Five Consecutive cases of Bronchial Thermoplasty

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Disclosures

none
Asthma Overview: Prevalence, Morbidity and Mortality

- 24.6 million People diagnosed with asthma
- 12.8 million People experience asthma attacks
- 1.8 million Emergency room visits
- 456,000 Hospitalizations
- 3,447 Asthma-related deaths

Approximately 9 People Die From Asthma Each Day in the U.S.

Stepwise Approach for Managing Asthma

1. **Short-acting Beta\(_2\)-agonists**

2. **Low-dose Inhaled Corticosteroids (ICS)**

3. **Low-dose ICS + Long-acting Beta\(_2\)-agonists (LABA) or Medium-dose ICS**

4. **Medium-dose ICS + LABA**

5. **High-dose ICS + LABA and Consider Omalizumab**

6. **High-dose ICS + LABA + Oral Corticosteroids and Consider Omalizumab**

*Alternatives Needed*

Challenges in Managing Severe Asthma

- Prevalence of severe asthma (NAEPP) = 5-10%
- Many patients remain symptomatic despite standard of care medications
- Medications are limited, require adherence, and can have serious side effects
- High economic costs and resource utilization associated with medications, hospitalizations, physician visits and lost days of work/school ~ $20.7B
- Additional therapeutic treatment options are needed...
What is Bronchial Thermoplasty?

- A procedure that delivers thermal energy to the airways via a bronchoscope to reduce excess airway smooth muscle and limit its ability to constrict the airways.

- Outpatient hospital procedure performed over 3 treatment sessions, routinely under moderate sedation.

- Complementary treatment, and not a replacement, to current asthma reliever and controller medications.
Bronchial Thermoplasty Rationale

- Reduced Excessive Airway Smooth Muscle (ASM)
- Reduced Ability for Bronchoconstriction
- Reduced Asthma Symptoms and Exacerbations
- Improved Asthma Control and Quality of Life
Reduced ASM
12 Days Post-Treatment

Untreated
Treated

Miller et al. CHEST 2005; 127:1999
The Alair® Bronchial Thermoplasty System

- **Alair Catheter** – a flexible tube with an expandable wire array at the tip (introduced into the lungs through a standard bronchoscope)

- **Alair Radiofrequency (RF) Controller** – supplies energy via the Catheter to heat the airway wall
Case # 1

- 44 year old female referred for difficult to treat Asthma.
- History of asthma since childhood.
- Worse in the last 5-7 years.
- Current symptoms include wheezing and chest tightness 2-3 times a day requiring rescue inhaler.
Case # 1

- She usually has 4-5 exacerbations a year requiring steroids and or hospitalizations.
- Last hospitalization in 2004 and last ER visit in Dec 2011.
- Never been intubated.
- Patient has been seen by multiple pulmonologist in the past
Case # 1

- Spent 3 month in the national Jewish center and weeks at Duke for Asthma management.
- Symptoms persisted and as a teenager she was on steroids for 11 years.
Case # 1

Past Medical History:
- Asthma
- GERD
- Esophageal stricture

Surgical History:
- Esophageal dilatation
- Sinus polyps removed
- 3 C sections
- Plastic surgery
Case# 1

Social History:
- She is a nonsmoker.
- Marital Status: married
- Children: 3
- Education: Bachelor
- Occupation(s): Ultrasound technician full time job
- Pets: dog. Pets are indoor.
Case # 1

Medications:
- Advair HFA 230-21 2 Puffs BID
- Nasonex nasal spray
- Zafirlukast 20 mg PO BID
- Albuterol 90 mcg 2 puffs q 4hrs PRN
- Theophylline 300 mg CR BID
- Protonix 40 mg PO BID
Case # 1

PHYSICAL EXAM:

- BP 140/63 | Pulse 70 | Temp(Src) 36.3 °C (97.4 °F) (Oral) | Resp 20 | Ht 1.549 m (5' 1") | Wt 65 kg (143 lb 4.8 oz) | BMI 27.08 kg/m² | SpO2 97%

Body mass index is 27.08 kg/(m^2).
Case # 1

- **Pulmonary**: clear to auscultation bilaterally with no wheezes, rhonchi, or crackles
- **Cardiovascular**: S1, S2 normal, no murmur, rub or gallop, regular rate and rhythm
- **Abdomen**: soft, non-tender, non-distended and active bowel sounds.
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**Lung Volumes, Body Box**

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**Lung Volumes (DL)**

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**Diffusion Capacity**

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Case # 1
Case # 1

- Spiriva 18 mcg once daily
- Sleep study ordered
- Inhaler use assessed
- Xolair tried in past ...........
- Follow up in 3 months........
Case # 1

3 months later

1 more exacerbation requiring oral steroids.

