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Castro M, Rubin AS, Laviolette M, Fiterman J, De Andrade Lima M, Shah PL, Fiss E, 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.

Bronchial Thermoplasty is a procedure that inserts a radiofrequency catheter to deliver thermal energy to the bronchial smooth muscle. The procedure is done via bronchoscopy. The application of thermal energy reduces smooth muscle mass and contraction, thereby reducing bronchoconstriction and airflow obstruction. Preliminary investigations were performed in 2004 with larger nonrandomized trials to follow in 2006. This study was the first large randomized, double-blinded, sham-controlled trial looking at the effects of bronchial thermoplasty on asthma related quality of life.

This study was performed in 30 centers over 6 countries. The primary endpoint was the effect of this procedure on asthma quality of life questionnaire (AQLQ). Secondary endpoints looked at symptom free days, morning peak expiratory flow values, FEV1, asthma exacerbations, emergency room visits and doctor visits and missed day from work. Inclusion criteria were age 18-65, asthma diagnoses with need for inhaled corticosteroid and long acting beta agonist, nonsmoker x 1 year, FEV1 > 60%, and an AQLQ of < 6.25. All patients were followed up to 1 year at intervals of 3, 6, 9, and 12 months. A total of 297 patients were included in the study with 198 pts in the treatment arm and 101 patients in the sham group. The treatment group received application of bronchial thermoplasty at intervals of 0, 3, and 6 weeks. The bronchoscopist was unblinded to the treatment arm but patients as well as all follow up personnel remained blinded throughout the study.

The results of the study showed that patients receiving bronchial thermoplastic did improve their AQLQ score by 1.35 vs. 1.16 in the SHAM group. A value of > 1.0 in the AQLQ is considered to me a moderate improvement. Secondary outcomes showed a 32% reduction in severe asthma exacerbations within the treatment arm when compared to SHAM. In addition there was also a decrease in days lost from work/school in the treatment arm. Interestingly enough the treatment arm did not show an improvement in FEV1 when compared to SHAM. Main side effects were post procedure bronchoconstriction and asthma exacerbations with a higher rate of side effects in the treatment group.

With our current institution now offering this procedure we find ourselves asking "who is now the ideal candidate for bronchial thermoplasty?" Phenotypes in asthma vary greatly and I believe we need to identify the correct phenotype before this procedure gains mass appeal and acceptance. Given the post procedure rates of acute exacerbations and need for hospital admissions, the procedure needs to be used with caution. The long term data and safety profile

look promising, however we still need more information on the histologic response to bronchial thermoplasty. For now this new technology remains exciting but further longitudinal studies are needed to identify efficacy, safety and phenotype selection.

Manoj Mathew, MD
Associate Editor, Pulmonary Journal Club