

Anxiety level in severe asthmatics undergoing bronchial thermoplasty procedure

An observational study

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Abstract

Bronchial thermoplasty (BT) is one of the novel approved modalities in treating severe asthmatics to overcome their exacerbating symptoms such as increased anxiety. The purpose of this study was to evaluate anxiety level among severe asthmatics while undergoing BT procedure. This was an observational study where subjects self-evaluated their overall anxiety level using the burns anxiety inventory (BAI) questionnaire at baseline and prior to each of three BT treatments (broncho thermoplasty procedure 1, broncho thermoplasty procedure 2, and broncho thermoplasty procedure 3). The BAI questionnaire consisted of three different categories with each category having specific symptoms. Categories were grouped as: Anxious feelings, Anxious thoughts, and Physical symptoms. Subjects' Asthma Control Tests were also collected for analysis before and after the BT procedure. A total of 17 subjects with a mean age of 55.9 ± 14.5 years participated in the study. Fifty three percent were females ($n = 9$) and 41.2% ($n = 7$) were on prescribed anxiety medications. There was a significant drop in the patients' overall BAI anxiety level over time, $P < .0001$, in Anxious feelings ($P = .0001$), anxious thoughts ($P = .001$), and physical symptoms ($P = .025$). When analyzing the change in anxiety level among those who were not on prescribed anxiety medications, significant drop in overall anxiety level and in the subcategories were also noted. ($P < .05$). In addition, ACT scores showed a significant improvement (post vs pre) (18.5 ± 4.0 vs 13.3 ± 6.3 , $P = .03$; Cohen's $d = 0.73$). This study shows the effectiveness of BT in decreasing severe asthmatic anxiety levels from baseline to last BT treatment and this benefit was mostly noted in those who were not on any anxiety medications. A limitation of this study is that all subjects were recruited from a single center. Therefore, to further validate the study findings, a multi-center study needs to be conducted with a larger sample size.

Abbreviations: ACT = asthma control test, BAI = Burns Anxiety Inventory, BT = bronchial thermoplasty, BT1 = bronchial thermoplasty procedure 1, BT2 = bronchial thermoplasty procedure 2, BT3 = bronchial thermoplasty procedure 3.

Keywords: anxiety, bronchial thermoplasty, BT, severe asthma

1. Introduction

Asthma is a respiratory disease that affects approximately 19 million adults and 6.2 million children in the United States.^[1] The severity of asthma can range significantly from mild to severe, and treatments often need to be catered throughout their lives. A variety of factors are taken into account when selecting the best treatment regimen for the asthmatic patient and despite best efforts, asthmatic patients continue to experience asthma attacks. For the most severe asthmatics, these exacerbations

often result in trips to the emergency department. Annually, 10% of emergency department visits based on the national hospital ambulatory medical care survey are asthma-related.^[1,2] These visits cost the healthcare system around \$56 billion annually.^[3] According to the Center for Disease Control and Prevention, the number of deaths due to asthma was about 3274 in 2016, and 3564 in 2017.^[1,3,4]

The treatment and prevention of asthma attacks are often complicated and multifactorial. Severity, avoidance of triggers, adherence to the medication regimen, and anxiety are just some

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This study was approved by the institutional review board at Loma Linda University Health. All subjects provided a written consent to participate.

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of the factors contributing to the treatment and prevention of asthma attacks.^[5] Despite rigorous studies to improve outcomes and different asthma treatment plans, the prevalence of uncontrolled asthma in the United States still ranges between 52.4% and 73.3%, which is relatively high. In the most recent Global Initiative for Asthma report, asthmatics who are categorized to have severe asthma (step 5) represent approximately 4% of the asthmatic population.^[6,7] These difficult to treat severe asthmatics are considered uncontrolled (on oral corticosteroids with frequent or severe exacerbations of ≥ 1 -year requiring hospitalization) when asthma symptoms persist despite being on optimal therapy.

