IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – Commission No. H16-01

Targeted lung denervation using catheter ablation for chronic obstructive pulmonary disease[1]

Executive Summary

[1] Translation of the executive summary of the assessment according to §137h Social Code Book (SGB) V *Gezielte Lungendenervierung durch Katheterablation bei chronisch obstruktiver Lungenerkrankung* (Version 1.0; Status: 30 January 2017). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher:
Institute for Quality and Efficiency in Health Care

Topic:
Targeted lung denervation using catheter ablation for chronic obstructive pulmonary disease

Commissioning agency:
Federal Joint Committee

Commission awarded on:
19 December 2016

Internal Commission No.:
H16-01

Address of publisher:
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Im Mediapark 8
50670 Köln
Germany

Phone: +49 221 35685-0
Fax: +49 221 35685-1
E-mail: berichte@iqwig.de
Internet: www.iqwig.de

Medical-scientific advice:

- Thomas O. F. Wagner, University Hospital Frankfurt, Frankfurt, Germany

IQWiG thanks the medical-scientific advisor for his contribution to the §137h assessment. The sole responsibility for the content of this assessment lies with IQWiG.

IQWiG employees involved in the assessment:[2]

- Min Zhou
- Charlotte Guddat
- Marco Knelangen
- Julia Kreis
- Stefan Sauerland
- Guido Skipka

Keywords: catheter ablation, pulmonary disease – chronic obstructive, assessment of potential, benefit assessment

[2] Due to legal data protection regulations, employees have the right not to be named.

Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess targeted lung denervation (TLD) using catheter ablation for chronic obstructive pulmonary disease (COPD) according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were transferred to IQWiG on 19 December 2016.

According to the requesting hospital, TLD aims to avoid airway obstruction in patients with COPD by a permanent interception of parasympathetic nerve fibres in the area of both main bronchi, and thereby in particular to improve respiratory function, exercise capacity, and quality of life. In this context, TLD is to supplement or in part replace pharmaceutical therapy.

Four studies were available for the assessment. Overall, the data did not allow a direct comparison with other treatment options for COPD. Two cases series (IPS-I and IPS-II) referred to earlier TLD variants that showed relevant differences with regard to their energy dose and conduct compared with the TLD variant currently examined and could not be used for the assessment. The third case series (AIRFLOW-1-Extension), which examined the current TLD variant, only reported serious adverse events. The fourth study (AIRFLOW-1, n = 30 patients) compared 2 energy doses in TLD variants in a randomized manner; however, there have also been further procedural changes to these variants. Nevertheless, the results of this study could be seen as sufficiently applicable to the current TLD variant. However, the presentation of the AIRFLOW-1 study results in the assessment documents was incomplete and unclear. Even though in the pre-post comparison, spirometric surrogate outcomes evidently in part improved, no statistically significant improvement in health-related quality of life was found and the (planned) results on exercise capacity were missing. Several serious adverse events, including 5 cases of gastroparesis and 1 tracheal fistula, were observed.

The overall inspection of the documents shows that the study results submitted were incomplete and potentially chosen in a selective manner, so that an assessment of TLD is not possible on this basis. Therefore neither a benefit nor a potential of a required treatment alternative can be inferred for TLD. For this reason, no key points for a testing study are specified for the method.

The full report (German version) is published under
https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h16-01-targeted-lung-denervation-by-catheter-ablation-in-chronic-obstructive-lung-disease-assessments-according-to-137h-sgb-v.7712.html