Review of Single Centre Experience with Bronchial Thermoplasty in Obesity

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Abstract

Background

Bronchial thermoplasty (BT) is a bronchoscopic procedure that aims to reduce symptoms in patients with severe asthma by delivering controlled radiofrequency activations to reduce airway smooth muscle mass who are uncontrolled despite adequate therapy.

Objective

To evaluate response and outcomes of BT in asthma patients with obesity.

Methods

A retrospective review of patients who had BT for severe asthma performed at our institution. We examined baseline differences in eosinophil, IgE levels, controller agent uses before and after BT, symptomatology and exacerbation rates post-procedure. A comparative analysis was done using t-test for unequal variables for those reported to have benefitted from the procedure against those who did not.

Results

In total 23 patients were studied, 18 (78%) noted benefit from BT. Patients were predominantly female, 21/23 (91%) with average BMI of 37.9 and 35.3 kg/m² in improved and not improved groups. Patients with improvement following completion of all three BT procedures were likely to be weaned off chronic oral steroids or biologicals, reduced albuterol uses, report a subjective improvement in symptoms or reduced exacerbations within 1 year following completion of procedures. There was a statistically significant average weight loss reduction in the improved group compared to not benefitted of 6.4kg versus a gain of 2.5kg; hospitalization rates for exacerbations were higher than those reported in the AIR2 and PAS2 studies at 43%.

Conclusion

BT can be beneficial for obese patients with a potential decrease in exacerbations and reduced oral corticosteroid dosage and an anticipated increased rate of post-procedure exacerbation hospitalization.

Introduction:

Bronchial thermoplasty (BT) is a bronchoscopic procedure that aims to reduce symptoms in patients with severe asthma who are uncontrolled despite adequate therapy. BT works by delivering controlled radiofrequency activations to reduce airway smooth muscle mass. Decreasing mass and contractility of airway smooth muscle could decrease morbidity associated with asthma by lessening bronchoconstriction and airflow obstruction.
In 2009, the Asthma Intervention Research (AIR2) Trial was published showing that following completion of BT, the Asthma Quality of Life Questionnaire scores showed superior improvement in the BT group compared with sham \(^3\). In respect to improvements, the AIR2 trial also showed benefit in severe exacerbations, a significant increase in symptom-free days, fewer exacerbations, and utilization of health care\(^3\). The benefit of BT was reportedly persisting for at least 1 year in the AIR2 trial.

Following, Chupp et al. described a 3-year interim results of the Post-FDA Approval Clinical Trial Evaluating BT in Severe Persistent Asthma (PAS2) Study which importantly showed observational data amongst a population with higher mean body mass index (BMI) 32.5 versus 29.3 kg/m\(^2\)\(^4\). Comparing the PAS2 subjects and the AIR2 trial, PAS2 patients had an overall higher age, higher doses of maintenance medications and higher rates of severe asthma in the PAS2 subjects. More PAS2 subjects experienced hospitalizations (15.3% versus 4.2) and more severe exacerbations (74% vs 52%) in the 12 months prior to BT compared to AIR2 \(^4\). During the treatment period PAS2 compared to AIR2 study patients has more severe exacerbations (55.8% vs 40.5%) and emergency department visits (15.8% vs 5.3%) indicating a higher risk of BT in the PAS2 subjects.

In the AIR2 trial, 16 subjects (8.4%) required hospitalization post-treatment with a total of 19 hospitalizations, of which 10 of the 19 occurred within the first day of the procedure; all events were mentioned to have resolved with standard therapy \(^3\). Periprocedural adverse events requiring hospitalization or prolongation of hospitalization were comparable with the PAS2 trial at a rate of 13.2% and there was no difference in respiratory-related serious adverse events during the follow-up periods outside the treatment phases \(^3,4\).

Safety and efficacy data amongst a patient population with a higher mean body mass index would be of most importance when it comes to treating our patients in the real-world experience. Here we describe an analysis to evaluate the response and outcomes of BT in asthma patients with obesity.

**Methods:**

This study was designed to analyze the differences in patients who had benefited or not benefited from bronchial thermoplasty for severe asthma. It was a retrospective, case series, single centre study for patients who had the procedure performed between August 2018 through December 2020 (n=37). The study was approved by the ethics committee at the site.

