Review of a New Treatment for Severe Asthma:

The Practicality of Bronchial Thermoplasty

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Abstract

A new treatment termed bronchial thermoplasty (BT) was recently approved by the Food and Drug Administration in 2010 for treatment of uncontrolled, severe asthma. This paper will provide a general summary of asthma and its negative implications that affect both patients suffering from it and the economy. Criteria that determine asthma to be severe and common treatment for less severe asthma will then be presented from research obtained by Pastis, Silvestri, and Shepherd (2013); this will be followed by an explanation of the BT procedure. Next, an analysis of several articles that review research studies conducted using BT will be given. The article by Thomson, Bicknell, and Chaudhuri (2012) indicates the use of BT is safe and effective, and includes minor adverse reactions. Doeing et al. (2013) has the same conclusion; considering minor adverse reactions, BT is a practical treatment for uncontrolled, severe asthma. These conclusions are validly challenged by Michaud and Ernst (2011). Using these articles, the practicality of using BT to control severe asthma will be studied.
A new treatment called “bronchial thermoplasty” (BT) is now available in the United States for patients suffering from uncontrolled, severe asthma. Although BT has been approved by the Food and Drug Administration, there is still much to be learned about it because of its modernity. The treatment is performed on adults; however, it is not approved for children or when more common treatments delivered via inhalers or nebulizers are effective in reducing symptoms. Not only are severe symptoms life-threatening; they also cause undue financial burdens. Asthma costs the United States millions of dollars in medical costs and work-related problems (Kelly III, 2012). If shown to be effective, BT could save both lives and money. The exact cost of BT is not reported, but its potential success as a treatment may reduce long-term costs of severe asthma and therefore be an invaluable step in the right direction for effective asthma care. The question being explored here is: Is bronchial thermoplasty a practical and safe treatment for reducing severe, uncontrolled asthma symptoms? Additional research should be conducted, but from the available information, BT appears to be a legitimate treatment for these patients.

Brief Review of Asthma

Asthma is an illness that affects one’s ability to breathe properly. It is “characterized by episodic reversible airway obstruction, increased bronchial reactivity, and airway inflammation,” and has various impacts on an individual (Kelly III, 2012). Aside from the physical health effects, asthma can negatively affect an individual’s social health and bank account, especially when it is severe. Many patients are given inhalers or nebulizers to control their asthma symptoms, but these treatments do not work for everyone. Those with uncontrolled asthma face
obstacles that can severely impact their social lives. It is worrisome to go out to social gatherings when one does not know where an asthma attack could occur. When an inhaler is not enough to control breathing, the uncertainty of one’s environment would be frightening; attacks can be triggered by factors such as pollen, cigarette smoke, and changing weather (Hatfield, 2010). These examples are nearly impossible to avoid when one is not in their own home. Trips to the emergency room and special doctors’ appointments are financial burdens to patients with severe asthma, not to mention the cost to the United States as a country. In 1998, Kelly III (2012) reports that the asthma cost the United States an estimated $12.7 million and worldwide, “more than half of all expenditures are attributed to the 10-20% of patients with the most severe disease.” The prevalence of asthma has been increasing over the past few years, which in turn increases the financial effects of the disease.

Description of Bronchial Thermoplasty (BT)

Decreasing the financial burden of asthma is a concern for patients and researchers, alike. BT could theoretically aid in this effort, assuming it is not only effective short term, but long-term as well. The goal of this internal procedure is to widen the airway: “energy provided by the Alair catheter (Asthmatx, Inc., Mountain View, CA, USA) introduced via a flexible bronchoscope [is used] in order to reduce airway smooth muscle mass and decrease bronchial reactivity” (Doeing et al., 2013). With less tissue present, the potential for intense inflammation is also lessened. BT is performed in an outpatient setting, and a full treatment consists of three rounds of the procedure while the patient is sedated. The procedures are conducted two to three weeks apart, and sterilization is maintained by utilizing a new, disposable catheter for each procedure. There are several indications and contraindications that doctors must consider before they perform this treatment on patients, and Diaz-Mendoza, Chong, Hai-dong and Simoff (2013)
provide a brief list of each in Perspective: Bronchial Thermoplasty. Indications include: severe, daily asthma symptoms; daily nighttime symptoms; and repeated daily use of short-acting beta 2-agonists (inhalers). Some contraindications include: implanted electronic device; sensitivity to medications used in procedure; and comorbidities with asthma. Taking these criteria into account, patients may or may not be cleared for BT.