Continues to have frequent bronchodilator use.

Sleep study: negative
Case # 1

- Bronchial Thermoplasty was performed……

- 1\textsuperscript{st} Session >>> LLL >>> 95 activations
- 2\textsuperscript{nd} Session >>> RLL >>> 108 activations
- 3rd Session >>> LUL and RUL >>> 178 activations
Case # 1

Follow up at 1 year

- Improved QOL including better effort tolerance
- Decreased frequency of rescue inhaler to once weekly.
- No exacerbations requiring prednisone or ER visit
Asthma Control during the Year after Bronchial Thermoplasty

AIR1 Study

- Randomized, nonblinded study BT vs usual medical care

- Inclusion criteria
  - Moderate or severe persistent asthma, defined according to the guidelines of the Global Initiative for Asthma
  - Requiring daily therapy with ICS equivalent to a dose ≥ 200 μg or more of beclomethasone and LABA at a dose of ≥100 μg salmeterol or the equivalent
  - Airflow obstruction: prebronchodilator FEV1 60-85% predicted value and airway hyperresponsiveness, defined by a methacholine challenge PC20 < 8 mg/mL

Cox et al. NEJM 2007; 356:1327
AIR1 Study

- 11 centers in four countries
- Randomly assigned 112 subjects treated with ICS and LABAs and in whom asthma control was impaired when the LABA were withdrawn to either bronchial thermoplasty (n=56) or a control group (n=56)
- Therapy with ICS and LABA was resumed for the treatment period
- At 3 months asked to refrain from using LABA after this point unless they had a severe exacerbation or poor asthma control

Cox et al. NEJM 2007; 356:1327
AIR1 Study

For subjects whose asthma could be controlled without LABA, evaluations were performed after 6 and 12 months of treatment with ICS alone.

Subjects who needed to resume LABA therapy before 6 and 12 months visits were evaluated at those assessment points after withdrawal from LABA therapy for 2 weeks.

Adverse events

- Increase in cough and dyspnea in some patients day after procedure, majority resolved by 7 days
- 3% of events were listed as severe
- 6 hospitalizations in BT group, 2 in control group
- Similar during the period from 6 weeks to 12 months after treatment

Cox et al. NEJM 2007; 356:1327
AIR1 Study

Results at 12 months significantly greater improvements in the BT group vs control group for:

- Morning peak expiratory flow (39.3±48.7 vs 8.5±44.2 liters per minute)
- Scores on the AQLQ (1.3±1.0 vs 0.6±1.1)
- ACQ scores (reduction, 1.2±1.0 vs 0.5±1.0)
- Percentage of symptom-free days (40.6±39.7 vs 17.0±37.9)
- Symptom scores (reduction, 1.9±2.1 vs 0.7±2.5)
- Fewer puffs of rescue medication were required

Cox et al. NEJM 2007; 356:1327
AIR1 Study

A

- Bronchial-thermolplasty group
- Control group

Mild Exacerbations (no./subject/wk)

Baseline 3 Months 6 Months 12 Months

B

- Bronchial-thermolplasty group
- Control group

Severe Exacerbations (no./subject/wk)

Baseline 3 Months 6 Months 12 Months
AIR1 Study

[Graphs showing symptom-free days and symptom scores over time for different groups, with statistical significance indicated by p-values.]
Case # 2

- 60 y F with history of severe asthma x 30yrs
- Intubation leading to tracheotomy in 2003
- Annual admissions for asthma exacerbations
- Albuterol 6 x a day and her duonebs 2 x daily
- Currently still taking 20mg of prednisone daily
Case # 2

Unable to tolerate ICS/LABA and or Spiriva due to:
- Increased SOB
- Recurrent URTI
- Increased cough

Could not tolerate Singulair due to gastric side effects.

Theophylline did not benefit
Case # 2

Work up so far has included:

- normal IgE levels
- Sinus surgeries several years ago with no more episodes of sinusitis
- negative sleep study
- negative allergy and autoimmune tests
- normal gastric pH testing
Case # 2

Past Medical History:
- asthma & bronchitis
- sinusitis

Surgical History:
- C section
- Tracheotomy
Case # 2

Social History:
- She reports that she has never smoked.
- Children: 4
- Passive Smoking Exposure: yes, exposed for 18 years
- Pets: cat and dog. Pets are indoor.
- Functional Capacity: Class 2
Case # 2

Medications:
- Albuterol HFA 90 2 puffs q 4 hrs PRN
- Duonebs (0.5/2.5) 3 mls q 6 hrs PRN
- Prednisone 20 mg PO daily
- Allegra 180 mg PO daily
Case # 2

