Tiotropium has advantages for patients with COPD

December 11 2012

In order to widen the narrowed airways in patients with chronic obstructive pulmonary disease (COPD), tiotropium bromide (tiotropium in brief) is one of the drugs available that can be prescribed for inhalation. The German Institute for Quality and Efficiency in Health Care (IQWiG) has examined whether tiotropium offers a perceptible advantage to patients compared to a dummy medication (placebo) and to other COPD drugs. In addition, the two currently marketed types of inhaler (HandiHaler and Respimat) for tiotropium (trade name: Spiriva) were compared.

According to the IQWiG report, there is proof that tiotropium offers patients with COPD advantages compared to placebo: they suffer fewer acute worsenings of their condition (exacerbations), they need to be hospitalized for this reason less often, and their quality of life is better. There are indications of a benefit in terms of less severe symptoms and complaints, e.g. breathing problems. In relation to the ability to carry out everyday practical activities, there is also a hint of a benefit of tiotropium.

An added benefit is also proven in comparison with the drugs salmeterol, formeterol, indacaterol and ipratropium: fewer exacerbations and related hospitalizations occurred under treatment with tiotropium. Compared to indacaterol there is, however, also a hint of a lesser benefit of tiotropium with regard to the COPD symptoms and quality of life.

Effects for COPD patients are the focus of interest

Tiotropium is a drug known as an "anticholinergic" that is used for the treatment of COPD, in which the airways are permanently narrowed and the lungs are damaged. The disease is characterized by chronic cough, increased sputum and shortness of breath on exercise. About 1 in 10 to 20 adults aged over 40 has COPD. Thus, the disease is much more common than asthma. Three-quarters of patients are men.

Because of the strong association with smoking, COPD is also commonly known as "smokers' cough".

The outcome measures of this benefit assessment, in addition to symptoms, acute exacerbations and the resulting need for hospitalization, included mortality (deaths), health-related quality of life and side effects.

Comparison with placebo shows advantages for patients

In its worldwide search for clinical trials and systematic reviews, the Institute found a total of 27 relevant studies.

The 21 studies comparing tiotropium with a placebo produced proof of a benefit in relation to exacerbations and hospitalizations due to exacerbations. Also proven is the benefit in respect of quality of life, because the study participants using tiotropium suffered less from breathing problems and their physical health was better than in the control group. In both cases, the proof applied to both types of inhaler.

An indication of a benefit from tiotropium (again for both inhalers) could be demonstrated in relation to symptoms. For the HandiHaler,

there is also a corresponding indication in terms of the mortality rate of ex-smokers.

IQWiG found a hint of a benefit for everyday practical activities. Here, the final report differed from the preliminary report because of additional data from a new study that IQWiG identified during the routine supplementary search.

Tiotropium compared to other COPD drugs

In 10 studies tiotropium was compared with other drugs, namely with ipratropium, with the combination of salmeterol and fluticasone and with the group of drugs known as "LABA". The conjoint analysis of the long-acting beta-2 sympathomimetics salmeterol, formeterol and indacaterol in the LABA group takes account of arguments from the commenting procedure on the preliminary report. As a consequence, advantages of tiotropium that are shown with one of the LABA drugs, apply to the entire group. The results of these 10 studies in general apply only to the HandiHaler inhaler, because only placebo-controlled studies were available for the Respimat.

Added benefit compared to LABA and ipratropium

Unlike in the preliminary report, the comparison with ipratropium showed not only proof of a benefit of tiotropium in relation to exacerbations, but - because of new analyses submitted during the commenting procedure - also an indication of a benefit in relation to COPD symptoms. In contrast to tiotropium and LABA, ipratropium is short-acting and must therefore be taken more often.

Proof of an added benefit of tiotropium over the LABA drug class could be demonstrated in relation to exacerbations and resulting

hospitalizations.

However, compared to indacaterol there were also two hints of a lesser benefit of tiotropium, namely in respect of symptoms and quality of life. Although indacaterol belongs to the jointly considered LABA drug class, the study results vary a great deal in respect of these patient-relevant outcomes. The drugs were therefore assessed separately for the two above-named outcomes.

The comparison of tiotropium with the combination of salmeterol and fluticasone produced no differences for the patients with COPD.

No differences for other outcomes and as add-on medication

In relation to other patient-relevant outcomes such as exercise capacity, mortality, rate of cardiovascular diseases and side effects, the studies showed no differences between tiotropium and the other alternative treatments investigated.

Two studies compared the additional administration of tiotropium with the respective comparator drug alone: in one study tiotropium was added to treatment with LABA and in another study, it was given in addition to the combination of salmeterol and fluticasone. But again, no differences in benefit or harm from the additional administration of tiotropium could be derived from the results.

Evidence is basically good

The worldwide search on the topic was supplemented by requests to drug manufacturers for further studies, including unpublished ones. Boehringer Ingelheim, the sponsor of many tiotropium studies, supplied IQWiG with all the requested data and other additional information, as did the manufacturers of comparator products, GlaxoSmithKline and

Novartis.

Although all studies were well-designed, some of the results could not be reliably interpreted because, for example, too many study participants were not considered in the analysis. This is why weaker conclusions about benefit, such as "indications" or "hints" were drawn, instead of "proof".

No direct comparison of the inhalers

None of the relevant studies compared the two inhalers directly with each other: there were 4 exclusively placebo-controlled studies on Respimat, while all the others were carried out with the HandiHaler.

Therefore, the respective results for the two inhalers from the placebo-controlled studies were compared with each other. The effects did not differ substantially in the studies, so that the benefit assessment based on the placebo-controlled studies in respect of almost all outcomes essentially applies also to the Respimat inhaler.

The benefit applies solely to the HandiHaler only in relation to the lower death rate of ex-smokers, because this result is based exclusively on a study conducted with this particular inhaler. The benefit assessment based on the studies comparing drugs also applies only to the HandiHaler.

Procedure of report production

IQWiG published the preliminary results in the form of the preliminary report in November 2011 and interested parties were invited to submit comments. When the commenting procedure ended, the preliminary report was revised and sent as a final report to the contracting agency,

the Federal Joint Committee (G-BA), in June 2012. The written comments were published in a separate document at the same time as the final report. The report was produced in collaboration with external experts.

More information: An overview of the background, methods and further results of the final report is provided in the English-language summary (PDF, 138 kB). www.iqwig.de/download/A05-18_E … bromide-for-COPD.pdf

Provided by Institute for Quality and Efficiency in Health Care

Citation: Tiotropium has advantages for patients with COPD (2012, December 11) retrieved 4 May 2024 from https://medicalxpress.com/news/2012-12-tiotropium-advantages-patients-copd.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.