GUIDELINES

Guidelines on the use of oesophageal dilatation in clinical practice

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1.0 INTRODUCTION

Oesophageal dilators or bougies have been used since the Middle Ages. Early bougies were made of natural materials and were used to disimpact food boluses by pushing them “blindly” into the stomach. The technique of oesophageal dilatation has evolved considerably in recent years. A range of purpose built dilators is now available, and with present day diagnostic techniques it is possible to select a dilator and dilatation technique appropriate to the clinical setting.

The relatively low morbidity and mortality of oesophageal dilatation has encouraged its widespread use. Despite this wealth of clinical experience however, the practice of oesophageal dilatation has been subject to surprisingly few controlled studies. The purpose of these guidelines is to highlight areas of good practice and promote the use of standardised protocols within and between centres.

2.0 FORMULATION OF GUIDELINES

These guidelines have been produced to conform to the North of England evidence based guidelines development project. They are based on a Medline literature search using the search term “oesophageal dilatation” and on expert opinion and review. Although oesophageal dilatation may be performed during rigid oesophagoscopy and under radiological screening, this guidance relates primarily to oesophageal dilatation performed during flexible upper gastrointestinal endoscopy. Oesophageal dilatation in the paediatric population is considered outside the scope of these guidelines.

2.1 Categories of evidence

The strength of evidence used to formulate these guidelines was graded according to the following system:

- Grade A—requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency, addressing the specific recommendation (evidence categories Ia, IB).
- Grade B—requires the availability of clinical studies without randomisation on the topic of recommendation (evidence categories IIa, IIb, III).
- Grade C—requires evidence from expert committee reports or opinions, or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).

The grading category is indicated in the summary and recommendations section at the end of these guidelines.

2.2 Grading of recommendations

The strength of each recommendation is dependent on the category of evidence supporting it, and is graded according to the following system:

- Grade A—requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency, addressing the specific recommendation (evidence categories Ia, IB).
- Grade B—requires the availability of clinical studies without randomisation on the topic of recommendation (evidence categories IIa, IIb, III).
- Grade C—requires evidence from expert committee reports or opinions, or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).

The grading category is indicated in the summary and recommendations section at the end of these guidelines.

3.0 INDICATIONS

Oesophageal dilatation is indicated in the treatment of symptomatic obstruction of the oesophagus. Obstruction may develop as a consequence of a wide range of anatomical and functional oesophageal disorders. Reflux induced strictures, malignant strictures, and achalasia are the most frequent indications but patients with anastomotic, sclerotherapy, radiation, medication, and corrosive induced strictures, and those with rings and webs frequently require dilatation. Patients with diffuse oesophageal spasm and other motility disorders may occasionally require dilatation of the lower oesophageal sphincter when conservative measures fail.

The primary aim of oesophageal dilatation is to alleviate symptoms, permit maintenance of oral nutrition, and reduce the risk of pulmonary aspiration. The technique may also be used to facilitate diagnostic gastroscopy when a stricture prevents passage of the endoscope, and to permit oesophageal stent insertion in the palliation of patients with oesophageal malignancy.

4.0 CONTRAINDICATIONS

Active oesophageal perforation is an absolute contraindication to oesophageal dilatation as it may extend the oesophageal defect and promote mediastinal soiling. The procedure should be undertaken with caution in those who have suffered a recent perforation or undergone recent upper gastrointestinal surgery.

The risks of dilatation are likely to be greater in patients with pharyngeal or cervical deformity and in those with large thoracic aneurysms. The risks of a perforation developing are greater during dilatation of malignant disease of the oesophagus.

Severe cardiorespiratory disease is a relative contraindication to all endoscopic procedures. The balance of risks and benefits should be individualised and carefully considered.

Major bleeding is uncommon following oesophageal dilatation but is more likely in patients with severe coagulopathy and in those taking anticoagulant drugs.
Anticoagulants should be withdrawn and coagulopathy corrected prior to dilatation (see 5.5).
Concurrent radiotherapy is not a contraindication to oesophageal dilatation and mucosal biopsies do not prohibit dilatation during the same procedure.¹

5.0 PATIENT PREPARATION
Oesophageal dilatation is best undertaken as a planned procedure in patients who have been appropriately investigated, prepared, and consented.