**PHYSICAL EXAM:**
- BP: 130/75 mmHg
- Temp: 36.8 °C (98.2 °F)
- Pulse: 112
- Resp: 24
- SpO2: 96%
- Height: 160 cm (5' 3'')
- Weight: 55.339 kg (122 lb)
- Body mass index is 21.62 kg/(m²).
Case # 2

- **Pulmonary:** Wheezing bilaterally
- **Cardiovascular:** S1, S2 normal, no murmur, rub or gallop, regular rate and rhythm
- **Abdomen:** soft, non-tender, non-distended.
### Pulmonary Function Test Results:

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Case # 2

- Bronchial Thermoplasty was performed.......
- 1st Session >>> RLL >>> 76 activations
- 2nd Session >>> LLL >>> 65 activations
- 3rd Session >>> LUL and RUL >>> 98 activations
Case # 2

Follow up after 3 Months

- Improved QOL including better effort tolerance
- No exacerbations requiring prednisone or ER visit
- Patient weaned off oral prednisone
### Case # 2

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Safety and Efficacy of Bronchial Thermoplasty in Symptomatic, Severe Asthma

Ian D. Pavord¹, Gerard Cox², Neil C. Thomson³, Adalberto S. Rubin⁴, Paul A. Corris⁵, Robert M. Niven⁶, Kian F. Chung⁷, Michel Laviolette⁸, and the RISA Trial Study Group*

¹Glenfield General Hospital, University Hospitals of Leicester NHS Trust, Leicester, United Kingdom; ²St. Joseph’s Healthcare–McMaster University, Hamilton, Canada; ³Gartnavel General Hospital, University of Glasgow, Glasgow, United Kingdom; ⁴Irmandade Santa Casa de Misericórdia, Porto Alegre, Brazil; ⁵Institute of Cellular Medicine, Newcastle University, Newcastle-upon-Tyne, United Kingdom; ⁶Wythenshawe Hospital, University of Manchester, Manchester, United Kingdom; ⁷National Heart and Lung Institute, Imperial College, London, United Kingdom; and ⁸Laval Hospital, Laval University, Quebec, Canada
RISA Study

- 32 patients with severe, symptomatic asthma randomized to BT vs usual care

Inclusion criteria

- High-dose ICS (750 mcg fluticasone/day or equivalent) and LABA (> 100 mcg salmeterol per day or equivalent)
- With or without oral prednisone (<30 mg/d), LTA, or theophylline
- Prebronchodilator FEV1 > 50% of predicted
- Demonstrable airway hyperresponsiveness by methacholine challenge with methacholine or increase in FEV1 of at least 12% with SABA
- Uncontrolled symptoms despite taking maintenance medication
  - Use of rescue medication on at least 8 of the 14 days before enrollment
  - Daytime symptoms on at least 10 of the 14 days before enrollment)
- Abstinence from smoking for 1 year or greater and past smoking history of less than 10 pack-years

Pavord et al. Am J Respir Crit Care Med 2007; 176:1185
RISA Study

After the treatment period
- Subjects entered a 16-week steroid stable phase (Weeks 6–22)
- Followed by a 14-week steroid wean phase (Weeks 22–36)
- A 16-week reduced steroid phase (Weeks 36–52)

During the steroid wean phase
- Attempted to wean subjects, following a prospectively defined protocol, from oral corticosteroids (OCS) or ICS
- OCS dose was reduced by 20 to 25% of the baseline dose in steps of 2 weeks each
- For subjects successfully weaned to OCS daily doses of 5–7.5 mg, further attempts to reduce the OCS dose were per investigator discretion
- For subjects taking only ICS/LABA, the ICS dose was tapered in three stages by 20 to 25% of the baseline dose every 4 weeks to a minimal dose of 100–600 mcg/day of fluticasone or equivalent

Pavord et al. Am J Respir Crit Care Med 2007; 176:1185
RISA Study

Black bars - BT group; White bars - control group

Change in rescue inhaler: puffs/7 days

Change in AQLQ scores

Change in pre-BD FEV1: % predicted

Change in ACQ scores

Black bars-BT group; White bars-control group
BT subjects had significant improvements vs control subjects in:
- Rescue medication use (-26.6 vs -1.5 puffs/7 d, P<0.05)
- Prebronchodilator FEV1% predicted (14.9 vs -0.94, P=0.04)
- ACQ scores (-1.04 6 vs -0.13 6 1.00, P=0.02)

4/8 BT patients vs 1/7 controls weaned off OCS

Reduction in OCS dose 63% vs 26%

7 hospitalizations for respiratory symptoms in 4/15 BT subjects during the treatment period
- 5 hospitalizations were within 3 days of treatment
- 2 subjects had segmental collapse involving the most recently treated lobe; 1 required bronchoscopy and aspiration of a mucus plug

Pavord et al. Am J Respir Crit Care Med 2007; 176:1185
Case # 3

- 44 y F with refractory Asthma.
- Diagnosed with Asthma at the age of 31 after her last pregnancy.
- Multiple ER and unscheduled office visits for asthma exacerbations.
- Several courses of oral prednisone in the last 2 years.
Case # 3

Work up so far has included:
- Positive GERD w/u s/p fundoplication
- Chronic sinusitis s/p sinus surgeries
- Negative sleep study
- Normal IgE levels and RAST panel.
Case # 3

Past Medical History:
- Asthma; GERD; and Obesity.

