INFORMATION ON THE USE OF BRONCHIAL THERMOPLASTY FOR SEVERE ASTHMA IN GLASGOW

(For use in a fully assessed and monitored patient as part of a difficult asthma service)

Background

Bronchial thermoplasty to the airways is a new treatment technique that involves the delivery of radio frequency energy to the airways with the aim of reducing airway smooth muscle mass and responsiveness in asthma\(^1\). Pre-clinical studies in experimental animals show that bronchial thermoplasty reduces airway smooth muscle\(^2\), increases airway size\(^3, 4\) and decreases airway responsiveness to methacholine\(^2, 4\).

Efficacy

Bronchial thermoplasty has shown efficacy in three RCTs in patients with moderate to severe asthma\(^5-7\). The AIR2 trial, involved the use of bronchoscopy with sham bronchial thermoplasty in 288 adult subjects with severe asthma\(^6\). Bronchial thermoplasty resulted in improvements from baseline in AQLQ scores compared with sham (bronchial thermoplasty, 1.35 versus sham, 1.16), with 79% of bronchial thermoplasty and 64% of sham subjects achieved changes in AQLQ of 0.5 or greater. In the post-treatment period, the bronchial thermoplasty group experienced fewer severe exacerbations, emergency department visits, and days missed from work/school compared with the sham group.

Safety

Bronchial thermoplasty is associated with short-term increases in asthma-related morbidity which can include hospital admission for asthma\(^5-7\). Long-term safety of bronchial thermoplasty in patients recruited to the AIR1 trial reported the absence of clinical complications and the maintenance of stable lung function over a 5-year period post-bronchial thermoplasty\(^8\).

Place in management of severe asthma

Factors that predict a therapeutic response to the bronchial thermoplasty in patients with severe asthma have not been identified from published clinical trials. Patients that may be considered suitable for bronchial thermoplasty should fulfil all the following eligibility criteria:

Eligibility criteria for thermoplasty

- Step 4 or 5 of the British Guideline i.e. asthma requiring regular maintenance medication that includes
  - High dose inhaled corticosteroid (greater than 750 μg fluticasone MDI per day or equivalent) AND
  - Long acting β2 agonist (LABA), with or without other asthma maintenance medications: oral prednisone, leukotriene modifiers, theophylline
- Patient with chronically poorly controlled asthma (ACT score <19) and considered compliant with their usual asthma medication
Bronchial Thermoplasty for Severe Asthma

- Adult age above 18 years of age
- Post-bronchodilator FEV₁ ≥ 55% predicted [Patients with values between 50-55% will be discussed by the team prior to considering the procedure]
- Patient must be considered suitable for bronchoscopy

**Assessment of patients for Bronchial Thermoplasty**

Patients with severe asthma who are considered potentially suitable for bronchial thermoplasty should be referred to the Difficult Asthma Clinic, Gartnavel General Hospital, Glasgow for further assessment.

At the clinic, the following review will be performed prior to the procedure:

- **Assessment of asthma control & quality of life**
  - Questionnaires: Asthma control score [Juniper, 6 questions], Asthma control test, Juniper AQLQ.
  - Number of hospital admissions in last year
  - Number of short courses of high dose oral steroids in last year
- **Assessment of co-morbidities affecting asthma control and adequacy of treatment**
- **Assessment of compliance with medication** [clinical/drug assays] and inhaler technique
- **Spirometry**: pre & post salbutamol
- **Exhaled nitric oxide levels**
- **Blood tests**: coagulation screen, FBC.
- **ECG**
- **Patient will be given information about the procedure and an information sheet to take home to consider**

**Arrange the following investigations:**

- **Peak expiratory flow diary for at least 1 week recordings of morning and evening PEF**
- **Detailed lung function test** [lung volumes and DLCO], body box technique
- **CT scan of the chest** [if not performed within the past 2 years]. To use the Leicester protocol for CT scans.
- **Methacholine challenge test** [Asthma/COPD Research Unit]
- **Induced sputum** [Asthma/COPD Research Unit]