Common Treatments for Asthma

Before determining the practicality of BT, other treatments for asthma should be examined. Pastis et al. (2013) and Hatfield (2010) provide useful analyses of various asthma treatments, which will be summarized now. One class of treatment is short-acting beta agonists which are usually delivered via inhaler or nebulizer. These medications are useful for sudden onset of asthma symptoms and can also be used in preparation for exercise. Short-acting beta agonists work as bronchodilators; they relax the muscle which opens up the airway and allows for improved ventilation. Another class of treatment is inhaled corticosteroids. Because these medications are classified as steroids, they are stronger, and potentially have more risks, than short-acting beta agonists. Like short-acting beta agonists, however, inhaled corticosteroids are delivered via inhalers. Their goal is to reduce inflammation in the bronchial tubes, and they also tend to reduce the amount of mucous in the airway. While short-acting beta agonists are intended for short-term treatment of asthma, inhaled corticosteroids are intended for long-term relief. Sometimes, a combination of these two medications is used in one inhaler to receive the combined effects. (Pastis et al., 2013; Hatfield, 2010)

A less common treatment for asthma is a leukotriene receptor antagonist. These are similar to short-acting beta agonists, but are not typically preferred over inhaled corticosteroids. A fourth type of treatment, long-lasting beta agonists, are similar to short-acting beta agonists but
are mostly combined with inhaled corticosteroids. An important determinant for the type of treatment one receives is age; most children will receive inhalers as their first treatments. For patients with mild or moderate asthma, one or a combination of these medications is used to effectively control their symptoms. Unfortunately, not all levels of asthma required simple treatment. (Pastis et al., 2013; Hatfield, 2010)

Studies Examining BT

Various studies have been done to determine the effectiveness of BT for treatment of severe asthma. One article entitled *Bronchial Thermoplasty for Severe Asthma* (Thomson et al., 2012) reviews three studies regarding the effectiveness of BT, two of which will be mentioned. The first study examined a group of thirty-two individuals with severe, uncontrolled asthma. These patients had asthma that did not respond to treatments with inhaled corticosteroids, long-acting beta agonists, or leukotriene antagonists. The individuals were split into two groups; one group received the common treatments described above and the other group received BT in addition to the common treatments. Weeks after the initial treatments, the patients were assessed and patients treated with BT reported more improvement in asthma symptoms than those without it. A year after the initial treatment, there was a re-assessment that showed the same results; patients with BT still reported more improved symptoms. Fortunately, this study not only suggested immediate relief of asthma symptoms, but longer-term relief as well. (Thomson et al., 2012)

In the same article, another similar study was reviewed. A major difference between this and the previous study was that this study employed a placebo effect. All patients were told they received BT, however not all did. Beginning at six months, patients were evaluated at three-month intervals up to one year, and the results were again promising. Patients that actually
received treatment consistently reported better quality of life. This article notes that a five-year follow-up is being conducted and shows a mostly positive outlook, with only two adverse reactions which will be mentioned later. (Thomson et al., 2012)