Surgical History:
- Sinus surgery; partial hysterectomy;
- Cholecystectomy; Gastric fundoplication;
- Carpal tunnel release (2011);
- Bunionectomy;
Case # 3

**Social History:**
- She reports that she has never smoked.
- Marital Status: married
- Children: 3
- Education: high school
- Occupation(s): administrative assistant in medical office full time job
- Pets: dog. Pets are indoor.
Case # 3

Medications:

- Albuterol 90 mcg 2 puffs bid q 4 hrs PRN
- Albuterol 2.5 mg nebulizer q 6 hrs PRN
- Montelukast 10 mg nightly
- QVAR 80 mcg 1 puff bid
- Advair (50/500) 1 puff bid
- Nasonex
- Prilosec 20 mg Po bid
Case # 3

PHYSICAL EXAM:
- BP 106/72 | Pulse 86 | Temp(Src) 36.8 °C (98.2 °F) | Resp 20 | Ht 1.524 m (5') | Wt 87.317 kg (192 lb 8 oz) | BMI 37.59 kg/m2 | SpO2 98% BMI is 37.59 kg/(m2).
Case # 3

Physical Exam:

- **Pulmonary**: clear to auscultation bilaterally wheezes present L base
- **Cardiovascular**: S1, S2 normal, no murmur, rub or gallop, regular rate and rhythm
- **Abdomen**: soft, non-tender, non-distended and active bowel sounds.
Case # 3

**Pulmonary Function Test Results:**

<table>
<thead>
<tr>
<th>Date</th>
<th>FVC (L)</th>
<th>%Pred</th>
<th>FEV1 (L)</th>
<th>%Pred</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/22/2012</td>
<td>2.47</td>
<td>78</td>
<td>1.77</td>
<td>69</td>
<td>72</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TLC (L)</th>
<th>TLC %Pred</th>
<th>RV (L)</th>
<th>RV % Pred</th>
<th>DLCO</th>
<th>DLCO % Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.49</td>
<td>119</td>
<td>3.37</td>
<td>231</td>
<td>29.82</td>
<td>134%</td>
</tr>
</tbody>
</table>
Case # 3

Bronchial Thermoplasty was performed……..

1st Session >>> LLL >>> 127 activations

2nd Session >>> RLL >>> 102 activations

3rd Session >>> LUL and RUL >>> 197 activations
Case # 3

- Pt had Chest pains and tightness after each treatment.
- Required unscheduled office visit 3 days after last treatment.
- Received 7 days of Prednisone and antibiotics.
Case # 3

On 3 months follow up:

- No more exacerbations
- Improved QOL and ability to perform ADL’s
- Decreased use of rescue medications.
Case # 3

### Spirometry

<table>
<thead>
<tr>
<th>Units</th>
<th>Pre Drug Reported</th>
<th>Pre Drug % Predicted</th>
<th>Predicted</th>
<th>Post Drug Reported</th>
<th>Post Drug % Predicted</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC L, btps</td>
<td>3.17</td>
<td></td>
<td>2.38 &lt;</td>
<td>75 &lt;</td>
<td></td>
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<tr>
<td>FEV1 L, btps</td>
<td>2.57</td>
<td></td>
<td>1.93 &lt;</td>
<td>75 &lt;</td>
<td></td>
</tr>
<tr>
<td>FEV1/FVC %</td>
<td>81</td>
<td></td>
<td>81</td>
<td>99</td>
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</tr>
<tr>
<td>FEFmax L/s</td>
<td>6.30</td>
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<td>4.03 &lt;</td>
<td>64 &lt;</td>
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</tr>
<tr>
<td>FEF25-75% L/s</td>
<td>2.76</td>
<td></td>
<td>2.03</td>
<td>74 &lt;</td>
<td></td>
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</table>

### Pulmonary Function Test Results:

<table>
<thead>
<tr>
<th>Date</th>
<th>FVC (L)</th>
<th>%Pred</th>
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<table>
<thead>
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<th>TLC(L)</th>
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<th>DLCO % Pred</th>
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<td>29.82</td>
<td>134%</td>
</tr>
</tbody>
</table>
Effectiveness and Safety of Bronchial Thermoplasty in the Treatment of Severe Asthma