Regarding anxiety experienced by asthmatics, a recent study showed that anxiety is a risk factor of poorly controlled asthmatics (odds ratio 3.76) and considerably influences asthma control by fourfold.^[8] Boulet et al^[9] reported that near-fatal asthmatics had shown more psychogenic disturbances in their personality and less adaptive to changes when it comes to disease control. In addition, this group of severe asthmatics tends to be 1.6 times more likely to have anxiety symptoms.^[10] According to Amelink et al,^[10] severe asthmatics who were dependent on prednisone had a significantly higher level of anxiety than those with mild and severe non-prednisone dependence. In a recent dissertation by Adejumo,^[11] daily use of inhaled corticosteroids was associated with an increase in asthma-specific emotional stress.^[11] Asthma symptoms have been reported to be directly attributed to psychological factors that are hypothesized to be the result of a disruption of normal homeostasis of vagal mediated parasympathetic activity, disrupting the balance between bronchoconstriction and bronchodilation.^[12] Moreover, Ciprandi et al^[13] found that asthma control test (ACT) scores were significantly lower in the group that had higher anxiety scores.

To relieve symptoms in severe asthmatics and to improve their quality of life, an innovative Food and Drug Administration approved treatment called bronchial thermoplasty (BT) became part of the treatment regimen in 2010.^[14-16] Selection criteria for BT include adults diagnosed with severe asthma according to Global Initiative for Asthma guidelines, able to undergo BT safely, caution with prebronchodilator forced expiratory volume in one second of less than 60% predicted, and no internal pacemaker or neurostimulator.^[14,15] BT is a medical procedure done in multiple sessions to assist and improve asthma control using radiofrequency-generated heat applied to the airway.

The purpose of this study was to assess severe asthmatic patients' anxiety level at baseline and during the bronchial thermoplasty procedure using a validated anxiety scoring questionnaire (Burn Anxiety Inventory questionnaire).^[17] The study hypothesis is that the self-reported anxiety levels would progressively decrease with each BT treatment and ACT scores would increase from pre to post BT treatment.

2. Methods

This was a prospective observational study approved by the Loma Linda University Institutional Review Board. A total of 17 subjects participated in this study. Inclusion criteria were patients who were already scheduled to undergo BT procedure in our clinics from 2016 to 2018. Subjects self-evaluated their anxiety level using the burns anxiety inventory (BAI) questionnaire, and asthma control using the ACT questionnaire.

2.1. Main outcome measures

2.1.1. Anxiety evaluation tool. All subjects reported their anxiety level using the BAI questionnaire at baseline and prior to each BT treatment. A total of three BT treatments were completed. The questionnaire consisted of three different categories with each category having specific symptoms. Categories were grouped as: Anxious feelings (6 symptoms),

Anxious thoughts (11 symptoms), and Physical symptoms (16 symptoms). Each symptom was scored on a 0-4 scale (0-Not at all, 1-Somewhat, 2-Moderately, 3-A lot). Scores were then added up to give a total range score between 0 and 99 (0-4 = Minimal or No Anxiety, 5-10 = Borderline Anxiety, 11-20 = Mild Anxiety, 21-30 = Moderate Anxiety, 31-50 = Severe Anxiety, 51-99 = Extreme Anxiety or Panic).^[17]

2.1.2. Asthma control test. Subjects also completed the ACT pre and post BT treatment. The ACT consists of 5 short questions to assess asthma control with total score of 19 and above indicating good asthma control.^[18]

2.2. Data analysis

Data was analyzed using SPSS version 28.0 for windows. A sample size of 17 subjects was estimated using a large effect size ($f = 0.25$), a power of 0.84, and a level of significance of 0.05. The estimated sample size was calculated using the BT scores of the BAI questionnaire as a primary outcome. The normality of the quantitative outcomes was assessed using the Kolmogorov-Smirnov test. Data was summarized using mean \pm standard deviation for approximately normal quantitative variables, median (minimum, maximum) for ordinal variables, and frequency (%) for categorical variables. A Friedman test was used to examine changes in total BT scores over time (baseline, preBT1, preBT2, and preBT3) and for the subcategories (anxious feelings, anxious thoughts, and physical symptoms.) If the results were significant, Wilcoxon signed ranks test was used to determine which median scores were significantly different over time. The same analysis was conducted for those who take medication for anxiety and those who do not separately. A paired t test was used to examine post versus pre-ACT scores. Results were considered significant at $P \leq .05$.

