Benefit unproven for self-administered high-flow therapy in COPD and type 1 respiratory failure

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No benefit of high-flow therapy (HFT) can be derived from the available study data for patients with advanced chronic obstructive

pulmonary disease (COPD) or chronic type 1 respiratory failure. It therefore remains unclear whether this form of treatment has advantages over long-term oxygen therapy (LTOT) or non-invasive ventilation (NIV).

This is the conclusion of the benefit assessment that the Institute for Quality and Efficiency in Health Care (IQWiG) has now completed. The Federal Joint Committee (G-BA) had commissioned IQWiG to investigate the advantages and disadvantages of HFT in patients with stable, advanced COPD or chronic respiratory failure with oxygen deficiency (chronic type 1 respiratory failure). Treatment was to be self-administered at home, in inpatient care or rehab, etc.

However, no data were available for the final report that would have been sufficient for a benefit assessment. Since HFT fulfills the legal requirements for the intervention to be classified as having a potential, IQWiG formulated key points for two testing studies: for COPD with type I respiratory failure and for type II.

Different medical indications require different treatment approaches

In HFT, humidified and heated room air with increased flow rates is supplied via a nasal cannula; if necessary, oxygen can also be added. This aims to support breathing problems and secretion clearance and to relieve the respiratory muscle pump. Depending on the type of respiratory failure, the pathophysiology of the disease and thus the modes of action of treatment differ: In chronic type 1 respiratory failure with pulmonary impairment and corresponding respiratory failure (pulmonary failure) in connection with an undersupply of oxygen (hypoxaemia), patients require different treatment than in type 2 respiratory failure, where the respiratory muscle pump is impaired

(ventilatory failure) and the disease is associated with carbon dioxide excess in the blood (hypercapnia).

The primary treatment goal, regardless of the type of failure, is to avoid acute worsening of chronic dyspnoea (exacerbations). However, the main treatment approaches differ: (long-term) oxygen therapy (LTOT) is recommended for the treatment of (chronic) hypoxaemia in type 1 respiratory failure. Various applications such as breathing masks are available for this purpose. For the treatment of type 2 (hypercapnic) respiratory failure, besides oxygen administration, CO_2 release must be supported, so invasive (intubation) or non-invasive ventilation therapy (with a breathing mask or helmet) is used.

Key points for testing studies

For the different medical indications, the IQWiG project team identified both completed and ongoing randomized controlled trials (RCTs) on HFT. However, these are insufficient to assess the benefit of HFT in patients with type 1 respiratory failure. For a robust conclusion on the benefit of HFT, further studies are needed to generate more evidence. Based on the identified potential of the intervention, IQWiG proposes two testing studies.

Because of the different treatment mechanisms, it is not meaningful to conjointly consider the studies on HFT versus long-term oxygen therapy (LTOT) or non-invasive ventilation (NIV). IQWiG therefore proposes to test the intervention in two studies: In COPD and chronic type 1 respiratory failure, HFT should be investigated as an add-on to LTOT versus LTOT alone. In COPD and chronic type 2 respiratory failure, HFT can be used instead of NIV.

Procedure of report production

In February 2021, IQWiG published the preliminary results, the preliminary report, for discussion. After completion of the commenting procedure, the project team revised the preliminary report and in May sent the final report to the contracting agency, the G-BA. The final report contains changes resulting from the commenting procedure. The written comments received are published in a separate document at the same time as the final report.

More information: Final report (in German): www.iqwig.de/download/n20-02_h … _v1-1.pdf?rev=212619

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