A Multicenter, Randomized, Double-Blind, Sham-Controlled Clinical Trial

Mario Castro¹, Adalberto S. Rubin², Michel Laviolette³, Jussara Fiterman⁴, Marina De Andrade Lima⁵, Pallav L. Shah⁶, Elie Fiss⁷, Ronald Olivenstein⁸, Neil C. Thomson⁹, Robert M. Niven¹⁰, Ian D. Pavord¹¹, Michael Simoff¹², David R. Duhamel¹³, Charlene McEvoy¹⁴, Richard Barbers¹⁵, Nicolaas H.T. ten Hacken¹⁶, Michael E. Wechsler¹⁷, Mark Holmes¹⁸, Martin J. Phillips¹⁹, Serpil Erzurum²⁰, William Lunn²¹, Elliot Israel²², Nizar Jarjour²², Monica Kraft²³, Narinder S. Shargill²⁴, John Quiring²⁵, Scott M. Berry²⁶, and Gerard Cox²⁷, for the AIR2 Trial Study Group*
AIR2 study

Multicenter, international, randomized trial BT vs usual medical care with sham control group

Inclusion criteria

- Maintenance medications of ICS (≥1,000 mcg/d beclomethasone or equivalent) and LABA (≥100 mcg/d salmeterol or equivalent)
- Other medications allowed: LTAs, omalizumab (if used for at least 1 year prior), and oral corticosteroids (10 mg/d or less)
- Key inclusion criteria were
  - Subjects on stable medication regimen
  - Baseline Asthma Quality of Life Questionnaire (AQLQ) score 6.25 or lower
  - Prebronchodilator FEV1 >60% of predicted
  - Airway hyperresponsiveness (methacholine PC20 <8 mg/ml)
  - At least 2 days of asthma symptoms during the 4-week baseline period
  - Nonsmoker for at least 1 year with less than 10 pack-years smoking history

Castro et al. Am J Respir Crit Care Med 2010; 181:116
Changes in AQLQ Scores

Percentage of Subjects Achieving AQLQ Score ≥ 0.5 (MID)
Treated Per Protocol

** Posterior Probability of Superiority = 99.6%

- Sham
- BT

Change in Baseline from Average AQLQ Score

- < -0.5: 7.4%
- > 0.5 to < 0.5: 29.5%
- > 0.5: 80.9%

Percentage of Subjects
Health Care Utilization for Respiratory Symptoms During Post-Treatment Period

6 weeks after the last bronchoscopy procedure to 12 month follow-up

Events / Subject/ Year

Severe Exacerbations (Steroid) 32% decrease over Sham

Unscheduled Physician Office Visits 22% decrease over Sham

Emergency Room Visits 84% decrease over Sham

Hospitalizations 73% decrease over Sham

* Posterior Probability of Superiority = 95.6%
** Posterior Probability of Superiority = 99.9%
## Respiratory Symptoms Resulting in Hospitalization Following Procedure

<table>
<thead>
<tr>
<th></th>
<th>BT (N=190)</th>
<th>Sham (N=98)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>19 Hospitalizations in 16 Subjects</td>
<td>2 Hospitalizations in 2 Subjects</td>
</tr>
<tr>
<td>No. of Events (Incident Rate %)</td>
<td></td>
<td>No. of Events (Incident Rate %)</td>
</tr>
<tr>
<td>Asthma Aggravated</td>
<td>12 (6.3%)</td>
<td>Asthma Aggravated</td>
</tr>
<tr>
<td>Atelectasis</td>
<td>3 (1.6%)</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Lower Resp. Tract Infect.</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Low FEV&lt;sub&gt;1&lt;/sub&gt;</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Aspirated prosthetic tooth in airway</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
</tbody>
</table>

Castro et al. Am J Respir Crit Care Med 2010; 181:116
Case # 4

- 57-year-old white male with history of asthma since childhood.
- Worsening symptoms in the last few years.
- Several asthma hospitalizations.
- No intubations.
- Symptoms include: daily tightness and almost daily nighttime awakenings
Case # 4

- Rescue inhaler use from 5 times/day to 5 times a week.
- Impaired effort tolerance: Police officer pulled off from field to desk.
- On Xolair for the last 3 years and multiple bouts of Prednisone.
Case # 4

Past Medical History:
- Asthma, hypertension, sinus polyps/allergies.

Past Surgical History:
- Polypectomy years ago.

