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Benefit assessment of non- drug treatment strategies in patients with essential hypertension: smoking cessation¹

Executive Summary

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This report was prepared in collaboration with external experts. According to § 139b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received." The Institute received the completed form "Disclosure of conflicts of interest" from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external experts is presented in Appendix E of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

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IQWiG thanks the external reviewer for her comments on the rapid report. However, the external reviewer was not involved in the preparation of the rapid report. Individual sections and conclusions in the rapid report therefore do not necessarily reflect her opinion.

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Background

Blood pressure-lowering drugs – known as antihypertensives – as well as various non-drug treatment options are available for the treatment of essential hypertension. National and international medical societies recommend the consistent, long-term implementation of non-drug interventions, including smoking cessation, within the framework of antihypertensive therapy to reduce the individual cardiovascular risk.

Numerous studies have demonstrated the importance of tobacco smoking as a key risk factor for increased mortality and an increase in cardiovascular risk. Apart from the negative influence on cardiovascular risk, smoking is universally recognized as having many other harmful effects. In addition to the detrimental effect on the cardiovascular system, other health factors – largely independent of hypertension and the cardiovascular system – are also negatively influenced by smoking.

Whereas there is no dispute that smoking encourages the development of many diseases and has a deleterious influence on the course of numerous disorders, there is less clarity about the actual effect of smoking cessation on blood pressure and the direct treatment of hypertension.

Various observational studies have shown that smokers tend to show the same or even lower blood pressure values than non-smokers or former smokers. In some long-term observational studies, it was also reported that both the blood pressure as well as the incidence of hypertension were higher in patients who had given up smoking than in those who had continued to smoke unchanged over the same period. Furthermore, differing effects on the implementation of antihypertensive therapy in smokers and non-smokers were observed. For example, in a re-analysis of the Hypertension Optimal Treatment (HOT) study, it was reported that in smokers the attempt to achieve particularly low diastolic blood pressure values was associated with an increase in the risk of cardiovascular events (with the exception of myocardial infarction), in the sense of a J-shaped risk curve, whereas a reduction in this risk was observed in non-smokers. In another study, an influence of smoking behaviour on the effects of antihypertensive drugs was also described.

Hence it is currently unclear whether, in addition to general cardiovascular effects, smoking cessation has direct effects on blood pressure and antihypertensive treatment, with resulting positive or negative consequences for health.

Aim of investigation

The aim of this investigation was to assess, with regard to patient-relevant outcomes and criteria for blood pressure control, the benefit of a smoking cessation intervention versus no such intervention in patients with essential hypertension.

The investigation of the fundamental benefit of smoking cessation, i.e. independent of the treatment of hypertension, was not the object of this report – this benefit is regarded as undisputed.

Methods

It was originally planned to conduct a benefit assessment on the basis of the results of systematic reviews of data from randomized controlled trials (RCTs). However, preliminary searches on this subject revealed that a benefit assessment based on secondary literature was not possible because insufficient high-quality systematic reviews or health technology assessment (HTA) reports were available. Therefore, this benefit assessment was to be based solely on primary literature.

RCTs of a minimum duration of 24 weeks in adult patients with essential hypertension were to be included. The intervention to be examined was smoking cessation. Primary studies were excluded in which the smoking cessation intervention as a primary intervention was compared with another antihypertensive treatment as a primary intervention (e.g. smoking cessation versus diet or versus medicinal blood pressure reduction).

The highest priority in the report was to answer the question as to the benefit regarding “morbidity”, “mortality” and “quality of life” as outcomes of direct relevance to patients. Specifically, the following outcomes were pre-defined: “all-cause mortality”, “cardiovascular mortality”, “cardiovascular morbidity”, “end-stage renal disease”, “health-related quality of life”, “discontinuation of and/or reduction in antihypertensive medication”, “all adverse events”, and “duration and extent of changes in blood pressure”.

A systematic literature search was conducted in the bibliographical databases MEDLINE and EMBASE, the Cochrane databases and PsycInfo. The search for primary literature took place on 16.02.2010, that for secondary literature on 23.03.2010. In addition, a search was performed for relevant studies in the list of references of relevant secondary literature and in publicly accessible trial registries.

Results

Neither the search for primary literature in the named bibliographical databases nor the manual search in relevant secondary literature and trial registries were able to identify studies corresponding to the inclusion criteria that investigated the effect of smoking cessation in patients with hypertension, or at least reported results for a corresponding subpopulation.

It should be pointed out that there are indeed RCTs that investigated, over a very long period, the effect of a smoking cessation intervention compared to standard care without such an intervention and which also analysed the patient-relevant outcomes specified in this report.

It is therefore rather surprising that not a single RCT was found which investigated the effect of smoking cessation interventions in people with hypertension in respect of patient-relevant outcomes such as “mortality”, “morbidity” and “health-related quality of life”, or was able to provide findings on a specific effect on blood pressure and the direct treatment of hypertension. For it is quite conceivable that the effect of smoking cessation in patients with hypertension, who per se show an increased cardiovascular risk, might indeed differ from that

of a mixed population of persons with and without hypertension. The demonstration of a positive effect of smoking cessation on blood pressure could, e.g., represent an additional motivation for persons with hypertension to give up smoking. On the other hand, a negative effect could result in the recommendation of a stricter control of blood pressure as an accompanying measure in smoking cessation.

Regardless of that, it must of course be clearly emphasized that smoking has a considerable potential for harm, irrespective of the treatment of hypertension. In this regard, the fundamental benefit of smoking cessation is not questioned in any way.

Given the fact that there are no suitable studies which investigated the effects of smoking cessation on blood pressure and cardiovascular morbidity and mortality in patients with hypertension, in no way can it be inferred that smoking cessation generally leads to no health benefits.

Conclusions

No studies are available that provide data for a benefit assessment of a smoking cessation intervention in patients with essential hypertension in respect of the patient-relevant outcomes “all-cause mortality”, “cardiovascular mortality or morbidity”, “end-stage renal disease”, “health-related quality of life” and “adverse events”. It is also not possible to assess effects on the antihypertensive medication or regarding the surrogate parameter “blood pressure”.

The fundamental benefit of smoking cessation (i.e. the benefit independent of antihypertensive therapy) is by no means called into question by the results of this report.

Keywords: hypertension, smoking cessation, benefit assessment, systematic review

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