**Arrangement for bronchial thermoplasty**

- **Thermoplasty appointment arranged.**
- **Instructions given:**
  - To phone Asthma Research unit and Prof Thomson’s secretary if any chest infection or asthma exacerbation occurs to cancel the procedure.
  - Oral prednisolone 50 mg for 5 days prescribed – 1 day before procedure, day of procedure and 3 days after.
  - Antibiotics [Augmentin 625 mg tid x5] prescribed for all, with instructions for it to be used if a chest infection occurs post procedure.
Bronchial Thermoplasty for Severe Asthma

Bronchoscopy instructions – fasting 4 hours, take asthma inhalers and other medication in the morning, no driving post procedure, bring an overnight bag in case the asthma worsens and requires admission, no anti-coagulants.

Bronchial thermoplasty procedure

Patients will be treated as day cases. Following pre-treatment assessment including review by the members of the Difficult Asthma Service, the procedure will be performed in the endoscopy suite, Gartnavel General Hospital by a team lead by Dr Steve Bicknell and Prof Neil Thomson. The ‘Alair’ bronchial thermoplasty system consists of a small radiofrequency generator and single use catheters in which an expandable electrode array is deployed by a handle mechanism. Bronchial thermoplasty is delivered to patients with asthma by flexible bronchoscopy under moderate sedation over three outpatient sessions.

On the day of the procedure:

Prior to procedure

- Check asthma stable and no infection in the past 2 weeks.
- Check spirometry is above 55% predicted post salbutamol
- Check consent form signed for bronchoscopy.
- Nebulised salbutamol 2.5 mg
- Atropine 0.6 mg prior to procedure
- Sedation with midazolam and alfentanyl, or as advised by anaesthetist
- Local anaesthesia of nose and throat

Perform procedure

- Use 1-2 litres of oxygen during procedure
- Monitor saturation and ECG if possible
- Ensure arrest trolley available

Post procedure:

- Monitor oxygen saturation, BP and pulse every 15 minutes for the first hour and then every 30 minutes for the next 4 hours.
- Check asthma stable before sending home. To be checked by respiratory physician.
- Repeat spirometry [PFT lab]
- Instruction sheet – contact details of hospital registrar, prednisolone continuation, antibiotic instructions, asthma clinic appointment 2 weeks where next procedure will be booked in if patient stable.
References


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May 2013

Review Date: May 2015
# ASSESSMENT AND FOLLOW UP AT THE ASTHMA CLINIC

<table>
<thead>
<tr>
<th>DATE</th>
<th>Screening</th>
<th>Follow up visits</th>
<th>3 month Visit</th>
<th>6 month Visit</th>
<th>12 month visit</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Prior to thermoplasty</td>
<td>2 weeks after each procedure</td>
<td>3 months after last procedure</td>
<td>6 months after last procedure</td>
<td>12 months after last procedure</td>
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<tr>
<td>Check all entry criteria met</td>
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<tr>
<td>Check risk factors for bronchoscopy</td>
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<tr>
<td>Check aspirin, clopidogrel, warfarin</td>
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<td>Blood- coagulation screen, FBC [+ as per BTS registry-IgE total and specific, IgG, IgA, IgM, auto antibody screen, ANCA, cortisol level, theophylline and prednisolone level where applicable] + genetic study blood and Paxgene tube</td>
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<td>ECG</td>
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<td>Exhaled nitric oxide</td>
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<td>CT scan of the chest</td>
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<td>FEV₁</td>
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<td>Asthma Control Test Score</td>
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<td>Mini Asthma Quality of Life Score [Juniper]</td>
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<td>Asthma Control Questionnaire [Juniper, 6 questions]</td>
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<td>EuroQoL questionnaire</td>
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<td>Hospital Anxiety and Depression Scale</td>
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<td>Lung volumes and DLCO</td>
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<td>Methacholine challenge test</td>
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<td>Induced sputum</td>
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<td>Any side effects?</td>
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<td>Any asthma exacerbation?*</td>
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* at baseline record steroid courses/exacerbations taken or increased from maintenance dose in the past year and at follow up visits record courses excluding those given for the procedure prophylaxis.