Social History:
- He has never smoked. Occasional use of alcohol. He works as a major in the police department.
Case # 4

Medications:
- Advair 500/50 1 puff bid
- Spiriva 18 mcg 1 puff daily
- Albuterol 80 mcg 2 puffs q 4 hrs PRN
- Albuterol 2.5 mg nebulizer PRN
- Xolair once every 4 weeks
Case # 4

Physical Exam:
- Height 182 cm, weight 92.5 kg, temperature 98.2, pulse 87, respiratory rate 20, oxygen saturation 93% on room air, blood pressure 134/73.
Case # 4

**HEENT:** PERRILA. EOMI. Conjunctivae nonicteric. Intraoral nasopharynx normal.

**Cardiovascular:** Regular rate and rhythm. No murmurs, rubs, or gallops.

**Respiratory:** Bilateral inspiratory and expiratory wheezes.

**Abdomen:** Soft, nontender, nondistended. No hepatosplenomegaly.
Case # 4
Case # 4

- FVC of 4.36 liters or 90% predicted
- FEV1 of 2.33 liters or 61% predicted
- FEV1/FVC ratio of 53%
- FEF 25/75 was 1.26 liters or 35% predicted.
- DLCO 76% of predicted
Case # 4

Bronchial Thermoplasty was performed……..

1st Session >>> RLL >>> 79 activations
2nd Session >>> LLL >>> 111 activations
3rd Session >>> LUL and RUL >>> 129 activations
Case # 4

- 6 months follow up:
  - Patient had no more flares.
  - No use of PO Prednisone.
  - Back to field work with no DOE.
  - Patient stopped using ICS as he did not feel the need for it.
### Case # 4

<table>
<thead>
<tr>
<th># Spirometry #</th>
<th>Pre-dilator</th>
<th>Post-dilator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actual</td>
<td>%Pred</td>
</tr>
<tr>
<td>FVC</td>
<td>5.99</td>
<td>119.79</td>
</tr>
<tr>
<td>FEV1</td>
<td>3.18</td>
<td>89.78</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>53.05</td>
<td>74.95</td>
</tr>
<tr>
<td>FEFmax</td>
<td>6.11</td>
<td>66.22</td>
</tr>
<tr>
<td>FEF25-75%</td>
<td>1.29</td>
<td>38.68</td>
</tr>
</tbody>
</table>

- FVC of 4.36 liters or 90% predicted
- FEV1 of 2.33 liters or 61% predicted
AIR1 Follow-Up

Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial

Neil C Thomson¹*, Adalberto S Rubin², Robert M Niven³, Paul A Corris⁴, Hans Christian Siersted⁵, Ronald Olivenstein⁶, Ian D Pavord⁷, David McCormack⁸, Michel Laviolette⁹, Narinder S Shargill¹⁰, Gerard Cox¹¹, the AIR Trial Study Group
AIR1 5 Year Follow-up

- Rate of respiratory adverse events (AEs/subject) was stable in years 2 to 5 following BT (1.2, 1.3, 1.2, and 1.1, respectively.)
- No increase in hospitalizations or emergency room visits for respiratory symptoms in Years 2, 3, 4, and 5 compared to Year 1.
- FVC and FEV1 values showed no deterioration over the 5 year period in the BT group.
- Mean reduction from baseline in ICS dose for BT subjects was 182 μg/day, 135 μg/day, 150, 151 μg/day, and 194 μg/day at Years 1, 2, 3, 4, and 5 respectively.
- 57% of BT subjects reported a decrease in LABA use, 40% of subjects reported no change in LABA use, and 3% reported an increase in LABA use.
- Sustained improvement over baseline in the methacholine PC20 doubling in the BT group compared to the control group in each year out to Year 3.

Thomson et al. BMC Pulmonary Medicine 2011; 11:8
RISA 5 Year Extension Study

- Overall hospitalization rate 0.23 per patient per year vs 0.71 prior to BT
- ED visits 0.12 per patient per year vs 0.36 prior to BT
- FEV1 remained stable over 5 years

Pavord et al. Ann Allergy Asthma Immunol 2013; 111:402
Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma

Mario Castro, MD, MPH*; Adalberto Rubin, MD†; Michel Laviolette, MD‡; Nicola A. Hanania, MD, MS§; Brian Armstrong, MS¶; and Gerard Cox, MB|| for the AIR2 Trial Study Group
AIR2 Follow-up

- Long-term safety follow-up phase of the Asthma Intervention Research 2 (AIR2) Trial
- Evaluated proportion of subjects who experienced exacerbations, adverse events, or healthcare utilization during the first 2 years after treatment
- Pre- and post-bronchodilator FEV1 values remained stable between year 1 and year 2 after BT

