IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Literature search on angiotensin-II antagonists and ACE inhibitors[1]

Executive Summary

[1] Translation of the executive summary of the working paper "Literaturrecherche zu Angiotensin-II-Antagonisten und ACE-Hemmern" (Version 1.0; Status: 18.04.2011). 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.

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Background

This project presents a literature search for evidence from long-term studies on angiotensin-II (AT-II) antagonists and angiotensin-converting enzyme (ACE) inhibitors in therapeutic areas approved for AT-II antagonists. The project was conducted within the framework of an IQWiG general commission on the basis of a letter of 15 July 2010, sent to the Institute for Quality and Efficiency in Health Care (IQWiG) by the Federal Joint Committee (G-BA) and containing a request for such a search. The search supplements final report A05-09, already published on 15 July 2009 ("Comparative benefit assessment of different antihypertensive drug classes as first-line therapy in patients with essential hypertension"). As in project A05-09, the search was restricted to randomized, controlled long-term studies according to the definition in the corresponding final report.

Research questions

The aim of the present literature search was to identify long-term studies investigating AT-II antagonists and ACE inhibitors in therapeutic areas approved for AT-II antagonists and comparing the drug classes with each other and with placebo.

Methods

The methodology for generating the working paper was described a priori in a project outline.

Randomized, controlled long-term studies on AT-II antagonists and ACE inhibitors were identified by means of a bibliographic literature search. Eligible long-term studies were those with a minimum observation period of one year and including at least 500 patients per treatment group, as well as studies with at least 1000 patient years of observation time per treatment group. All placebo-controlled studies and direct comparative studies on the two drug classes were included, insofar as they were conducted according to the German approval status and provided relevant analyses.

The search was performed in two steps. In a first step a search for relevant systematic reviews (SRs) was undertaken in the databases MEDLINE, EMBASE, Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The search covered the period from 1 January 2005 to 4 October 2010.

The relevant current SRs were assessed with regard to whether the literature searches contained in them were suited to identify relevant studies on one or more research questions (treatment comparisons and therapeutic areas) of the present working paper. The assessment was based on both general aspects (literature sources, search period), as well as on search aspects specific to the studies (study duration and design, number of patients) and to the research questions (population, intervention, outcomes). In a second step, a supplementary search for primary studies was conducted for the period not sufficiently covered by the SRs. This search was undertaken in the databases MEDLINE, EMBASE, and the Cochrane Central

Register of Controlled Trials (Clinical Trials), covering the period from 1 January 2009 to 24 February 2011.

Two reviewers selected the relevant publications (SRs and primary studies) independently of each other. Discrepancies between reviewers in the selection process were resolved by consensus.

Due to the limited objectives of this project, no assessment was performed of the potential risk of bias in the studies considered. The studies were described by means of design characteristics (study design and duration, location and period of recruitment, number of randomized patients, and primary outcomes). In addition, the test intervention(s) and comparator treatment(s) were presented.

Results

A total of 31 current SRs published on or after 1 January 2009 were identified and assessed. The publication period up to February 2009 was sufficiently covered by the SRs; the supplementary search for primary studies was therefore conducted for the period after 1 January 2009.

A total of 32 publications on 20 different relevant studies conducted in the therapeutic areas of AT-II antagonists were identified from the reference lists of the SRs and the supplementary search for primary studies. For each drug class (AT-II antagonists and ACE inhibitors) at least one placebo-controlled study was found for each therapeutic area. Likewise, direct comparative studies were identified for most therapeutic areas, except for arterial hypertension. Even though at least one study was available for most research questions (treatment comparisons and therapeutic areas), this did not apply to the individual drugs themselves; in arterial hypertension in particular, long-term studies designed to analyse patient-relevant outcomes were lacking for many drugs. This applied equally to AT-II antagonists and ACE inhibitors.

Conclusions

Several placebo-controlled long-term studies with AT-II antagonists or ACE inhibitors have been conducted in the therapeutic areas of AT-II antagonists. Direct comparative studies between these drug classes are also available in all therapeutic areas except for arterial hypertension.

On the basis of the long-term studies identified, an assessment of AT-II antagonists versus the drug class of ACE inhibitors seems possible.

Keywords: angiotensin-II type I receptor blockers, angiotensin-converting enzyme inhibitors, systematic review

The full working paper (German version) is published under www.iqwig.de