

Boston Scientific Presents Real-World Data Demonstrating Improvement of Severe Asthma in Patients Treated with Bronchial Thermoplasty

Global BT registry data presented at European Respiratory Society Conference

Boston Scientific today announced positive results from the Bronchial Thermoplasty Global Registry (BTGR) observing patients with severe asthma undergoing treatment with bronchial thermoplasty (BT). The data, presented at the European Respiratory Society Conference in Paris, demonstrated that treatment with BT reduced severe asthma exacerbations and decreased emergency healthcare visits.

Patients in the BTGR have asthma that is more severe than those in any other study conducted on BT to date as indicated by higher rates of severe exacerbations, ER visits and hospitalizations in the 12 months prior to BT treatment compared to previously published studies.

Asthma, a chronic inflammatory disease of the airways which affects more than 235 million people worldwide and 30 million people in Europe, causes recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person.^{1,2} During an asthma attack, the lining of the bronchial tubes swell, causing the airways to narrow and reducing the flow of air in and out of the lungs.³ For the 10 percent of asthma patients who suffer from severe asthma, even the highest dose of standard medications may not alleviate the risk of frequent and life-threatening asthma attacks.⁴

The Alair™ Bronchial Thermoplasty System, which received CE Mark in 2002 and was approved by the U.S. Food and Drug Administration (FDA) in 2010, is the first non-drug, device-based treatment for severe, persistent asthma not well controlled by medications. The system delivers controlled thermal energy to the airway wall to reduce the amount of excess smooth muscle tissue in the airways. With less smooth muscle, the airways constrict less, reducing severe asthma attacks and making breathing easier.

One-year data from the registry showed patients treated with BT achieved significant clinical improvement and less time spent using healthcare services compared with the 12 months prior to BT treatment:

- The percentage of patients who experienced severe asthma exacerbations decreased from 90.3 percent to 56.9 percent;
- The percentage of patients who required emergency room visits for respiratory symptoms decreased from 53.8 to 22.0;
- The percentage of patients who needed unscheduled office visits decreased from 59.0 percent to 44.7 percent; and
- The percentage of patients requiring hospitalizations for respiratory symptoms decreased from 42.9 to 19.5.

It was also observed that the percentage of patients using daily maintenance oral corticosteroids decreased from 47.8 percent to 23.5 percent and the percentage of patients using omalizumab for maintenance decreased from 9.6 to 3.5.

These results support data derived from other clinical studies on BT, such as the pivotal AIR2 study results from 2010 and post-FDA approval PAS2 study from 2017.^{5,6}

“Real-world data analysis from the BTGR is an important indicator of improved asthma control for these patients, evidenced by fewer severe exacerbations during the first year of treatment,” said Professor Pallav Shah, Consultant Physician, Royal Brompton Hospital and Chelsea & Westminster Hospital and Professor of Respiratory Medicine, Imperial College, London. “The unrestricted patient population expands insights into the long-term effectiveness of BT for patients with severe asthma as compared to the previously published PAS2 study.”

BTGR is an open-label, single-arm, observational registry, which enrolled 157 asthmatic patients from 18 centers across Europe, Africa, and Australia. Registry participants were adults who had asthma and were scheduled to undergo BT. The patients were treated with BT and followed at intervals of six months after treatment. At the beginning of the study, BTGR participants were, on average, 49.8 years old with a body mass index of 29.2 kg/m², took mean inhaled corticosteroids and long-acting beta agonists doses of 1721 µg/day and 84.8 µg/day, respectively, with 47.8 percent using oral corticosteroids and 9.6 percent using omalizumab prior to treatment with BT. BTGR is an ongoing registry and patients will be observed 2 years post-BT treatment.

About Boston Scientific

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performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and [Facebook](#).

1. WHO: Asthma <https://www.who.int/respiratory/asthma/en/>.
2. European Federation of Allergy and Airway Diseases Patients Association. Asthma. Available at: <https://www.efanet.org/asthma>
3. WHO. Asthma Fact sheet N°307. November 2013. Available at: <https://www.who.int/mediacentre/factsheets/fs307/en/index.html>(accessed December 2016).
4. "The Prevalence of Severe Refractory Asthma | AAAAI." The American Academy of Allergy, Asthma & Immunology. The Journal of Allergy and Clinical Immunology, Oct. 2014. Web. 05 May 2017. .
5. Castro M, Rubin AS, Laviolette M, Fiterman J, De Andrade Lima M, Shah PL, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. Am J Respir Crit Care Med 2010; 181:116-24
6. Chupp G, Laviolette M, Cohn L, McEvoy C, Bansal S, Shifren A, et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies. Eur Respir J 2017; 50.

<https://news.bostonscientific.eu/2018-09-17-Boston-Scientific-Presents-Real-World-Data-Demonstrating-Improvement-of-Severe-Asthma-in-Patients-Treated-with-Bronchial-Thermoplasty>