jorveza is highly effective at both achieving and maintaining remission, and reducing the fibrotic complications of EoE[18]

Discharge of FBO patients without a gastroenterology consultation may result in a missed underlying diagnosis[19]

A MISSED EoE DIAGNOSIS IS A MISSED OPPORTUNITY TO TREAT

BUDESONIDE Jorveza® ORODISPERSIBLE TABLETS

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 glucocorticosteroids. 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 diabetes, 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 lowdose 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. Visit https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Dr Falk Pharma UK Ltd. at PV@drfalkpharma.co.uk

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A&E: accident & emergency
EoE: eosinophilic oesophagitis
eos: eosinophils
FBO: food bolus obstruction
GORD: gastro-oesophageal reflux disease
hpf: high power field
OGD: oesophagogastroduodenoscopy

UK--2400004
Date of preparation: December 2023

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