

- Title** Assessment of bronchial thermoplasty for the treatment of uncontrolled severe asthma
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- Reference** ISBN number: 978-2-11-139122-2, link to full report in French: [http://www.has-sante.fr/portail/jcms/c\\_2045264/fr/evaluation-de-la-thermoplastie-bronchique-pour-le-traitement-de-l-asthme-severe-non-controle](http://www.has-sante.fr/portail/jcms/c_2045264/fr/evaluation-de-la-thermoplastie-bronchique-pour-le-traitement-de-l-asthme-severe-non-controle)

### Aim

Assessment of the efficacy and safety of bronchial thermoplasty for the treatment of uncontrolled severe asthma despite optimal drug therapy, in patients above 18 years of age.

### Conclusions and results

In all, the literature analysis and the points of view of the parties concerned show that:

- uncontrolled severe asthma is a public health problem due to its potential impact on functional impairment, lost quality of life and the burden of care it entails. Some patients are at a therapeutic impasse; therefore, there is a real therapeutic need in this population;
- bronchial thermoplasty is a new treatment modality that is positioned as a final therapeutic resort in uncontrolled severe asthma. Bronchial thermoplasty does not change the therapeutic management of the disease, but could notably improve the quality of life of patients;
- there are few published data and these do not formally demonstrate a clinical benefit in terms of reduced exacerbations, reduced numbers of hospitalisations or lessening pharmacological treatment. A statistically significant impact on quality of life was observed in one of the studies. However this effect did not attain the clinical significance set beforehand by the investigators. In this same study, BT showed a statistically significant reduction in the number of exacerbations, emergency visits and sick leave (secondary endpoints). Finally, as the authors emphasise, there has been no long-term follow-up;
- the position of the professional organisations surveyed, as the parties concerned, on whether or not this technique should be introduced into the standard therapeutic arsenal is not completely consistent. Respiratory medicine specialists and immunologists-allergists believe that, as long as there is a strict framework for dissemination of the technique and a system of care for severe asthma is created, bronchial thermoplasty has an interest for patients at a therapeutic impasse and could therefore be integrated into the practical care to be offered. General practitioners, in return, believe that the available data are insufficient for this invasive technique and that it

should therefore be reserved for clinical research. Patients have stressed their hope to have a therapeutic modality that can improve their quality of life in case of uncontrolled severe asthma. However, all the parties concerned have insisted on the need to have long-term efficacy and safety data and to establish a framework and care pathway for these patients with severe asthma.

Based on these elements, HAS, considering the situation of uncovered medical need for serious patients and the current dissemination of this new treatment modality, concluded that bronchial thermoplasty is a therapeutic modality for patients with uncontrolled severe asthma despite maximal treatment followed for at least 1 year and with good compliance, and a modality to be regulated to ensure optimal quality of care and follow-up of all patients treated.

HAS believes that making this novel technique available falls within a framework, in the sense of Article L1151-1 of the Public Health Code. Thus, bronchial thermoplasty is reserved for expert centres that have both expertise in interventional bronchoscopy and expertise in the management of severe asthma; these centres are to be part of a care pathway setting up different levels of asthma management. HAS recommends that patients be clearly informed of the limited experience underlying the currently available data, that a protocol be developed defining the conditions for the creation and implementation of a comprehensive national registry of long-term safety and efficacy data for bronchial thermoplasty, and that participation in this registry be required to access this technique.

### Methods

This assessment is based on:

- a systematic literature search for information related to the assessment criteria defined;
- a medical and scientific analysis of the publications selected;
- consultation with organisations of the healthcare professionals concerned, particularly on the conditions for performing the technique and criteria for patient eligibility for the technique;
- survey of patient associations.

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