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Benefit assessment of non-drug treatment strategies in patients with essential hypertension: Special diets without the primary aim of reducing weight or salt intake[1]

Executive Summary

[1] Translation of the executive summary of the rapid report "Nutzenbewertung nichtmedikamentöser Behandlungsstrategien bei Patienten mit essenzieller Hypertonie: Spezielle Ernährungsformen ohne primär körpergewichts- oder kochsalzreduzierende Intention" (Version 1.0; Status: 19.09.2011). 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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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 and external reviewers 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 his comments on the rapid report. However, he was not involved in the preparation of the rapid report. Individual sections and conclusions in the rapid report therefore do not necessarily reflect his opinion.

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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, including a dietary change to a specific diet, the Dietary Approaches to Stop Hypertension "(DASH) diet".

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 a specific diet known as the "DASH diet" versus no such diet in patients with essential hypertension.

Methods

The assessment was performed on the basis of relevant randomized controlled trials (RCTs). For this purpose, a systematic literature search was conducted in the databases MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials (Clinical Trials). In addition, a search for relevant systematic reviews was conducted in the databases MEDLINE, EMBASE, 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). These secondary publications were screened for further relevant studies. The literature search covered the period up to 17 March 2011.

The investigation included randomized controlled trials (RCTs) of at least 24 weeks duration in adult patients with essential arterial hypertension. The intervention to be examined was a change in dietary habits to a specific diet known as the "DASH diet". The comparator treatment was the absence of such a specific diet, with otherwise the same antihypertensive treatment as in the intervention group. RCTs were excluded in which DASH as the sole treatment was compared with another antihypertensive treatment (e.g. DASH diet versus a stress coping-intervention or a different dietary intervention).

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

Results

Twelve publications, all of which could be allocated to a single study, were identified. This study met all inclusion criteria of the report in full and was used in the benefit assessment.

This was a multicentre study that investigated persons with high-normal blood pressure or Grade 1 hypertension over 18 months. The mean age of the participants was 50 years and about two-thirds were women. Three treatment groups were compared with each other in an RCT with an open study design. The treatment of patients in one group consisted of a

complex behavioural intervention with the aim of reducing calorie, salt and alcohol intake and increasing physical activity. Another group received the same behavioural intervention and, in addition, advice about the DASH diet. A third group received general advice about lifestyle. Only the comparison of the first two treatment groups was suitable for an assessment of the benefit of a DASH diet. The study results were shown separately for the subpopulation of patients with hypertension, but these results were only available for the surrogate outcomes "duration and extent of change in blood pressure" and "changes relating to antihypertensive medication (new prescription / discontinuation of antihypertensive medication or reduction / increase in existing antihypertensive medication)". There was no information on the patient-relevant outcomes "all-cause mortality", "cardiovascular mortality and morbidity", "end-stage renal disease", "health-related quality of life", or "all adverse events" for the subgroup relevant to the report. Hence, an assessment of the benefit or harm from a change in diet to the DASH diet as antihypertensive therapy in patients with essential hypertension was not possible for these outcomes.

The study showed a low risk of bias at study level and at outcome level for the outcomes "change relating to antihypertensive medication" and "duration and extent of change in blood pressure".

Compared to the study group with solely behavioural intervention, at the end of the study there was a 0.4 mmHg difference in systolic blood pressure in favour of the group with additional DASH diet recommendation. In contrast, the group difference for diastolic blood pressure at the end of the study amounted to 0.1 mmHg to the disadvantage of the DASH group. None of these differences were statistically significant. There was also no statistically significant difference between the two comparator groups regarding the outcome "change relating to antihypertensive medication".

Conclusions

There are no studies available that provide adequate data for a benefit assessment of a dietary change to a specific diet known as the "DASH diet" 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 "all adverse events".

Adequate data were only available for the two surrogate parameters "duration and extent of change in blood pressure" and "changes relating to antihypertensive medication (new prescription / discontinuation of existing antihypertensive medication)". Neither proof nor an indication of a benefit or harm from a DASH diet could be derived from these data.

There is thus overall no proof or indication of a patient-relevant benefit or harm from a change in dietary habits to the specific "DASH diet".

Keywords: hypertension, DASH diet, benefit assessment, systematic review

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