5.1 Predilatation investigations
The cause of oesophageal obstruction should be carefully assessed. Endoscopy and contrast radiology are both helpful and are often complimentary. Although some recommend a barium swallow examination in all patients presenting with dysphagia, many patients may be reasonably assessed by endoscopy alone. However, it should be remembered that patients with proximal dysphagia may be harbouring pathology which increases the risks of perforation—for example, pharyngeal pouch, post-cricoid web—and in these circumstances endoscopy should only be undertaken by an experienced endoscopist.

Many oesophageal strictures will allow passage of a standard or narrow diameter gastroscope. The site and length of the stricture and the mucosal appearances should be documented. Features that may make dilatation more hazardous, such as angulation of the stricture and the presence of diverticulae, a hiatus hernia, or a small stomach, should also be noted. When a stricture prevents passage of the endoscope, a barium swallow examination will provide useful anatomical detail. This is particularly helpful in patients with long, tight, or complex strictures in whom dilatation may be technically difficult and associated with greater risks.

Biopsies or brush cytology should be taken for histological or cytological analysis. A tissue diagnosis is desirable, prior to dilatation, as it will influence overall management and the estimation of perforation risk.⁴ In patients with short, simple, benign looking strictures however, it is common practice for biopsies to be taken and dilatation performed during the same examination. When the stricture is tight or when the endoscopic features suggest malignancy, the results of biopsies are best awaited unless the patient has absolute urgency. Confirmation of malignancy should prompt a detailed assessment, including imaging to look for evidence of locoregional and distant spread. In patients with an inoperable tumour, dilatation may then be combined with stent insertion or other palliative procedures.

Patients with suspected achalasia should undergo detailed assessment to confirm the diagnosis and exclude occult carcinoma. The clinical features and endoscopic or barium swallow findings suggest the diagnosis but oesophageal manometry should be performed to confirm the diagnosis. Careful endoscopic assessment of the gastro-oesophageal junction should be performed to exclude malignancy. Computed tomography scanning and endosonography may be useful when a neoplasm is suspected and other modalities fail to confirm the diagnosis.⁵

5.2 Information and consent
Patients should receive information, giving details of oesophageal dilatation, prior to the procedure. It is particularly important that patients are aware of the perforation risk and that operative intervention may be required should perforation occur. Patients should also be informed of the therapeutic alternatives to oesophageal dilatation.

Written consent should be obtained in line with local hospital policies.

5.3 Fasting
All patients should be asked to fast for 4–6 hours to ensure an empty oesophagus and stomach during the procedure. Patients with achalasia are particularly prone to oesophageal stasis and may require a more prolonged fast or oesophageal lavage.

5.4 Patient premedication
Although some patients tolerate dilatation using only local anaesthesia, for many the procedure is uncomfortable and sedation is usually required. Patients with achalasia may find dilatation painful and the addition of an intravenous opiate is common practice.

The endoscopist is responsible for assessing the need for topical anaesthesia and intravenous sedation may increase the risk of aspiration and some suggest the use of one or the other.⁶ Furthermore, the combination of intravenous sedation and analgesia is associated with adverse cardiorespiratory events and death during endoscopy.⁷ The elderly and those with coexistent cardiorespiratory, renal, and hepatic disease (ASA grades III–V) are at particular risk. Doses of sedation and analgesia should be kept to a minimum compatible with patient comfort and a successful procedure. Opioid and benzodiazepine antagonists should be immediately available.

5.5 Patients taking oral anticoagulants and antiplatelet agents
In patients taking oral anticoagulants, dilatation has the potential to produce bleeding, which may be difficult to control endoscopically. It is therefore advisable that patients at low risk of thromboembolic events should discontinue anticoagulants prior to the dilatation. A preprocedure prothrombin time should be performed. In patients at high risk of thromboembolic events, oral anticoagulants should again be discontinued prior to the procedure. Monitoring should be undertaken and intravenous heparin started once oral anticoagulation becomes subtherapeutic. Heparin should be discontinued 4–6 hours before dilatation and resumed 4–6 hours thereafter. Anticoagulants are generally resumed on the night of the procedure.⁶

The limited data available suggest that aspirin and non-steroidal anti-inflammatory drugs do not increase the risk of significant bleeding after therapeutic endoscopy.

