IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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# Benefit assessment of non-drug treatment strategies in patients with essential hypertension: stress-coping interventions[1]

# Executive Summary

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## Background

Blood-pressure-lowering drugs, known as antihypertensive drugs, as well as various non-drug treatment strategies, are available for the treatment of essential hypertension. Leading national and international medical societies recommend the consistent, long-term implementation of non-drug interventions within the framework of antihypertensive therapy.

## Research question

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

## Methods

It was originally planned to conduct the benefit assessment on the basis of the results of systematic reviews of randomized controlled trials (RCTs). 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 underlying primary literature, according to our procedure the latter approach was to be directly adopted. This eventuality arose during the course of the project, so that ultimately the benefit assessment was based directly on primary studies (RCTs).

In a first step, a literature search for relevant systematic reviews was conducted in the following databases: MEDLINE, EMBASE, PsycINFO, the Cochrane Database of Systematic Reviews (Cochrane Reviews), the Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The period up to 31.05.2010 was covered. The systematic reviews were screened for further relevant studies. Subsequently, a systematic search for RCTs was conducted in the databases MEDLINE, EMBASE, PsycINFO, and the Cochrane Central Register of Controlled Trials (Clinical Trials) for the period between 01.01.2007 and 27.07.2010.

The investigation included RCTs of at least 24 weeks in adult patients with essential hypertension. The intervention to be examined was an intervention to manage stress. RCTs were excluded in which the stress-coping intervention as a primary intervention was compared to another antihypertensive treatment as a primary intervention (e.g. stress reduction versus diet or versus blood-pressure-lowering drugs).

The following outcomes were predefined: all-cause mortality, cardiovascular morbidity and mortality, end-stage renal disease, health-related quality of life, discontinuation of and/or reduction in anti-hypertensive medication, all adverse events, as well as duration and extent of changes in blood pressure.

## Results

Fourteen systematic reviews meeting the inclusion criteria for secondary literature were identified. These reviews included 15 RCTs relevant to the report. According to the procedure planned in the event of such a ratio of primary literature to secondary literature, a benefit assessment was conducted directly on the basis of the primary literature. In this context, the previously identified systematic reviews served as an evidence source covering part of the

relevant area of the literature search. Ultimately, 16 relevant RCTs were identified via these systematic reviews, a handsearch of further secondary literature, as well as a supplementary search to cover gaps in the evidence basis.

Fourteen of the 16 RCTs were designed to investigate the effect of differently instructed stress-coping therapies on systolic and diastolic blood pressure in patients with hypertension. The 2 other studies also investigated the effect of a corresponding intervention; however, the primary outcome here was a change in antihypertensive medication, with prespecified blood pressure target levels.

The RCTs included were all smaller studies with 9 to a maximum of 72 participants with hypertension per study group. Most of the studies were published in the 1970s and 1980s. The studies lasted 6 to 60 months. The risk of bias in all included studies was classified as high for all reported outcomes, except for the results on all-cause mortality and on cardiovascular morbidity and mortality in Patel 1988.

The RCTs included provided no data or only insufficient data on the following patient-relevant outcomes: all-cause mortality, cardiovascular and morbidity and mortality, end-stage renal disease, health-related quality of life, and adverse events. Consequently, an assessment of the benefit or harm of a stress-coping intervention as an antihypertensive therapy in patients with essential hypertension was not possible for these outcomes.

In contrast, for the assessment of changes in blood pressure, 14 studies provided data on systolic and diastolic blood pressure; 2 studies were designed as an attempt to reduce or omit antihypertensive medication and could therefore not be considered here.

These 14 studies investigated different forms of stress-coping interventions and were markedly heterogeneous with regard to the interventions. Differences also existed in the handling of antihypertensive concomitant medication during the study. In 7 RCTs this was to remain consistent, which is why they seemed more likely to be suited to assess an isolated effect of stress-coping interventions. However, a corresponding sensitivity analysis, which compared the results of these studies with those of the studies where it was unclear whether antihypertensive concomitant medication had remained consistent, did not provide indications that this factor influenced the effect of stress-reducing interventions on blood pressure. Ultimately, the observed heterogeneity of the results on changes in blood pressure could neither be explained satisfactorily by the concomitant medication nor by the type of stress-coping intervention. Due to great statistical heterogeneity, which could not be resolved reliably, no common effect estimate was calculated.

Compared to controls, the observed mean reduction in diastolic blood pressure by stress-coping interventions lay between −10 and +1 mmHg; in 13 studies the point estimate was in favour of the intervention. A statistically significant reduction in diastolic blood pressure was observed in 6 studies. The point estimate for the mean change in systolic blood pressure varied between −12 and +10 mmHg: 5 studies showed a statistically significant reduction in blood pressure; however, several point estimates were in favour of the control intervention. No statistically significant increase in either blood pressure parameter compared with controls was found in any study.

The available data provide an indication of a lowering effect on diastolic blood pressure through stress-coping interventions in patients with hypertension over a period of 6 months or longer. However, no such indication was provided for systolic blood pressure. Nevertheless, for both blood pressure parameters the results were numerically similar, indicating a positive effect of the interventions. The data provide neither proof nor an indication of an effect on systolic blood pressure or a change in antihypertensive medication.

Nine of the 16 studies included provided details on changes in antihypertensive medication during the course of the study. A statistically significant effect of the stress-coping intervention on blood pressure, with a resulting change in antihypertensive medication, was only reported in 2 studies; in both cases this was in favour of the stress-coping intervention. At the same time, no statistically significant change in blood pressure was shown in these studies. Therefore, the data provide neither proof nor an indication of an effect of stress-coping interventions on antihypertensive medication.

It should therefore be noted that with regard to the patient-relevant outcomes investigated, the current insufficient information basis does not provide proof of a benefit of stress-coping interventions in patients with hypertension. However, the available data do provide an indication of a diastolic blood-pressure lowering effect.

As many of the studies had already been conducted in the 1970s and 1980s, the transferability of the results to present society is possibly limited, as since then both lifestyle and the general extent and quality of stress levels have changed. Even though the data provide an indication of a blood-pressure-lowering effect of interventions for stress reduction, appropriate studies investigating a potential patient-relevant benefit are necessary in order to improve the quality of health care in this patient group.

**Conclusions**

No studies are available that provide sufficient data for a benefit assessment of a stress-coping intervention in patients with essential hypertension in respect of patient-relevant outcomes (all-cause mortality, cardiovascular morbidity and mortality, end-stage renal disease, health-related quality of life, or adverse events).

The available data provide an indication of a diastolic blood-pressure-lowering effect in patients with hypertension through stress-reducing interventions lasting at least 6 months. The data provide neither proof nor an indication of an effect on systolic blood pressure or on a change in antihypertensive medication.

Overall, the data therefore neither provide proof nor an indication of a patient-relevant benefit or harm of a stress-coping intervention in patients with essential hypertension.

**Keywords:** hypertension, stress management, biofeedback, relaxation therapy, benefit assessment, systematic review

*The full rapid report (German version) is published under www.iqwig.de*