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Effectiveness and Safety of the Bronchial Thermoplasty Procedure

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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.

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 benefit 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$550/QALY
- Financial savings can be observed three to four years after initiating the Bronchial Thermoplasty procedure in patients who are either Omaluzumb or responders or on corticosteroids who were contraindicated for Omaluzumab.
- In patients with moderate-to-severe allergic asthma, there is more than a 60% chance that BT compared to Omaluzumab 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), failing 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 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 were who were 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

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; each 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 financial and significantly reduced expenses associated with the emergency room – covered by Medicaid

References


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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.