3. Results

A total of $N = 17$ subjects with a mean age of 55.9 ± 14.5 years participated in the study. Fifty three percent were females ($n = 9$) and 41.2% ($n = 7$) were on prescribed anxiety medications.

Results of the changes in median (minimum, maximum) overall anxiety scores and for the subcategories over time for all subjects and for those who were on prescribed anxiety medications and those not on medications are displayed in Table 1. There was a significant drop in the patients' overall BAI anxiety level over time, $P < .0001$. This significant drop was seen from baseline to BT2 and baseline to BT3 ($P = .004$, $P = .001$) and broncho thermoplasty procedure 1 (BT1) to broncho thermoplasty procedure 2 (BT2) and BT1 to broncho thermoplasty procedure 3 (BT3) ($P = .02$, $P = .008$), Figure 1. In the subcategories of the BAI, a significant drop was seen in all subcategories over time; for Anxious feelings ($P = .0001$), anxious thoughts ($P = .001$), and physical symptoms ($P = .025$); Table 1. This significant drop was seen in Anxious feelings from baseline to BT2 (showed a significant reduction from baseline to BT2 and BT3 ($P = .005$, $P = .006$), and from BT1 to BT2 ($P = .015$) and BT1 to BT3 ($P = .015$). In addition, the anxious thoughts subcategory showed a significant drop from baseline to BT2 and BT3 ($P = .046$ and $P = .002$), BT1 to BT3 ($P = .021$) and from BT2 to BT3 ($P = .040$). Finally, the physical symptoms subcategory showed a significant drop from baseline to BT3 ($P = .023$).

For patients who reported taking medications for anxiety, there was a significant drop in overall anxiety level over time ($P = .025$). Results using Wilcoxon signed rank test, showed that the drop was only significant between baseline BT3 ($P = .028$). When looking at subcategories, a significant drop was also found in anxious thoughts over time ($P = .029$), and the drop was significant from baseline to BT3 ($P = .026$), BT1 to BT2 ($P = .042$), and from BT1 to BT3 ($P = .046$). However, there was

Table 1

Median (minimum, maximum) anxiety scores over time. Data are reported based on all subjects, on those on anxiety medications and those who are not on anxiety medications.

	Baseline	BT1	BT2	BT3	P value
Overall BAI score	9 (0.97)	3 (0.87)	1 (0.41)	1 (0.39)	<.0001
On anxiety medication	17 (0.46)	14 (0.41)	6 (0.39)	6 (0.39)	.025
Not on anxiety medication	8 (0.97)	2 (0.86)	1 (0.8)	0(0.4)	<.0001
Feeling anxious	2 (0.17)	2 (0.13)	1 (0.7)	0 (0.7)	.0001
On anxiety medication	2 (0.14)	2 (0.13)	1 (0.7)	1(0.7)	.606
Not on anxiety medication	2.5 (0.17)	1.5 (0.13)	0.5 (0.1)	0 (0.1)	<.0001
Anxious thoughts	2 (0.31)	0 (0.31)	0 (0.13)	0 (0.7)	.001
On anxiety medication	2 (0.10)	4 (0.27)	1 (0.13)	0 (0.7)	.029
Not on anxiety medication	1.5 (0.31)	0 (0.31)	0 (0.2)	0 (0.0)	.005
Physical symptoms	4 (0.49)	2 (0.47)	0 (0.25)	0 (0.25)	.025
On anxiety medication	5 (0.32)	8 (0.45)	5 (0.25)	4 (0.25)	.357
Not on anxiety medication	1.5 (0.49)	0.5 (0.42)	0 (0.5)	0 (0.3)	.002

BAI = burns anxiety inventory, BT1 = broncho thermoplasty procedure 1, BT2 = broncho thermoplasty procedure 2, BT3 = broncho thermoplasty procedure 3.
*P < .05.

