Therapeutic sialendoscopy

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of therapeutic sialendoscopy appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

2 The procedure

2.1 Indications

- 2.1.1 Therapeutic sialendoscopy is used in the treatment of suspected salivary gland obstruction. Obstruction of the ducts is most commonly caused by sialolithiasis (stones).
- 2.1.2 Symptoms of salivary gland obstruction are varied and include swelling of the face or neck, swelling in front of the ear, pain in the face or mouth and decreased ability to open the mouth.
- 2.1.3 Treatment of salivary gland obstruction depends on the underlying cause and location. For most benign ductal disorders such as sialolithiasis treatment includes surgical excision of the stone from within the mouth if it is easily accessible. Interventional sialography and extracorporeal or endoscopic lithotripsy may also be used. Removal of the affected salivary gland may be required for large or less accessible stones.

2.2 Outline of the procedure

2.2.1 The procedure is typically performed under local anaesthesia. Progressive dilatation of the salivary duct, with or without stents, is performed until the

opening is large enough to allow the introduction of an endoscope. The duct is irrigated initially with a local anaesthetic solution and then with saline as the scope is passed through the ductal system. Instruments (such as wire retrieval baskets) are then introduced through the endoscope to remove stones. A stent may sometimes be left in the duct postoperatively.

2.3 Efficacy

- 2.3.1 The evidence of efficacy was based on five case series. Across these studies therapeutic sialendoscopy relieved duct obstruction in between 82% (90 out of 110) and 87% (47 out of 54) of cases.
- 2.3.2 In a study of 72 patients, 8% (6 out of 72) had continuing symptoms or other clinical problems which did not improve after the procedure and required removal of the gland (sialadenectomy). In another study of 129 patients, 110 of whom underwent therapeutic sialendoscopy, the treatment was considered a failure in 18% (20 out of 110) of patients, 5 of whom required gland removal.
- 2.3.3 Recurrence of obstructive symptoms was reported in two of the studies, with rates of 2% (4 out of 236) and 5% (3 out of 55), respectively. All recurrences occurred between 15 and 24 months after the procedure. For more details, see the <u>overview</u>.
- 2.3.4 The Specialist Advisers did not consider there to be any uncertainties about this procedure. One Adviser noted that high success rates are reported in the published literature.

2.4 Safety

2.4.1 Few complications were reported in the five case series reviewed. Temporary swelling of the gland was common. In one study of 129 patients, ductal wall perforation occurred in 11 patients (9%), with two of these patients requiring hospitalisation and one patient undergoing gland resection. Three other studies reported cases of salivary gland perforation with an incidence of between <1%

and 5% (3 out of 55, 1 out of 103, 1 out of 236). One patient (1 out of 236) developed lingual nerve paraesthesia caused by the perforation. Ductal strictures were also reported in seven patients (3%) in a case series of 236 patients. Five patients underwent successful dilatation but two required open surgery. Other complications included difficulty in retrieving the wire basket after engaging the stone and postoperative infections. For more details, see the <u>overview</u>.

2.4.2 The Specialist Advisers stated the potential complications include infection, perforation of the duct, ranula formation, lingual nerve injury and duct stenosis.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.