NHS
National Institute for Health and Clinical Excellence

Bronchial thermoplasty for severe asthma

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NICE interventional procedure guidance 419

guidance.nice.org.uk/ipg419

Healthcare Improvement Scotland

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NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 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'

Contents

1 Guidance

1.1 Evidence on the efficacy of bronchial thermoplasty for severe asthma shows some improvement in symptoms and quality of life, and reduced exacerbations and admission to hospital. Evidence on safety is adequate in the short and medium term. More evidence is required on the safety of the procedure in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake bronchial thermoplasty for severe asthma should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and long-term safety, and the possibility of initial worsening of their symptoms, and provide them with clear written information. In addition, the use of NICE's information for patients (Understanding NICE guidance) is recommended.
- Clinicians should submit details of all patients undergoing this procedure to the Difficult asthma registry.
- Patient selection and treatment should be carried out by a respiratory team with special expertise in managing difficult and severe asthma.

1.3 NICE encourages further research into bronchial thermoplasty for severe asthma. Research outcomes should include objective measurements of lung function, symptom control, medication requirements and quality of life. Long-term safety and efficacy outcomes are particularly important. Collaboration between units to publish data on patients not involved in research studies would also be valuable.

2 The procedure

2.1 Indications and current treatments

2.1.1 Asthma is characterised by increased responsiveness to various allergic or other stimuli, and airflow obstruction. Symptoms include recurring episodes of wheezing, chest tightness and coughing.

2.1.2 In the UK, the management of asthma is currently based on a stepwise approach to treatment, ranging from inhaled therapy for mild intermittent asthma to continuous or frequent courses of oral corticosteroids.

2.2 Outline of the procedure

2.2.1 The aim of bronchial thermoplasty for severe asthma is to reduce airway smooth muscle mass, thereby decreasing the ability of the airways to constrict.

2.2.2 Bronchial thermoplasty is usually performed with the patient under sedation or general anaesthesia. A specially designed catheter is introduced into the bronchial tree. Short pulses of radiofrequency energy are applied circumferentially to sequential portions of the airway wall, moving from distal (diameter > 3 mm) to proximal (main bronchi) at 5 mm intervals. Treatment is usually delivered in 3 sessions with an interval of at least 3 weeks between each session. After the first treatment session, previously treated airways are evaluated by bronchoscopy before proceeding with further treatment.

> 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 randomised controlled trial (RCT) of 288 patients treated by bronchial thermoplasty or sham reported a mean increase in Asthma Quality of Life Questionnaire (AQLQ) score (on a scale from 1 to 7; higher score indicates

better quality of life) of 1.35 and 1.16 respectively at 12-month follow-up (posterior probability of superiority [PPS] = 0.960).

2.3.2 An RCT of 109 patients treated by bronchial thermoplasty or medical management alone reported an improvement in mean morning peak expiratory flow of 39.3 and 8.5 litres/minute respectively at 1-year follow-up ($p = 0.003$) and a reduction in short-acting beta-2 agonist use of 26 puffs per 7 days in the bronchial thermoplasty group compared with 6 puffs per 7 days in the control group ($p < 0.05$).

2.3.3 The RCT of 288 patients treated by bronchial thermoplasty or sham reported 0.48 and 0.70 severe exacerbations per patient per year respectively, during the post-treatment period (6 to 52 weeks after the procedure; PPS = 0.995). The patients who were treated by bronchial thermoplasty reported 0.39 severe exacerbations per patient per year during the second year of follow-up (n = 166).

2.3.4 The Specialist Advisers listed key efficacy outcomes as lung function, reduction in hospital admissions, and days lost from work or school because of asthma symptoms.

2.4 Safety

2.4.1 The RCT of 288 patients treated by bronchial thermoplasty or sham reported that 8% (16/190) and 2% (2/98) of patients respectively were admitted to hospital for respiratory symptoms during the treatment period (weeks 0–6). Admissions in the bronchial thermoplasty group were for worsening of asthma (n = 10), segmental atelectasis (n = 2), lower respiratory tract infection (n = 1), low forced expiratory volume in 1 second (FEV_1) (n = 1), haemoptysis (n =1) and 1 aspirated prosthetic tooth; most events resolved with conservative management but the haemoptysis required bronchial artery embolisation.

2.4.2 The RCT of 109 patients treated by bronchial thermoplasty or medical management alone reported that 7% (4/55) and 4% (2/54) of patients respectively, were admitted to hospital during the treatment period.

2.4.3 The Specialist Advisers considered bronchial stenosis to be a possible complication in the long term.

2.5 Other comments

2.5.1 The Committee noted the poor quality of life often associated with severe asthma, and the fact that multiple medications are often needed. Bronchial thermoplasty has the potential to offer improvements in quality of life for many patients, if further evidence supports its efficacy.

2.5.2 The Committee received extensive specialist advice about the relevance of lung function tests for the evaluation of efficacy of bronchial thermoplasty for severe asthma. The Specialist Advisers stated that improvement in symptoms and quality of life, and reductions in exacerbations and in the need for admission to hospital were more relevant efficacy outcomes than the results of lung function tests.

2.5.3 The Committee noted that many patients are young and it is therefore particularly important to monitor them for any possible long-term adverse effects such as development of bronchial stenosis.

3 Further information

3.1 For related NICE guidance see the NICE website.

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.

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.

Changes after publication
May 2012: minor maintenance

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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