5.6 Patients at risk of endocarditis
Antibiotics should be given to patients with higher risk cardiac lesions (prosthetic heart valves, previous endocarditis, synthetic vascular grafts inserted within 12 months of the dilatation, and systemic pulmonary shunts) and those with neutropenia (<100 × 10⁹/l). The British Society of Gastroenterology guidelines on antibiotic prophylaxis during endoscopy should be followed.⁸

6.0 THE DILATATION PROCEDURE
6.1 Personnel and experience
Oesophageal dilatation is associated with clearly defined morbidity and mortality. It should only be performed by experienced endoscopists. Endoscopists who have performed less than 500 diagnostic procedures are four times more likely to cause perforation than their more experienced colleagues.⁹ All forms of therapeutic endoscopy should be taught only after adequate skills for diagnostic gastroscopy have been acquired (JAG recommend a minimum of 300 procedures¹⁰). Initially, oesophageal dilatation should be carried out only under direct supervision.

During oesophageal dilatation the endoscopist should be supported by at least two endoscopy assistants. Both have a
role in monitoring patient comfort and safety throughout the procedure. They should be familiar with the endoscopic and dilatation equipment and should be capable of helping the endoscopist in case of an emergency, such as cardiorespiratory arrest.

Personnel trained in radiological techniques should be present when the procedure is performed under x ray screening.

The principal risk of oesophageal dilatation is perforation. As patients who suffer perforation are best managed in conjunction with a surgeon, appropriate surgical support should be available.

### 6.2 Oesophageal dilators

Two types of oesophageal dilator are available: the push dilator (bougie) and the balloon dilator.¹¹

#### Push dilators

Push dilators may be weighted (mercury or tungsten filled rubber bougies) or wire guided (metal olives, Celestin type dilators, or polyvinyl bougies).

Weighted bougies are available in a range of sizes (7–20 mm diameter). They may be passed blindly, under local anaesthetic, with the patient in a sitting position, and selected patients may be taught self dilatation.

Eder-Puestow dilators comprise a series of graduated metal olives (6.6–19.3 mm diameter) mounted on a flexible shaft. For many years it was the only system available for dilating resistant or complicated strictures. The system is durable and is said to be useful in patients with tortuous strictures or small stomachs.

Celestin dilators are long, tapered, radio-opaque bougies. These are two dilators, which increase in small steps, the larger to a maximum diameter of 18 mm. They offer the advantage of full dilatation in two passages but because of their length should be used with care in patients with small stomachs and significant hiatus hernias.

Polyvinyl dilators have become popular in recent years. Savary Gillard dilators consist of a range of polyvinyl tubes (5–20 mm diameter), each with a 20 cm tapered tip. A radio-opaque band at the widest point of the dilator aids radiological localisation. The American system is similar but dilators are impregnated with barium sulphate for easier radiological localisation and the distal tapering segment is shorter. Multiple passages may be required to achieve full dilatation.

#### Balloon dilators

Balloon dilators are widely used and may be passed through the scope or be wire guided. Balloon sizes range from 6 to 40 mm, with the larger balloons reserved for the treatment of achalasia. The principal disadvantage of balloon dilators is their cost.

### 6.3 The dilatation technique

Prior to dilatation the endoscopist should consider five points:

(a) The diameter to which the obstruction should be dilated

In patients with benign peptic strictures, the results of dilatation appear best when a luminal diameter of 13–15 mm is achieved. This diameter is therefore usually recommended although greater diameters may be required when patients remain symptomatic.¹¹ Large calibre dilators (16–20 mm) are advised in the treatment of patients with Schatzki’s rings.¹²

In patients with achalasia the aim of oesophageal dilatation is to forcibly disrupt the lower oesophageal sphincter.

