NHS

National Institute for Health and Clinical Excellence

Incisionless otoplasty

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NICE interventional procedure guidance 422

www.nice.org.uk/ipg422

NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for three years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

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1 Guidance

1.1 Incisionless otoplasty comprises a variety of surgical techniques, carried out via minimal percutaneous access, that have been poorly described in the evidence, which includes a very small number of patients. The evidence on efficacy and safety is inadequate both in quality and quantity, and therefore the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake incisionless otoplasty should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and/or their parents or carers understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having incisionless otoplasty (see section 3.1).

1.3 Further research on incisionless otoplasty should describe the precise surgical techniques used and should report both short- and long-term outcomes, including the need for further procedures.

2 The procedure

2.1 Indications and current treatments

2.1.1 Protruding or prominent ears result when normal cartilaginous folds fail to form within the ear.

2.1.2 Surgery to correct protruding ears aims to reposition the elastic cartilage permanently while preserving a natural appearance. Cartilage-sparing techniques avoid radical excision, but reduce the cartilage spring by such measures as scoring, drilling and suturing. All techniques usually involve a post-auricular incision of the skin.

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2.2 Outline of the procedure

2.2.1 Incisionless otoplasty avoids the use of a standard incision, which can sometimes be complicated by anterior skin necrosis or keloid scar formation.

2.2.2 The procedure is usually carried out with the patient under general anaesthesia, but it can also be done under local anaesthesia. Precise details of the procedure depend on the nature of the ear abnormalities, the needs of the individual patient and the preferences of the surgeon. In an optional first stage, a needle is inserted into the anterior aspect of the ear and used to score the anterior surface of the cartilage and render it more malleable. A posterior approach is then used to insert subcutaneous retention sutures (usually non-absorbable) to create a natural looking antihelix with less ear protrusion. Conchal cartilage may also be anchored onto the mastoid bone by a subcutaneous stitch attached to non-elastic tissue such as the periosteum.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A case series of 13 patients (5 of whom were treated by incisionless otoplasty) reported that photographs showed good correction and that all patients and their families were satisfied with the outcome.

2.3.2 A case series of 11 patients reported that all results were 'satisfactory' with no recurrence during 6- to 30-month follow-up.

2.3.3 The Specialist Advisers listed key efficacy outcomes as aesthetic ear correction and avoidance of recurrence.

2.4 Safety

2.4.1 No safety concerns were reported in the published literature.

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2.4.2 The Specialist Advisers listed anecdotal adverse events as anterior skin necrosis, collapse of the ear necessitating reconstruction with costal cartilage, poor aesthetic outcome and bleeding.

2.5 Other comments

2.5.1 The Committee noted the psychological distress caused by protruding ears and the potential benefit of effective treatment, in particular by procedures that minimise scarring. However, the limited publications available provided inadequate evidence to suggest that incisionless otoplasty is an efficacious procedure. The Committee expressed particular disappointment at the paucity of the evidence base.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), which will be available when the guidance is published.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

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We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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