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Kathy Mohammadi  
*University of North Dakota*

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# Effectiveness and Safety of the Bronchial Thermoplasty Procedure

## Procedure

Kathy Mohammadi, PA-S

Department of Physician Assistant Studies, University of North Dakota School of Medicine & Health Sciences

Grand Forks, ND 58202-9037

### Abstract

- Asthma: a heterogeneous disease characterized by chronic airway inflammation resulting in respiratory difficulty.
- Bronchial Thermoplasty (BT): a bronchoscopy procedure that delivers radiofrequency energy to the tissues of airway walls thus heating the tissue, causing ablation to reduce the mass of the airway smooth muscle (ASM), hence attenuating bronchoconstriction.
- BT was designed to decrease, de-bulk or partially eliminate excess smooth muscle tissue in the distal airways, with a subsequent decrease in the number of severe asthma attacks.
- BT is an alternative treatment for patients with severe, uncontrolled asthma in which the airway smooth muscle is eliminated using radio ablation.
- In this project, several studies are presented to demonstrate the effectiveness and potential adverse impacts of BT.
- Special attention to a study performed to evaluate the safety and the effectiveness of BT in 580 asthma patients across 6 nations with symptoms despite being treated with high doses of Inhaled corticosteroid (ICS) and long acting beta agonist (LABA), the current standard of care for severe asthma.

### Introduction

- Asthma is the fourth leading cause of absence from work for adults, resulting in approximately 15 million missed or less productive workdays each year
- Severe asthma includes a multitude of heterogeneous group of phenotypes rather than one disease entity.
- Treatment for severe uncontrolled asthma is concentrated on tailoring to specific phenotypes driven by the endotypes.
- Per American Thoracic Society guidelines, severe asthma requires management with high-dose inhaled corticosteroids in addition to a second asthma controller, including potential utilization of systemic corticosteroids.
- Advances in treatment in the past six years have now provided us with new plans to modulate the airway smooth muscle with BT.

### Statement of the Problem

- High-cost ER bills for patients with uncontrolled asthma
- Some hospital administrators & pharmacy directors choose medications based on pricing, not on efficiency of treatment.
- Studies are needed to show the effectiveness and impact of Bronchial Thermoplasty in severe asthma patients and qualifications for it.

### Research Question

- What is the effectiveness and safety of the Bronchial Thermoplasty procedure on Asthma patients?
- What are the criteria to be qualified for Bronchial Thermoplasty in patients with severe asthma?

### Literature Review

#### Pathophysiology of BT

- Contractility of the airway smooth muscle is governed by pacemakers within the proximal airways, and when the thermoplasty ablates these pacemakers, the distal airway constriction relaxes.
- There also may be a phenotype of patients whose asthma is more likely to be characterized by large airway inflammation and obstruction, making these patients better candidates for benefiting from BT.

#### Safety & Effectiveness of BT

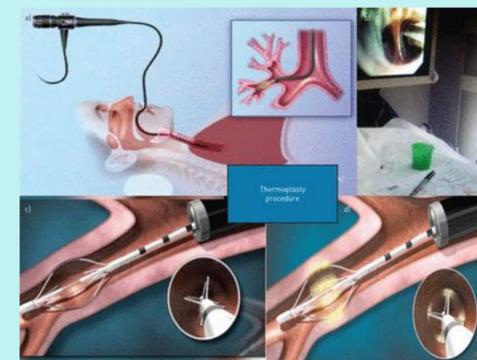
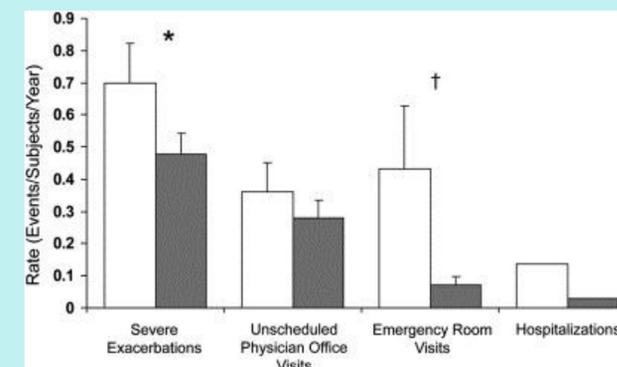
- AIR2 Trial Study: A multi-center, randomized, double-blind, sham-controlled trial with 297 patients with severe asthma despite being managed by ICS and LABA
- 32% reduction in severe exacerbations, 84% reduction in number of ER visits for respiratory symptoms, and 66% reduction in time lost from work, school and other daily activities as the result of asthma.
- 3 months of BT significantly decreased autonomic nerve fibers of the parasympathetic system leading to reduction in the number of severe asthmatic symptoms
- Reduction of airway structural abnormalities and the reduction of neuroendocrine epithelial cells.
- Thickening of submucosal nerves and the SBM

#### Cost Effectiveness of BT

- Markov model: sensitivity to the cost of the Bronchial Thermoplasty procedure and to the rate of hospitalizations.
- Patients who had one or more hospitalizations within a year, using Bronchial Thermoplasty would be cost-effective at US\$5500/QALY
- Financial savings can be observed three to four years after initiating the Bronchial Thermoplasty procedure in patients who are either Omalizumab non-responders or on corticosteroids who were contraindicated for Omalizumab.
- In patients with moderate-to-severe allergic asthma, there is more than a 60% chance that BT compared to Omalizumab and standard therapy becomes cost-effective at the patients willingness to pay (WTP) of \$100,000/QALY

### Discussion

- Patients treated with BT had only 0.19 points enhancement in AQLQ scores (1.35 vs. 1.16 with sham procedure), falling well short of the cutoff of 0.5 points for a “clinically meaningful” improvement in the AQLQ over the sham group
- Patients treated with BT had significantly fewer emergency room visits, reduced exacerbations, and fewer days missed from school or work
- Both the sham and BT groups exhibited clinically significant AQLQ improvement, raising the question that it may have been the perception of undergoing an invasive procedure that led to the patient-perceived benefits. The authors cited no reported differences in FEV1, peak flow, or rescue medication usage between the sham and treatment groups.
- Treated subjects who were already taking high doses of ICS and LABA were found to have a similar magnitude of improvement when compared to subjects in previous asthma studies taking less medication.
- Additional long-term clinical trials are needed to approve the benefits of BT
- AIR2 trial criticized for its method to patient selection - Patients with more severe asthma (low FEV1, greater than 2 exacerbations or pneumonias in the previous year, or greater than 3 oral steroid bursts in the previous year) were excluded from the study, raising doubts on extending the benefits of Bronchial Thermoplasty to such patients



### Applicability to Clinical Practice

- Minimally invasive procedure
- Per the Global Initiative for Asthma, BT may be considered for patients with uncontrolled asthma, whose symptoms remain severe despite treatment with drug-based regimens
- ACAAI recommends that insurers provide coverage for Bronchial Thermoplasty for those adult patients who meet the strict requirements
- BT is not expected to be done on individuals who have a known allergy to atropine, benzodiazepines, and lidocaine; neither is it suggested for those with a pacemaker, implantable cardioverter defibrillator or other implantable electronic devices
- Three treatment periods with approximately 3-week intervals are suggested: first session involves the right lower lobe; the second session targets the left lower lobe; the third session follows with both upper lobe
- Each bronchus is treated along its entire visible length - No area should be treated more than once
- tremendously impacted the government financials and significantly reduced expenses associated with the emergency room – covered by Medicaid

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