Eosinophilic oesophagitis (EoE)

causing food bolus obstruction in adults: an integrated pathway

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PRESENTATION AND DIAGNOSIS

Patient presents at A&E with food bolus obstruction

Suspect EoE in all patients with food bolus obstruction

Patient presents to GP with dysphagia

- No medical therapies* are recommended for resolving food bolus obstruction
- Book OGD and biopsies
- Refer to gastroenterology admissions
- Patient leaflet/information for all patients with food bolus obstruction

* Non recommended medical therapies include glucagon, PPI, diazepam, fizzy drinks.

OGD, 6 biopsies from multiple sites (ideally 3 levels)

EoE diagnosed (eosinophils >15/0.3 mm²*)

Every patient is required to have OGD and six biopsies (ideally, two biopsies from each of upper, mid and lower oesophagus) **prior to discharge.**

If not possible, these are the minimum standards as suggested by an expert panel:

- **OGD and biopsy within 6 hours** if patient is distressed
- **OGD and biopsy within 24 hours** if acute FBO/patient cannot swallow own saliva with high risk of aspiration
- **OGD and biopsy ideally within 2 weeks** if FBO resolves.

INITIAL MANAGEMENT

Initiate treatment

Licensed option

Budesonide ODT
- 1 mg twice a day
- Sufficient supply until gastroenterology review

Alternative options that may be discussed with patient

PPI
- Omeprazole 20 mg twice a day
- Sufficient supply until gastroenterology review

Step-up elimination diet
- 2 food to 4 food to 6 food

Letter to GP
- Diagnosis
- Treatment plan
- Gastroenterology review

Patients may have already been given a PPI, but symptoms persisted.

If the course has been of sufficient length (8–12 weeks of double-dose PPI, equivalent to omeprazole 20 mg twice a day), there is no value to using further PPI and they should be started on budesonide ODT.

Repeat OGD, 6 biopsies at ideally 3 levels at 12 weeks

Symptomatic on diet or PPI

Asymptomatic

Gastroenterology follow-up 2 weeks after OGD (in person or virtual) with symptom check

Dysphagia on budesonide ODT

Repeat OGD, with dilatation if required

Continue budesonide ODT, PPI or diet
- Budesonide ODT 0.5 mg twice a day or 1 mg twice a day, 3-month supply
- Omeprazole 20 mg twice a day, 3-month supply
- Current step of diet

Offer patient PIFU

Letter to GP
- Treatment plan
- Gastroenterology review/PIFU

Direct patient to EOS Network/other information sources

LONG-TERM MANAGEMENT

3-month gastroenterology review (virtual or phone)

Continue on maintenance dose of budesonide ODT, or other with current treatment regimes of PPI or diet (under dietician guidance)**

- Budesonide ODT 0.5 mg twice a day or 1 mg twice a day, 3-month supply
- Omeprazole 20 mg twice a day, 3-month supply
- Current step of diet

Symptomatic

Asymptomatic

Letter to GP
- OGD results
- Treatment plan
- Gastroenterology review

PIFU if requested

Repeat OGD on treatment, 6 biopsies from multiple sites (ideally 3 levels)
Optimise treatment if needed

Annual gastroenterology review

Asymptomatic

Treatment to continue in primary care with repeat prescribing (GP, PCN pharmacist)

Symptomatic – contact gastroenterology for advice

A&E - accident and emergency
EoE - eosinophilic oesophagitis
GP - general practitioner
ODT - oral dispersible table
OGD - oesophago-gastro-duodenoscopy
PCN - primary care network
PIFU - patient initiated follow-up
PPI - proton pump inhibitor

*Formerly per-high power field. ** Ensure appropriate maintenance shared care treatment plan is in place.

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 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 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.

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