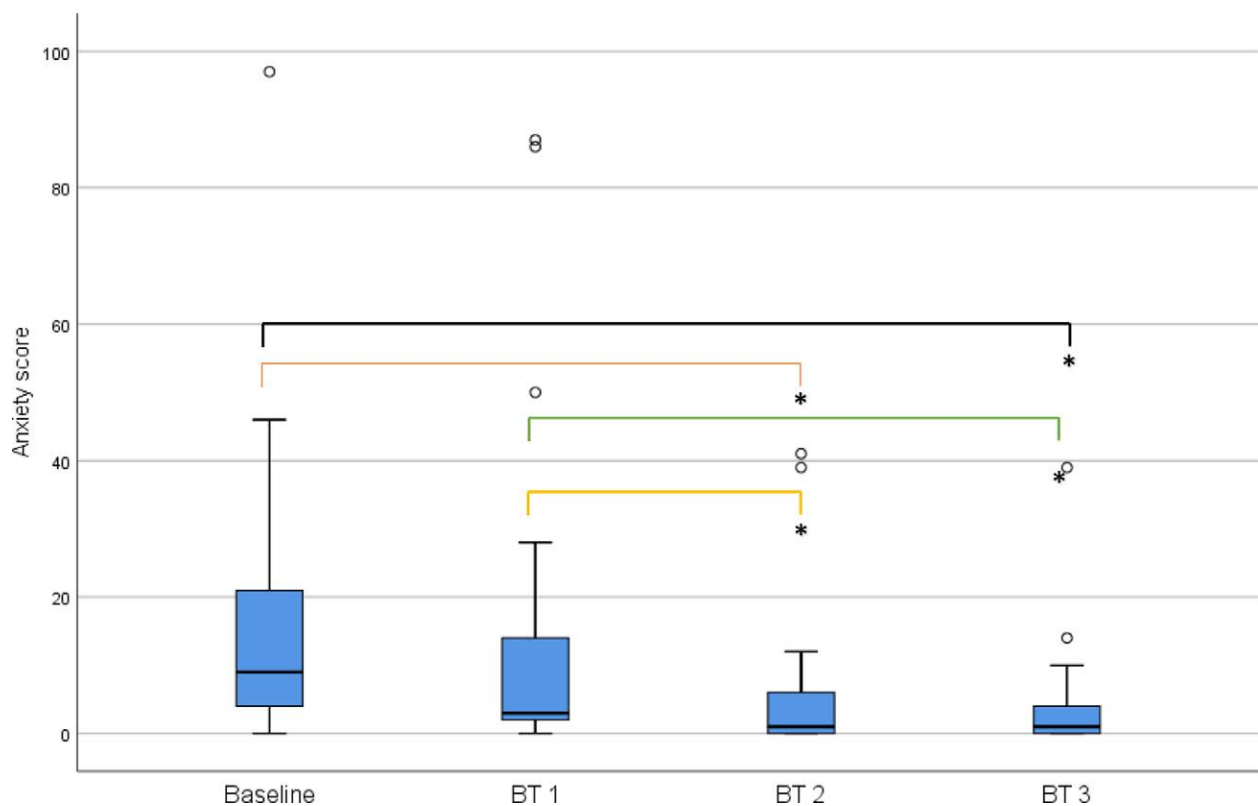


Figure 1. Changes in overall anxiety score overtime. Asterisk (*) indicates a significant drop.

no significant change in anxious feelings nor in physical symptoms over time ($P > .05$).

The overall BAI anxiety level dropped significantly over time for patients who are not on anxiety medications, $P < 0.0001$. This significant drop was seen from baseline to BT1, BT2, and BT3 ($P = .012$, $P = .008$, and $P = .008$ respectively), and from BT1 to BT3 ($P = .011$). In the subcategories of the BAI, a significant drop was seen in all subcategories over time. This significant drop was seen in Anxious feelings over time ($P < .0001$), from baseline to BT2 and BT3 ($P = .011$ and $P = .012$), from BT1 to BT2 ($P = .024$), and from BT1 to BT3 ($P = .016$). In addition, the anxious thoughts subcategory showed a significant drop over time ($P = .005$) and from baseline to BT1, BT2, and BT3 ($P = .042$, $P = .043$, and $P = .028$ respectively). Finally, the physical symptoms subcategory showed a significant drop over time ($P = .002$) and from baseline to BT1, BT2, and BT3

($P = .027$, $P = .017$ and $P = .018$ respectively). In addition, subjects' ACT scores showed a significant improvement (post vs pre) (18.5 ± 4.0 vs 13.3 ± 6.3 , $P = .03$; Cohen's $d = 0.73$).