Patients were examined those that had any BT procedure performed at our centre. Exclusion criteria consisted of patients who did not have all 3 procedures performed to completion or those who had incomplete data without the electronic medical records due to following up at another institution. Charts were examined to include the age of subjects, body mass index, eosinophil levels, IgE levels, controller agents used for asthma (inhalers, oral corticosteroids, biological agents), spirometry performed pre and post procedure, and hospitalization rates. The statistical comparisons were performed using the t-test for unequal variables. Patient’s charts were reviewed for up to a 12-month period post procedure completion.
Comparisons were performed of identifying patients who had a clinical benefit from the procedure. Success of bronchial thermoplasty was defined by self-reported improvement in quality of life, self-reported or documented reduction of exacerbation rate, reduction in controller agents over a 12-month period (ability to wean off chronic steroids or biologicals), or reduced use of rescue albuterol inhaler

**Results:**

In total twenty-three patients were included in the final analysis of the retrospective review. Fourteen of the thirty-seven patients who had BT procedure were excluded from the analysis either from not having completed all three bronchial thermoplasty procedures or having post procedure follow up at another institution from where follow up patient data was not able to be obtained.

Of the patients included, the majority were females (21/23, 91%), with an average age of 51 years old and average body mass index (BMI) 37.4 kg/m\(^2\) (Table 1). The average Eosinophil counts noted prior to BT were 235 ± 255 \(10^3/uL\) and average IgE count 262 ± 427 kU/L; all patients were on a minimal control of dual-inhaler therapy in addition to 15 patients on chronic oral corticosteroids (OCS) and 13 patients on biological agents.

In total 18/23 (78%) of patients were noted to have benefitted from BT while 5/23 (22%) did not. Both groups were predominantly female (94% vs 80%). There were no statistical differences in average age between the two groups, (53.3 ± 12.5 vs 43.4 ± 8.9 years, p = 0.052) in improved vs not improved respectfully, in addition to average BMI (37.9 ± 7.2 vs 35.3 ± 7.9 kg/m\(^2\) p = 0.28), average eosinophil count (212 ± 223 vs 320 ± 331 per uL, p = 0.28), average IgE levels (251 ± 427 vs 300 ± 424 IU/mL, p = 0.42) or average number of bronchial thermoplasty activations performed during the procedure (243 ± 49 vs 231 ± 67, p=0.38) (Table 1). There was no statistical difference in pre bronchial thermoplasty post-bronchodilator pulmonary function tests between the two groups of FEV1%, FVC% and FEV1/FVC ratio respectfully (68 ± 12 vs 77 ± 14, 71 ± 16 vs 89 ± 21, 81 ± 14 vs 75 ±1, p = 0.19, 0.11, 0.19) (Table 1).

In total 14/18 (78%) of improved patients were on chronic corticosteroids and 1/5 (20%) of non-improved, 8/18 (44%) were on biologics and all 5 of the non-improved patients were on biologics. Average dosage of daily prednisone of those on chronic corticosteroids was from improved and unimproved groups was 15 ± 10.8 mg and 20 ± 0 mg (p = 0.08), and average Beclomethasone dipropionate equivalent corticosteroids inhaler dose was 1389 ± 582 mcg and 1328 ± 578 mcg (p = 0.45) respectfully in improved and non-improved patients (Table 1).

Following completion of all three sessions of bronchial thermoplasty, all 18 patients with improvement reported clinical improvement of their asthma symptoms. Of the 18 patients, 10/18 (56%) were able to be titrated down or off their chronic oral corticosteroids or biologics, 3/18 (17%) were able to titrate down on their controller inhaler agents or reported a reduced use of rescue albuterol, and another 3/18 (17%) were able to report reduced hospitalizations, urgent care visits or exacerbations at the one year follow up (Table 2). For those patients on chronic oral corticosteroids, the average prednisone dose 15.0 ± 10.8 mg
compared to 4.3 ± 7.0 mg post BT treatment (p = <0.05). Prior to BT intervention, of the 18 patients, 14 were on chronic oral corticosteroids of which 12 patients were weaned down or off. Two patients were able to be weaned down and of the 10 that were completely weaned off had a pre-procedural average dose of 14.1 ± 12.3 mg Prednisone. Only 1/8 (12.5%) patients on biological agents’ pre-procedure were weaned off at the 12-month period. Most importantly, of the patients that improved, there was an average weight loss of 6.4 ± 5.9 kg compared to 2.5 ± 2.1 kg weight gain for those who did not benefit from BT (p < 0.05).