Dilators ranging from 30 to 40 mm are therefore usually employed.

In patients with malignant oesophageal disease however large calibre dilators are best avoided as perforation is more likely and dilatation is rarely the definitive treatment. Modest dilatation, sufficient to permit biopsy or endoscopic ultrasound or facilitate stent insertion, is the safest approach. In some patients expandable metal stents may be placed without the need for dilatation.

(b) How quickly dilatation should be achieved

Traditionally, it has been suggested that no more than three dilators of progressively increasing diameter (3×1 mm increments) should be passed in a single session to reduce the risk of perforation (“rule of three”).¹¹ Several sessions were therefore often required to achieve adequate dilatation. Recent experience suggests that the passage of a single large dilator (≥15 mm diameter) or incremental dilatation in larger steps may be safely employed in many patients with uncomplicated peptic strictures.¹⁴ However, it should be borne in mind that these observations were uncontrolled and it would be wise to employ a cautious approach in patients with tight, tough, or complex strictures.

(c) The dilator that should be employed

As balloon dilators generate only radial forces within a stricture, it has been suggested they are less likely to be associated with complications than the push dilators, which also generate longitudinal shearing forces. However, this has not been borne out by clinical studies and both push and balloon dilatations give good results in most situations.¹⁵–¹⁰

(d) The need for wire guidance or endoscopic control

In most patients who require oesophageal dilatation it is desirable to use wire guided or endoscopically controlled techniques.

Most authorities agree that the unguided passage of weighted bougies should be restricted to the treatment of patients with simple reflux induced strictures, rings, or webs. Weighted bougies are not suited to the management of tight strictures. Dilators less than 10 mm in diameter are floppy and require radiographic screening to confirm passage through the stricture.¹⁹ ²⁰ Weighted bougies should not be used in the treatment of patients with complex strictures as perforations are more likely.²¹

Wire guided dilatation gives greater assurance that the dilator is following the line of the oesophageal lumen, thus reducing the risk of perforation. Routine radiological screening was previously recommended when undertaking wire guided dilatation but this is not essential when the anatomy is well defined, axial alignments are maintained, and the wire passes easily into the stomach. The guidewire should be placed at least 20–30 cm below the lowest point of the stricture, usually in the gastric antrum. Liberal lubrication facilitates passage of both the wire and dilator. Once positioned, the guidewire should be fixed externally to minimise the risk of internal displacement. Slight counter tension facilitates passage of the dilator. The dilator is withdrawn over the guidewire and the next dilator passed. Studies have shown that dilatation following endoscopic placement of a marked guidewire is a safe and effective technique, which negates the need for routine radiological screening.²² ²³

Through the scope balloon dilatation is performed under direct endoscopic visualisation. An adequate channel size and lubrication facilitate easy passage. The balloon should be centred at the tightest point of the stricture. Maximum dilating pressures vary in relation to balloon size and range between 30 and 45 psi but optimum pressure is unknown.
Water is the standard agent used to expand the balloons although air or contrast agents may also be used. Recommended inflation times range from 20 to 60 seconds but again the optimum is unknown. A graded approach to dilatation is recommended by some with obliteration of the stricture waist seen during radiographic screening or endoscopic assessment of stricture dilatation as commonly used end points of success. Through the scope balloon dilatation has the additional advantage that it allows dilatation of the proximal part of a stricture. This may be helpful when a guidewire will not pass.

6.5 Monitoring during the procedure
The patient’s clinical condition should be observed throughout the procedure by both the endoscopist and nursing staff. Supplemental oxygen and pulse oximetry should be used routinely as dilatation is frequently performed in high risk patients, is occasionally prolonged, and some patients require both opioids and benzodiazepines. Monitoring should be continued into the recovery period.

7.0 AFTERCARE
Patients should be closely observed after oesophageal dilatation and pulse, blood pressure, and temperature should be measured regularly. Oesophageal dilatation is now frequently undertaken as an outpatient procedure, and this appears safe providing the procedure is routine and the patient is closely observed after the procedure. It is important to allow sufficient time for recovery, for the patient to have a drink (initially water), and to be assessed by appropriately trained staff (routine observations and a check for surgical emphysema). Patients with dysphagia are therefore best examined at the beginning of the endoscopy list. Facilities should be available to keep a patient overnight for observation.