# AIR2 Follow-Up

<table>
<thead>
<tr>
<th>Percentage of Subjects</th>
<th>Baseline Sham</th>
<th>Year 1 Sham</th>
<th>Baseline BT</th>
<th>Year 1 BT</th>
<th>Year 2 BT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe exacerbations</td>
<td>57.1</td>
<td>39.8</td>
<td>51.6</td>
<td>30.9</td>
<td>23.0</td>
</tr>
<tr>
<td>Respiratory adverse events</td>
<td>42.9</td>
<td></td>
<td>28.7</td>
<td></td>
<td>26.5</td>
</tr>
<tr>
<td>ER visits</td>
<td>31.6</td>
<td>15.3</td>
<td>28.9</td>
<td>5.0</td>
<td>6.6</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>4.2</td>
<td>4.1</td>
<td>6.1</td>
<td>3.3</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Respiratory adverse events: wheezing, dyspnea, cough, chest discomfort, nocturnal awakenings, URI, chest congestion, nasal congestion, throat irritation

AIR2 5 Year Follow-Up Data

- Severe exacerbations decreased by 44%
- ED visits decreased by 78%

Weschler et al. J Allergy Clin Immunol 2013; 132:1295
AIR2 5 Year Follow-Up Data

Weschler et al. J Allergy Clin Immunol 2013; 132:1295
AIR2 5 Year Follow-Up Data

- **HRCT evaluation**
  - 3 patients noted to have bronchiectasis
  - 1 with worsened pre-existing bronchiectasis
  - 1 had bronchiectasis in 2 lobes including untreated RML
  - 1 had new bronchiectasis
  - No evidence of bronchial stenosis or bronchiolitis obliterans in any patient

- **Medication changes**
  - 28% had a \( \geq 50\% \) decrease in ICS dose
  - 12% weaned off LABA
  - 9% weaned off LABA and ICS
  - 7% required no maintenance asthma medications

Weschler et al. J Allergy Clin Immunol 2013; 132:1295
Case # 5

- 60 year old female with dyspnea and cough.
- Symptoms since the last 18 months.
- Cough associated with greenish expectoration.
- DOE with ADL’s
- Multiple courses of antibiotics and steroids in the last 18 months.
- Lower extremity edema.
Case # 5

Past Medical History:
- Asthma
- COPD
- CAD

Social History:
- 50 pack year. Quit a year ago.
- Owner of a tile company.
- Denies any exposures.
- No pets.
Case # 5

**Medications:**
- Aclidinium 400 mcg 2 puffs bid
- Asmanex 80 mcg 2 puffs bid
- Albuterol MDI 2 puffs q 4 hrs PRN
- Prednisone 20 mg PO daily
- Daliresp 500 mcg PO daily
Case # 5

**Physical Examination:**
- BP: 111/78 mmHg
- Temp: 37.1 °C (98.8 °F)
- Pulse: 92
- Resp: 20
- SpO2: 93 % (2 lit/min)
- Height: 165.1 cm (5' 5'')
- Weight: 98.93 kg
- Body mass index is 36.29 kg/(m^2).
Case # 5

**Pulmonary:** clear to auscultation bilaterally with no wheezes, rhonchi, or crackles

**Cardiovascular:** S1, S2 normal, no murmur, rub or gallop, regular rate and rhythm

**Abdomen:** soft, non-tender, non-distended.
Case # 5
### Spirometry

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>Pre Drug Reported</th>
<th>Pre Drug % Predicted</th>
<th>Predicted</th>
<th>Post Drug Reported</th>
<th>Post Drug % Predicted</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>L/btps</td>
<td>2.28 &lt;</td>
<td>66 &lt;</td>
<td>3.43</td>
<td>2.45 &lt;</td>
<td>72 &lt;</td>
<td>8</td>
</tr>
<tr>
<td>FEV1</td>
<td>L/btps</td>
<td>1.12 &lt;</td>
<td>42 &lt;</td>
<td>2.65</td>
<td>1.15 &lt;</td>
<td>43 &lt;</td>
<td>3</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>%</td>
<td>49 &lt;</td>
<td>63 &lt;</td>
<td>78</td>
<td>47 &lt;</td>
<td>68 &lt;</td>
<td>-5</td>
</tr>
<tr>
<td>FEFmax</td>
<td>L/s</td>
<td>4.05 &lt;</td>
<td>69 &lt;</td>
<td>6.45</td>
<td>3.63 &lt;</td>
<td>56 &lt;</td>
<td>-10</td>
</tr>
<tr>
<td>FEF25-75%</td>
<td>L/s</td>
<td>0.32 &lt;</td>
<td>13 &lt;</td>
<td>2.41</td>
<td>0.37 &lt;</td>
<td>15 &lt;</td>
<td>13</td>
</tr>
<tr>
<td>FEF25%</td>
<td>L/s</td>
<td>1.19</td>
<td></td>
<td></td>
<td>1.16</td>
<td></td>
<td>-3</td>
</tr>
<tr>
<td>FEF50%</td>
<td>L/s</td>
<td>0.36</td>
<td></td>
<td></td>
<td>0.45</td>
<td></td>
<td>25</td>
</tr>
<tr>
<td>FEF75%</td>
<td>L/s</td>
<td>0.16</td>
<td></td>
<td></td>
<td>0.19</td>
<td></td>
<td>-14</td>
</tr>
<tr>
<td>MVV</td>
<td>L/min·btps</td>
<td>34.88 &lt;</td>
<td>37 &lt;</td>
<td>93.03</td>
<td>42.21</td>
<td>45 &lt;</td>
<td>21</td>
</tr>
<tr>
<td>BP</td>
<td>mmHg</td>
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<tr>
<td>Pimax /MIP</td>
<td>cmH2O</td>
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<td></td>
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<td>-74.22</td>
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</tr>
<tr>
<td>PEmax /MEP</td>
<td>cmH2O</td>
<td></td>
<td></td>
<td></td>
<td>94.31</td>
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</table>