A second article, *Safety and Feasibility of BT in Asthma Patients with Very Severe Fixed Airflow Obstruction: A Case Series* (Doeing et al., 2013), sheds more light on the subject. Eight patients with asthma determined to be severe and uncontrolled were chosen, but unlike in the first two studies, these patients had already received the three rounds of BT. Information about the eight patients was collected and included data from one year prior to and data from fifteen to seventy-two weeks after the procedure. No patients were reported to experience death or severe adverse reactions. Unfortunately, it is noted that quality of life reports were not given in this study, possibly because it is difficult to determine after such a short period of time. Even without the quality of life reports, the conclusion of the study states that the researchers believe BT could be a safe and effective treatment for severe asthma when performed by professionals. They support its use when common asthma treatments are not effective. (Doeing et al., 2013)

**Reported Risks of BT**

In the first two studies, the same risks were reported. The reported side effects were short term and included “wheeze, cough, chest discomfort, night awakening and discolored sputum,” along with increased hospitalizations (Thomson et al., 2012). At the five-year mark, two adverse reactions were reported; cold symptoms and bronchitis. However, these were not fatal and did not require hospitalization. (Thomson et al., 2012)

The second article does include several adverse reactions; however, they are described as not unexpected and therefore not severe relative to what could have happened. Between the eight study subjects, there were reports of “wheezing, increased bronchodilator use, atelectasis,
lower respiratory tract infection, [ ] hemoptysis,” and necessary overnight observation (Doeing et al., 2013).

Counter Argument

Michaud and Ernst’s (2011) Counterpoint: Efficacy of Bronchial Thermoplasty for Patients with Severe Asthma. Is There Sufficient Evidence? Not Yet is a journal entry that expresses concern over the safety of BT because of the limited amount of studies conducted. The author makes a valid point; because the treatment is so new, it is impossible to realistically gauge its long-term physical effects. Tissue is destroyed during the procedure which could, hypothetically, lead to future complications. Also, Michaud and Ernst mention that the researchers of the studies assumed some outcomes rather than recording them directly, which leaves room for error. The authors caution that patients interested in BT should be properly informed of all data collected regarding the procedure. It is important to note that this journal entry was written in 2011, which is only a year after the procedure was approved. Since then, further evaluations of patients have shown promising results for the longer-term effectiveness of BT. (Michaud et al., 2011)

Lack of Cost-Effectiveness Evidence

*Quality-of-life Improvement and Cost-effectiveness of Interventional Pulmonary Procedures* (Pastis et al., 2013) examines what the title suggests. One of the procedures mentioned in the study is BT. It asserts that there is not enough information collected about the financial cost of the procedure to determine if it is worth the risk; however, other factors indicate it is. These include “improved QoL [quality of life], reduced symptoms, reduction in the rate of severe exacerbations, fewer emergency department visits, and fewer days lost from school or
work” (Pastis et al., 2013). For patients who have lived their entire lives with severe asthma symptoms, BT is promising.

Conclusion

From the studies examined, BT appears to be a safe choice for treating severe, uncontrolled asthma. When quality of life was reported, all study subjects who received the treatment had positive reports, with no negative reports given. Their severe symptoms improved and they could lead healthier lives. However, there were reported immediate side effects to treatment that include infection, cough, wheezing, and hospitalization; luckily none of these were fatal. In addition, follow-up assessments after at least one year showed no hospitalizations and only reported cold symptoms and bronchitis in patients.

It would be beneficial to conduct more studies on BT in order to further assess and confirm its effectiveness. In years to follow, there should be more follow-ups for the discussed studies to determine if there are any adverse reactions. It would be useful to see if BT could be an effective treatment for other illnesses aside from severe asthma; or, its effectiveness on less-severe asthma could be examined. If BT could safely and permanently remedy other forms of asthma, there could be a large market for it.

As previously stated, there is not much information regarding the cost-effectiveness of this treatment. This makes it difficult to determine whether it is practical finance-wise. If BT is popularized, the cost of it will definitely be a popular point of research. With health care laws changing in the United States, it is also difficult to determine what portion of it would be covered. In conclusion, BT is a safe treatment for severe asthma, but not enough research has been done to determine its financial practicality.
References


