NICE guidance

Intraoperative nerve monitoring during thyroid surgery

Interventional procedures guidance
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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 Yellow Card Scheme.

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

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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 The evidence on intraoperative nerve monitoring (IONM) during thyroid surgery raises no major safety concerns. In terms of efficacy, some surgeons find IONM helpful in performing more complex operations such as reoperative surgery and operations on large thyroid glands. Therefore, it may be used with normal arrangements for consent, audit and clinical governance.

2 The procedure

2.1 Indications and current treatments

2.1.1 Removal of part or all of the thyroid gland (partial or total thyroidectomy) may be indicated in the treatment of thyroid enlargement (goitre), thyrotoxicosis or malignancy. The thyroid gland is located close to the right and left recurrent laryngeal nerves (RLNs) which innervate the vocal cords. Damage to an RLN during thyroid surgery may result in temporary or permanent hoarseness, or, in the case of bilateral damage, breathing difficulties and inability to speak.

2.1.2 Conventionally, thyroid surgery is done without continuous intraoperative nerve monitoring (IONM). Under general anaesthesia, an incision is made in the front of the neck and the underlying muscles are retracted to expose the thyroid gland. The RLNs are identified visually to avoid injuring them, but this is not always straightforward. A hand-held nerve stimulator can also be used, in combination with a finger placed behind the larynx to detect contraction of the vocal cord muscles and the arytenoid cartilages on nerve stimulation.

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2.2 Outline of the procedure

2.2.1 IONM is used as an adjunct to conventional thyroid surgery under general anaesthesia. It requires placement of electrodes close to the vocal cords. This can be achieved either by the use of a specially adapted endotracheal tube with surface or integral electrodes, which are positioned close to the vocal cords, or by the placement of electrodes into the vocal muscles on each side of the thyroid gland, when using a standard endotracheal tube. Following tracheal intubation, non-paralysing anaesthesia is used for the rest of the procedure as muscle relaxants can interfere with the nerve monitoring process.

2.2.2 The electrodes are connected to the neuromonitoring device, which uses sound and graphics on the monitor screen to alert the surgeon when a surgical instrument comes close to either RLN during surgery. A hand-held probe can also be used to confirm the location of either nerve at any time during the operation. Postoperative laryngoscopy is used to assess RLN function.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the overview.

2.3 Efficacy

2.3.1 Four non-randomised studies of 16,448, 684, 639 and 136 patients (29,998, 1,043, 1,000 and 190 nerves) reported permanent rates of vocal cord paralysis ranging from 0% to 2% in the IONM groups, compared with 0% to 1% in the control groups (visual RLN identification or no RLN identification). No statistically significant differences were seen between procedures undertaken with or without IONM. Three case series of 328, 288 and 171 patients reported rates of permanent vocal cord paralysis using IONM in 3% (15 out of 502), 1% (6 out of 429) and 1% (2 out of 271) of RLNs, respectively.

2.3.2 Four non-randomised studies of 684, 639, 165 and 136 patients (1,043, 1,000, 236 and 190 nerves) reported rates of transient vocal cord paralysis ranging from 3% to 5% in the IONM groups, compared with 3% to 4% in the control groups (none were statistically significant). Another non-randomised study reported that vocal cord immobility was detected at 3-month follow-up in 6% (6 out of 104) of

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patients when IONM was used and 5% (5 out of 100) of patients when IONM was not used (p=0.55). The three case series of 328, 288 and 171 patients reported rates of transient RLN palsy as 9% (43 out of 502), 9% (37 out of 429) and 5% (13 out of 271), respectively.

2.3.3 The non-randomised study of 639 patients (1,000 nerves at risk), which compared IONM with visual identification of the RLN, reported that IONM indicated no nerve damage in 10 out of 21 vocal cords that were paralysed as a result of surgery. Conversely, IONM indicated nerve damage in 27 out of 480 patients who were found to have normal postoperative vocal cord function.

2.3.4 The Specialist Advisers considered key efficacy outcomes to be reduction in nerve damage and subsequent vocal cord palsy. Two of the nine Advisers stated that this procedure is useful for teaching. One Adviser commented that there are significantly different opinions between surgeons as to whether this technology improves outcomes or whether it gives false reassurance to inexperienced surgeons.

2.4 Safety

2.4.1 No adverse events resulting from IONM were reported in the studies.

2.4.2 The Specialist Advisers considered the main safety concerns to be false-negative or false-positive readings leading to the misidentification of the nerve. In particular, a false-negative reading may lead to RLN damage. One Adviser suggested that there is also a potential for false signals if the electrodes are placed incorrectly.

3 Further information

3.1 All cases of recurrent laryngeal nerve (RLN) damage during thyroid surgery using intraoperative nerve monitoring (IONM) should be recorded at local clinical audit meetings and reported to the National Patient Safety Agency through local clinical governance mechanisms, as this may be associated with failure to identify

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the nerve (false-negatives) when using the technique.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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