Following oesophageal dilatation, particularly for achalasia, some recommend a chest x-ray and contrast study to exclude perforation. These investigations are not essential but should be performed urgently in patients who develop pain, breathlessness, fever, or tachycardia. As perforation risks are higher following dilatation for achalasia, many recommend a period of overnight observation.

On leaving hospital patients should be well and tolerating oral fluids. All patients should receive written information indicating the need to return immediately should they develop pain or breathlessness or become unwell.

8.0 COMPLICATIONS
The principal complications of oesophageal dilatation are perforation, pulmonary aspiration, and bleeding.

A UK regional audit reported an overall perforation rate of 2.6% with a mortality of 1%. Perforation was less common following dilatation of benign strictures (1.1% with a mortality of 0.5%) than following dilatation and/or intubation of malignant strictures (6.4% with a mortality of 2.3%). Elderly patients appeared more at risk. The risks are also greater when the endoscopist is inexperienced and when strictures are complex, particularly when weighted bougies are passed blindly.

Perforation usually occurs at the site of the stricture resulting in intra-abdominal or intra-thoracic perforation, the latter being more serious. Although perforation is often linked to the use of large dilators it may complicate the passage of a small dilator or be caused by the guidewire. Perforation should be suspected when patients develop pain, breathlessness, fever, or tachycardia. Transient chest pain is not uncommon following dilatation but persistent pain should prompt a chest x-ray and contrast study to look for perforation. Some recommend endoscopic reinspection immediately on completion of the dilatation procedure as the appearances may raise the possibility of perforation and prompt early treatment. A chest x-ray may show pneumomediastinum, pneumothorax, air under the diaphragm, or a pleural effusion but normal appearances do not exclude perforation and, if there is any clinical suspicion, a water soluble contrast study should be performed. Iatrogenic perforation is a medical emergency. The patient should be assessed by an experienced physician and experienced surgeon in order to formulate an appropriate management plan.

The risk of perforation in achalasia is reported as 0–7% (mostly 3–4%) with a mortality of <1%. The perforation rate may be lower with a graded approach to balloon dilatation but most perforations occur during the first dilatation. Post-dilatation reflux may occur but is usually mild and readily controlled with acid suppression.
9.0 OUTCOMES AND FOLLOW UP

Most patients respond well to oesophageal dilatation but outcomes are influenced by the underlying pathology. In patients with benign reflux induced strictures, a graded stepwise approach to between 13 and 20 mm gives good relief in 85–93% of cases. Dilatation appears less effective in those with radiation or corrosive induced strictures.

Some patients require repeat dilatation after an initial successful dilatation. Predictors for repeated dilatation are “non-peptic” causes of stricture, fibrous strictures, and a maximum dilator size less than 14 mm. Tight strictures may require short interval redilatation to ensure a reasonable duration of response. Weekly dilatation until easy passage of a greater than 14 mm dilator is a common strategy. Carefully selected patients with recurrent benign strictures may be taught self dilatation.

The need for redilatation in patients with peptic strictures is much reduced when maintenance acid suppression is prescribed following the initial dilatation. Standard dose proton pump inhibitor treatment is clearly more effective than H2 receptor antagonists. Twice daily dosing with proton pump inhibitors may be required when restenosis occurs rapidly. Further biopsies and imaging are also recommended under these circumstances to exclude occult malignancy.

Although oesophageal dilatation is effective in most patients with benign strictures, a small number require surgical intervention. Patients who need frequent dilatation despite proton pump inhibitor treatment and those who are technically difficult to dilate should be considered for operative treatment by antireflux surgery.

Most malignant strictures respond to dilatation but relief is usually short lived and more definitive treatment is necessary. Patients with malignant strictures should undergo imaging to assess the degree of locoregional and distant spread. Although there is as yet no clear consensus about the best palliation of malignant strictures, expandable metal stents have become popular and dilatation is often combined with stent insertion. The dysphagia caused by extrinsic compression of the oesophagus responds poorly to oesophageal dilatation.