4. Discussion

The objective of this study was to assess the anxiety level in severe asthmatics who underwent BT procedures. Patients undergoing multiple procedures for BT were evaluated using the ACT^[18] and the BAI^[17] questionnaires. The findings of this study showed that the subjects' overall anxiety level decreased significantly over time and ACT scores increased. The correlation of these two outcomes is consistent not just with the current literature on BT but may also suggest improvements associated with factors beyond physiologic changes to the lung tissue itself, including possible improved quality of life.^[15]

These findings support Seely et al results on BT improving quality of life indicators suggesting that emotional changes can affect a patient's psychosomatically-associated improvements in overall patient well-being as a subsequent result of BT treatment.^[5]

The results suggest that while some of these improvements can be associated with the already proven effects of the BT procedure itself, it can be hypothesized that some factors can be attributed to changes in patient familiarity with the procedure. However, when looking at the results from baseline, a significant difference was not seen until BT 2 and BT3 from baseline (Fig. 1). Thus, the argument can be made that a patient's actual anxiety level is, in fact, improving post-procedure and supports the effectiveness of BT. Interestingly, at the same time, our results showed that a significant drop in BAI scores was seen not only in subjects who were on anxiety medications but also in those who were not on anxiety medications. The familiarity with the procedure still could be a factor in this sub-analysis on those taking anxiety medications versus those not taking anxiety medications.

An established trigger for asthma exacerbations is excess stress.^[19] This means that asthmatic patients are more likely to experience exacerbations from emotional and social stressors and experience a decrease in quality of life.^[20–22] Additionally, Juniper et al showed that the quality of life for individuals with asthma is generally lower than non-asthmatics.^[23] This is understandable, given that severe asthmatics can have an ongoing fear of further exacerbations, which could elevate their baseline anxiety levels. Depending on the type of anxiety a patient exhibits, we believe the inverse corollary should also hold true. Suppose improvements made due to BT can downgrade the severity of a patient's asthma. In that case, the patient should also see a reduction in anxiety leading to associated improvement in overall well-being. The psychological aspects of asthma are complex and well described in a review article by Baiardini.^[24] Salient points discussed in the review include the bidirectional relationship between asthma and mental health. Specifically, psychological factors that are hypothesized to directly influence successful asthma treatment include an asthmatic's ability to perceive asthma symptoms (perception), the presence or absence of alexithymia (the inability to recognize or describe one's own emotions), coping strategies, and a current or past history of an anxiety or mood disorder.

In general, asthmatics with a more complicated disease course are likely to underestimate disease severity (reduced perception), have a higher prevalence of alexithymia, employ avoidant coping strategies (i.e. avoiding, ignoring, or denying the problem) and to receive treatment for a co-morbid anxiety or mood disorder. The ability to accurately perceive asthma symptoms is further complicated by the asthmatic's current emotional state, previous life experiences, attention and learning process, expectations, prior asthma experience, personality traits, and psychopathologic disturbances. Taken as a whole, severe asthmatics with these unhealthy or dysfunctional psychological characteristics along with frequent asthma attacks or near-fatal attacks will most likely experience higher levels of stress.

This study has several limitations. First, limitation of this study is that all subjects were recruited from a single center. Therefore, to further validate the study findings, a multi-center study needs to be conducted with a larger sample size. Second, measuring anxiety right before the procedure might have added more anxiety to the self-reported responses, future studies should consider doing multiple measurements of anxiety measurements such as pre and post procedure. In addition, following up with the subjects several weeks or months after the last procedure might have provided better assessment of anxiety levels. Lastly, more information about patients'

characteristics would have been helpful. Future studies should consider looking at further information about the patients such as co-morbidities.

5. Conclusion

This study shows the effectiveness of BT in decreasing severe asthmatic anxiety levels from baseline to last BT treatment and this benefit was mostly noted in those who were not on any anxiety medications. In addition, ACT scores showed significant improvement post BT treatment. Future studies should evaluate the reduction of any psychotherapy and anxiety treatments, if used, with BT in severe asthmatics.

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