Of the five patients who did not show significant benefit from bronchial thermoplasty, 3 were later found to have asthma-like symptoms related to either vocal cord dysfunction (VCD), severe tracheobronchomalacia, or heart failure with preserved ejection fraction. After further investigation one other patient was diagnosed with seronegative vasculitis and one other patient improved following the addition of Benralizumab. No patients with no significant improvement had reduction of controller agents 1 year post procedure.

8 patients with improvement had post-BT completion spirometry with no significant difference between pre- and post-BT FEV1 (63 ± 15 vs 62 ± 18 %, p = 0.46), FVC (73 ± 14 vs 72 ± 17%, p = 0.44) or FEV1/FVC (76 ± 19 vs 70 ± 12, p = 0.24) (Table 3).

**Discussion:**

Patients with severe persistent asthma experience significant morbidity and higher mortality. To the authors knowledge, this is a first report examining the effects of bronchial thermoplasty one year post procedure completion in a patient population with obesity.

Of the 18 patients who had improved with bronchial thermoplasty, 14 were on chronic oral corticosteroids of which 2 were able to be weaned down and 10 patients in total completely off their chronic oral corticosteroids. In the Research in Severe Asthma (RISA) Trial, a controlled safety study in which 32 severe asthma patients (15 receiving BT and 17 with continued usual care) where undergone forced steroid withdrawal (5), demonstrated that the BT group demonstrated improved asthma control and reduced use of rescue medications prior to forced withdrawal and continued to show reduced short-acting bronchodilator usage, more symptom-free days and improved ACQ scores. The use of OCS and ICS fell by 63.5% and 28.6% in the BT group compared to 26.2% and 20% in the control usual care group (5). Comparing BT to Mepolizumab over a 12-month period, one study showed improvement but no differences between the two modalities for ACQ score, exacerbation rate, reduction in reliever use or oral corticosteroids (-3.3 ± 7.5 vs - 5.8 ± 6.7 mg/day) (6). In another study comparing 199 patients who were treated with omalizumab, mepolizumab, benralizumab or BT and to evaluate the efficacy of these treatments over a 12-month observation period, all agents resulted in statistically significant reduction in hospitalizations and reduction of exacerbations; however, the best OCS sparing effect was obtained by BT (-76%, p < 0.0001) and mepolizumab (-90.2%, p = 0.002) compared Omalizumab and Benralizumab (7). In our study, although small sample size, 8/18 improved patients were on biological agents pre-BT (2
on Benralizumab, 1 on Mepolizumab, 1 on Omalizumab, 1 on Reslizumab, 2 on Dupilumab and 1 on Omalizumab with Benralizumab), of whom all 6/8 patients on both a biologic and chronic OCS were completely titrated off their OCS following BT therapy, in addition to one patient not on chronic OCS was weaned off their inhaled corticosteroid dose. Compared to biologics, BT may have a comparable effect in improving severe refractory asthma, however an observation in our severe patient population was showing that BT consistently reduced OCS by average 10.7 mg (p<0.002). If symptoms remain persistent while on biologics, BT addition may add further asthma control and reduction of OCS as seen in our study of 10.1 mg (p<0.02) reduction in BT patients previously on biologics.

Of the patients who had improvement following the BT procedure, 16/18 (89%) were effectively able to be weaned off some portion of their chronic regimen. Weight loss may help obese patients obtain better control of their asthma. As increased airways resistance and closing of bronchioles can lead to asthma related symptoms, weight loss can improve mechanics such as chest wall offloading or positive pressure ventilation to limit bronchiole closure helping to relieve symptoms (8). In a 2015 study by Parkhale et al. a study involving 22 asthmatics with a BMI > 32.5 kg/m$^2$, weight loss resulted in an improvement in airway hyperreactivity, asthma control, lung function, and quality of life (9); while a more recent 2017 study also showed reduction in inflammatory markers (10). A 2019 systematic review involving four trials (246 children and 502 adults) concluded that weight loss from any measure (dietary restrictions, exercise or behavioral therapy) generally resulted in improved asthma control and quality of life (11). A 2015 study of 330 severely obese adults (BMI avg 37.5 kg/m2) found that a weight loss of >10% was required to produce meaningful improvement in asthma (12). In our study, weight loss of average 6.4 kg was a significant outcome, this could be possibly explained from a couple different stand points. First those patients with the most weight loss also were on higher doses of chronic corticosteroids pre procedure or were able to come off the corticosteroids entirely following completion of bronchial thermoplasty. In addition, there may have been an effect of increased mobility in these patients as they would be able to accomplish more with their activities of daily living without being inhibited as much with their asthmatic symptoms.

