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**Benefit assessment of non-drug
treatment strategies in patients
with essential hypertension:
increase of physical activity¹**

Executive Summary

¹ Translation of the executive summary of the rapid report “Nutzenbewertung nichtmedikamentöser Behandlungsstrategien bei Patienten mit essenzieller Hypertonie: Steigerung der körperlichen Aktivität” (Version 1.0; Status: 23.08.2010). 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

The main treatments available for essential hypertension are blood pressure-lowering drugs, known as antihypertensive drugs, as well as various non-drug treatment options. Leading national and international professional associations recommend the consistent, long-term implementation of non-drug measures in the treatment of essential hypertension.

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 interventions for increasing physical activity versus no such intervention in patients with essential hypertension.

Methods

It was planned to conduct the benefit assessment on the basis of results of systematic reviews (SRs) that used data from randomized controlled trials (RCTs). Preliminary literature searches on this topic showed that in principle a benefit assessment on the basis of secondary literature was possible. However, if the effort involved in a benefit assessment conducted on the basis of the high-quality secondary literature available exceeded that required for one conducted on the basis of the primary literature available, according to our procedure the latter approach was to be directly followed. This eventuality arose during the course of the project, so that ultimately the benefit assessment was based directly on primary studies.

The primary studies relevant to the research question were identified by a systematic literature search. In a first step, high-quality SRs were systematically searched for and relevant primary literature extracted from them. A systematic search for primary literature was subsequently conducted to fill any gaps in the evidence base which may have been caused, for example, by periods not covered or by varying language restrictions in the secondary literature. The databases MEDLINE and EMBASE, as well as the Cochrane databases, were searched up till September 2009.

The investigation included randomized controlled trials (RCTs) of at least 24 weeks in adult patients with essential hypertension. The intervention to be examined in these studies was a measure to increase physical activity. Primary studies were excluded in which the increase in physical activity as a primary intervention was compared to another antihypertensive treatment as a primary intervention (e.g. increased physical activity versus diet or blood pressure-lowering drugs).

The main priority in the report was to answer the question as to the benefit of the test intervention regarding morbidity and mortality. The following outcomes were predefined: all-cause mortality, cardiovascular morbidity and mortality, end-stage renal disease, health-related quality of life, discontinuation of or reduction in anti-hypertensive medication, all adverse events, and duration and extent of changes in blood pressure.

Results

Three high-quality SRs were identified that met the inclusion criteria for secondary literature. Only 4 RCTs of all primary studies included in these reviews were relevant to the report. The effort involved in a benefit assessment conducted on the basis of this secondary literature would have exceeded that required by an assessment directly conducted on the basis of primary literature, which is why, according to the procedure planned, we chose the latter approach. The SRs previously identified served as an evidence source that covered part of the relevant search period. By means of these SRs, as well as a handsearch in further secondary literature and a supplementary systematic search to cover evidence gaps, 10 topic-relevant RCTs could finally be identified. However, 2 of these studies had to be excluded from the assessment after a detailed evaluation as, in all probability, a population including both hypertensive and normotensive patients had been investigated without a subgroup analysis for those patients with hypertension; no analysis of the target population relevant to our report had therefore been performed. We nevertheless examined whether these studies would have had an impact on the result of the report; this was not the case. Four of the 8 remaining studies investigated the effect of a prespecified endurance training programme, and the other 4 investigated the effect of physical activity advice on systolic and diastolic blood pressure in patients with hypertension.

Most of the RCTs included were small studies with a maximum of 20 participants per group and a follow-up of 6 to 12 months. Most had a high risk of bias; only 2 studies showed minor or no deficits and thus a low risk of bias.

The RCTs included provided insufficient or no data on the following patient-relevant outcomes: all-cause mortality, cardiovascular morbidity and mortality, end-stage renal disease, health-related quality of life, and adverse events (e.g. falls or injuries related to falls). An assessment of the potential benefit or harm of increased physical activity as antihypertensive therapy in patients with essential hypertension was therefore not possible with regard to these outcomes.

Sufficient data were not available on the outcome “change in antihypertensive medication”. Data on a change in systolic or diastolic blood pressure were recorded in all 8 studies included. The studies varied greatly with regard to the interventions applied and patient populations included, as well as to methodological characteristics. Substantial statistical heterogeneity was also evident, so that pooled effect estimates were not calculated.

A reducing effect on systolic and diastolic blood pressure was more likely to be shown in studies with small sample sizes, which at the same time showed a high risk of bias, than in studies with a larger sample size and low risk of bias.

The mean reduction observed in systolic blood pressure lay between -5 and -8 mmHg in 5 studies, while in 2 studies greater effects of up to -15 mmHg were found. However, in one

study a slight increase in blood pressure was reported. The point estimates for the mean diastolic reduction in blood pressure varied between 0 mmHg and -10 mmHg.

In patients with hypertension, overall neither robust evidence nor a clue regarding a reducing effect on diastolic blood pressure through increased physical activity over a period of ≥ 6 months can be inferred from the available data. In contrast, although no robust evidence can be inferred of a reducing effect on systolic blood pressure through increased physical activity, a clue regarding such an effect can be inferred.

Concerning the patient-relevant outcomes investigated, the current evidence base provides no proof of a benefit from increased physical activity in patients with hypertension.

In view of the far-reaching implications and the widespread recommendations for this non-drug measure, and in view of the fact that the data provide a clue regarding a blood pressure-lowering effect, appropriate studies examining potential patient-relevant benefit and harm are urgently needed in order to contribute to improving the quality of care in this patient group.

Conclusion

No studies are available that provide sufficient data to assess the benefit of increased physical activity in patients with essential hypertension regarding the following patient-relevant outcomes: all-cause mortality, cardiovascular morbidity and mortality, end-stage renal disease, health-related quality of life, and adverse events.

Although in patients with hypertension, the available data do not provide robust evidence of a reducing effect on systolic blood pressure through increased physical activity over a period of ≥ 6 months, a clue regarding such an effect can be inferred. In contrast, neither robust evidence nor a clue regarding a reducing effect on diastolic blood pressure through increased physical activity can be inferred.

Overall, the data therefore provide neither proof nor an indication of a patient-relevant benefit or harm.

Key words: hypertension, activity – physical, exercise therapy, benefit assessment, systematic review.

The full German-language report and related documents are available under www.iqwig.de