### Lung Volumes, Body Box

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>Pre Drug Reported</th>
<th>Pre Drug % Predicted</th>
<th>Predicted</th>
<th>Post Drug Reported</th>
<th>Post Drug % Predicted</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC</td>
<td>L/btps</td>
<td>2.54 &lt;</td>
<td>74 &lt;</td>
<td>3.43</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC</td>
<td>L/btps</td>
<td>1.88</td>
<td>72 &lt;</td>
<td>2.62</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ERV</td>
<td>L/btps</td>
<td>0.66</td>
<td>81</td>
<td>0.81</td>
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<td></td>
<td></td>
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<tr>
<td>FRC</td>
<td>L/btps</td>
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<td>2.76</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>RV</td>
<td>L/btps</td>
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<td>134 &gt;</td>
<td>1.95</td>
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<td></td>
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<tr>
<td>TLC</td>
<td>L/btps</td>
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<td>96</td>
<td>5.38</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV/TLC</td>
<td>%</td>
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<td>140 &gt;</td>
<td>36</td>
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<tr>
<td>RAW</td>
<td>cmH2O/L/s</td>
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<td></td>
<td>1.39</td>
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</table>

### Lung Volumes (DL)

<table>
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<tr>
<th></th>
<th>Units</th>
<th>Pre Drug Reported</th>
<th>Pre Drug % Predicted</th>
<th>Predicted</th>
<th>Post Drug Reported</th>
<th>Post Drug % Predicted</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC</td>
<td>L/btps</td>
<td></td>
<td></td>
<td>3.43</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC</td>
<td>L/btps</td>
<td></td>
<td></td>
<td>2.62</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ERV</td>
<td>L/btps</td>
<td></td>
<td></td>
<td>0.81</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRC</td>
<td>L/btps</td>
<td></td>
<td></td>
<td>2.76</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV</td>
<td>L/btps</td>
<td></td>
<td></td>
<td>1.95</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>TLC</td>
<td>L/btps</td>
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<td>5.38</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>RV/TLC</td>
<td>%</td>
<td></td>
<td></td>
<td>36</td>
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</tbody>
</table>

### Diffusion Capacity

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>Pre Drug Reported</th>
<th>Pre Drug % Predicted</th>
<th>Predicted</th>
<th>Post Drug Reported</th>
<th>Post Drug % Predicted</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dsb</td>
<td>ml/min/mmHg</td>
<td>10.79 &lt;</td>
<td>45 &lt;</td>
<td>23.88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DsbHb</td>
<td>ml/min/mmHg</td>
<td>10.79 &lt;</td>
<td>45 &lt;</td>
<td>23.88</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Case # 5

Other investigations to date:
- Normal IgE levels.
- Sleep study was normal.
- Normal AAT levels.
- ECHO shows diastolic dysunction.
Case # 5

Assessment:

- Patient has significant emphysema.
- Unlikely that patient has pure asthma.
- Patient will not benefit from BT since emphysema appears to be the predominant pathology.
Case # 5

Following Medications adjustments were made:

- Asmanex switched to Dulera
- Azithromycin 250 mg PO qod
- Theophylline SR 400 mg nightly
- Lasix 20 mg PO bid
Who is Appropriate for Bronchial Thermoplasty?

- **FDA Indication:** The Alair® Bronchial Thermoplasty System has been approved by the FDA for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

- Adult severe, persistent asthmatics (≥ 18 years old)

- Inadequate control despite combination of inhaled high dose corticosteroids (ICS) and a long-acting beta-agonists (LABA)

- Estimated 5% of asthma patients are severe persistent and not well controlled, therefore may be BT candidates

- Able to safely undergo bronchoscopy per hospital guidelines
Who is Not Appropriate for Bronchial Thermoplasty?

Contraindications:

- Patients that have a pacemaker, internal defibrillator, or other implantable electronic device

- Patients that have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines

- Patients that have previously been treated with the Alair® System