Another explanation of why BT may work in an obese population is the improvement potentially offered by improving airways resistance. In a 1993 study performed by Zerah et al, respiratory and airway resistance was determined of 46 individuals at three different stages of obesity and significant negative correlations with BMI were found (13). The authors of this study reported a significant correlation between airway conductance and functional reserve capacity in their study which suggest that low lung volume is crucial in determining the increase in resistance and previous studies by Briscoe had shown that airway conductance was linearly related to lung volumes (13–14). Along with a decrease in expiratory flow rates with a preserved FEV1/FVC ratio, the authors concluded that in obesity, airway abnormalities involved increase in proximal airways resistance rather than distal airways; an increase in respiratory resistance and airway resistance that was significant with the level of obesity that was related due to the decrease in lung volumes (13). In a study by Langton et al. utilizing body plethysmography, following BT treatment, they were able to show a significant 9% reduction in residual volume and 21%
reduction in airway resistance along with a 34% increase in airway conductance (15). Donovan et al. recently used human lung specimens to further describe the effects of BT. Using bronchial thermoplasty to cause a 75% reduction in airway smooth muscles, they were able to show a global redistribution of flow to the treated central airways leaning to reopening of small airways and improvement in lung function and flow patterns (16). This may help explain why in this obese population who are treated with BT, there is a clinical improvement in asthma without an improvement in spirometry values as was seen in our study in addition to previous studies demonstrated in the AIR2 trial and PAS2 study (3, 4). As increasing obesity may disrupt airways resistance and flow patterns, BT may lead to alterations causing more homogenous flow patterns which can reduce airway resistance and improve ventilation.

Although baseline weight or BMI is not reported, one observational study of 194 patients by Thomas et al. showed that the use of Mepolizumab had a significant reduction in mean oral corticosteroid dose and patient weight in those associated with positive clinical response 6 months following treatment initiation (17). Data on biological agents and weight loss is overall limited, further studies need to be conducted however BT may be of consideration sooner in obese patients who fail to show benefit from biological agents.

The post-procedure hospitalization rate for asthma exacerbations was higher than previously reported during the PAS2 and AIR2 studies at 43% compared to 13.2% vs 8.4% respectively (3, 4). Although our hospitalization rates were significantly higher, with a small sample size the value may not be as statistically significant in comparison to the previous larger studies. Nonetheless, patients who were hospitalized for asthma exacerbations did not have prolonged or complicated hospitalizations courses and over a 12-month period still received significant benefits from the BT procedure in relation to their asthma control.

The limitations of this study did revolve around the retrospective design. The groups of comparison were those patients with documented benefit from the procedure versus those who did not show significant improvement. With the retrospective design we were able to criticize those three of the five patients who may have been mis-diagnosed with severe asthma and had other uncontrolled etiologies to give them asthma-like symptoms. One patient who was later diagnosed with vocal cord dysfunction did have a suspicion prior to the therapy and was evaluated by Otolaryngology and was determined prior to the procedure that her symptoms were likely asthma related. Following the third procedure the patient required to be re-intubated for significant dyspnea and her diagnosis of VCD was confirmed at that time with direct laryngoscopy and improvement of stridor immediately following endotracheal intubation. Other limitations consisted of retrospective review of charts to determine how the patients best received benefit post BT and their exact asthma quality of life questionnaire (AQLQ) scoring was not able to be quantified.

In conclusion, bronchial thermoplasty may be a beneficial modality for obese patients with uncontrolled asthma in helping to reduce among of oral corticosteroids dependence, decrease in exacerbations faced and was associated with a significant reduction in weight loss 12 months post procedure. The procedure
may be offered to this patient population with an anticipated increased rate of post-procedure exacerbation hospitalization.

**Abbreviations**

Bronchial thermoplasty - BT, Body mass index - BMI, Eosinophil level - Eos, Immunoglobulin E - IgE, Oral corticosteroids - OCS

**Declarations**

Ethics approval and consent to participate:

The Institutional Review Board at Temple University approved the study IRB #: 28748 on Sept 2, 2021. Ethics Committee liaison is Shubhra Srivastava-Malhotra tud12873@temple.edu at Temple University.