Recent studies report that 58–95% of patients with achalasia have excellent to good results following pneumatic dilatation. If a single session does not produce satisfactory results, a second and third attempt may be appropriate before considering the surgical option. Younger patients may respond less well to balloon dilatation.

Patients with achalasia should be aware of the other therapeutic options. Surgical cardiomyotomy generally provides high rates of symptomatic relief, although this has to be balanced against operative risks and the problem of long term reflux. The surgical approach may be by open or laparoscopic routes. Botulinum toxin may be considered in elderly patients and those at high surgical risk but long term results are modest and repeated injection often required.

10.0 AUDIT

Many units perform relatively small numbers of oesophageal dilatations. In order to concentrate expertise, consideration should be given to limiting the number of clinicians who perform oesophageal dilatation. Audit standards should focus on the adequacy of predilatation investigation, consent procedures, and complication rates, notably perforation rates and mortality.

11.0 Summary and recommendations

(1) Oesophageal dilatation is indicated in the treatment of symptomatic oesophageal obstruction. When performed appropriately and carefully it is a highly effective technique with a low morbidity and mortality (grade B).

(2) Oesophageal dilatation should be undertaken as a planned procedure where possible in patients who have been adequately investigated and prepared. Endoscopy and contrast radiology are helpful and often complimentary. A tissue diagnosis is desirable prior to dilatation. Patients with suspected achalasia should be investigated to confirm the diagnosis and exclude occult malignancy (grade C).

(3) Informed consent should be obtained prior to upper gastrointestinal endoscopy and if dilatation is planned the risks and outcomes discussed. The patient should understand the perforation risk and the possible need for surgical intervention should perforation occur. Patients should be aware of the alternatives to dilatation (grade C).

(4) Local anaesthesia or intravenous sedation with or without intravenous analgesia should be given in accordance with the British Society of Gastroenterology guidelines on sedation during endoscopy. At risk patients should be identified before the procedure and monitored carefully throughout (grade C).

(5) Oral anticoagulants should be discontinued prior to oesophageal dilatation. In those at high risk of thromboembolism, heparin should be started when oral anticoagulation becomes subtherapeutic. Heparin should be discontinued 4–6 hours prior to the procedure and restarted 4–6 hours afterwards (grade C).

(6) Antibiotics should be given to patients with higher risk cardiac lesions and neutropenia in line with British Society of Gastroenterology guidelines (grade C).

(7) Oesophageal dilatation should only be undertaken by experienced endoscopists (grade B). The endoscopist should be supported by two assistants during the procedure. Surgical expertise should be available in case of perforation.

(8) Both push dilators (bougies) and balloon dilators give good results (grade A). Results appear best when a luminal diameter of 13–15 mm is achieved. The passage of a single large dilator appears safe in simple uncomplicated strictures but a cautious graded approach is recommended in patients with tight, tough, or complex strictures (grade B). In most cases it is desirable to use either wire guided or endoscopically controlled techniques. The addition of radiographic screening is helpful when the stricture is tortuous or complex or associated with large hiatus hernia or diverticulae and when difficulty is encountered passing the guidewire (grade C).

(9) Most patients with achalasia respond well to pneumatic dilatation of the lower oesophageal sphincter. Optimal distension pressures are unknown but the 3.0 cm balloon inflated for a short period appears effective (grade A).

(10) Patients should be closely observed following oesophageal dilatation. In uncomplicated cases the procedure may be safely performed as an outpatient (grade B). Perforation should be suspected and a chest x ray and contrast study should be performed urgently in patients who develop pain, breathlessness, fever, or tachycardia.

(11) Oesophageal dilatation is often only one part of the management of the patient. Those with malignant strictures for example, require detailed assessment by a multidisciplinary team (grade C), those with reflux induced strictures require maintenance acid suppression therapy with standard or high dose proton pump inhibitors to reduce the need for further dilatation (grade A).

(12) Audit standards should focus on the adequacy of investigations, consent procedures, and complication rates, notably perforation and mortality.
12.0 REFERENCES
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