Consent for publication: Not applicable

Availability of data and materials:

Data has been de-identified and can be requested from the authors and provided in an excel format. They are not publicly available due to institutional policy but are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

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Authors’ contributions:

ER analyzed and interpreted the patient data regarding the effects on bronchial thermoplasty. ER was a major contributor in the writing of the manuscript.

KS is the primary investigator and was a major contributor in the writing of the manuscript.

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Tables

Table 1: Demographics
| Demographics                  | Total (n=23) | Improved (n=18) | No improvement (n=5) | P-value (improved vs no-improvement) |
|------------------------------|--------------|-----------------|----------------------|--------------------------------------|
| Gender                       | 21 Female    | 17 Female       | 4 Female             |                                      |
|                              | 2 Male       | 1 Male          | 1 Male               |                                      |
| Average Age (years)          | 51.1 ± 12.5  | 53.3 ± 12.5     | 43.4 ± 8.9           | 0.052                                |
| Avg Body Mass Index (kg/m²)  | 37.4 ± 7.5   | 37.9 ± 7.2      | 35.3 ± 7.9           | 0.28                                 |
| Average Eosinophils before BT (x10³/uL) | 235 ± 255 | 212 ± 223       | 320 ± 331            | 0.28                                 |
| Average IgE before BT (kU/L) | 262 ± 427    | 251 ± 427       | 300 ± 424            | 0.42                                 |

Controller Medications

| ICS/LABA Dual Therapy | 7 | 7 | 0 |
|-----------------------|---|---|---|
| Triple Inhaler Therapy| 16 | 9 | 5 |
| Chronic Corticosteroids | 15 | 14 | 1 |
| Biologicals           | 13 | 8 | 5 |

| Avg Prednisone Dose | 15.4 ± 10.5 mg | 15.0 ± 10.8 mg | 20.0 ± 0 mg | 0.08 |
|---------------------|----------------|----------------|-------------|------|
| Avg Beclomethasone dipropionate equivalent | 1360 ± 582 mcg | 1389 ± 582 mcg | 1328 ± 578 mcg | 0.45 |

Pre-BT Spirometry Post-bronchodilator

| FEV1% | 70% ± 13% | 68% ± 12% | 77% ± 14% | 0.19 |
|-------|-----------|-----------|-----------|------|
| FVC%  | 75% ± 18% | 71% ± 16% | 89% ± 21% | 0.11 |
| FEV1/FVC | 73 ± 14 | 81% ± 14% | 75% ± 11% | 0.19 |
| FEF25-75% | 62% ± 26% | 66% ± 27% | 40% ± 5% | <0.05 |
**Table 2: Results**

| Demographics                              | Total (n=23) | Improved (n=18) | No improvement (n=5) | P-value (improved vs no-improvement) |
|-------------------------------------------|--------------|-----------------|---------------------|-------------------------------------|
| Avg weight change (kg)                    | -4.5 ± 6.5   | -6.4 ± 5.9      | +2.5 ± 2.1          | <0.05                               |
| Avg # activations                         | 240 ± 54     | 243 ± 49        | 231 ± 67            | 0.38                                |
| Reduced exacerbations or subjective clinical benefit | 17           | 0               |                     | <0.05                               |
| Reduced albuterol usage                   | 3            | 0               |                     | <0.05                               |
| Titrated off LAMA                         | 2            | 0               |                     | 0.08                                |
| Titrated off ICS                          | 4            | 0               |                     | <0.05                               |
| Decreased chronic steroids Dose           | 12           | 0               |                     | <0.05                               |
| Weaned off Biologics                      | 1            | 0               |                     | 0.17                                |

**Table 3: Spirometry performed prior to and following bronchial thermoplasty treatment in improved patients.**

| Peri/Post-BT spirometry (n=8) | Pre-BT | Post-BT | p-value |
|-------------------------------|--------|---------|---------|
| FEV1%                         | 63% ± 15% | 62% ± 18% | 0.46    |
| FVC%                          | 73% ± 14% | 72% ± 17% | 0.44    |
| FEV1/FVC                      | 76% ± 19% | 70% ± 12% | 0.24    |
| FEF25-75%                     | 56% ± 30% | 45% ± 29% | 0.26    |