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**Benefit assessment of  
non-drug treatment  
strategies in patients with  
essential hypertension:  
reduction in salt intake<sup>1</sup>**

**Executive Summary**

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<sup>1</sup> Translation of the executive summary of the rapid report “Nutzenbewertung nichtmedikamentöser Behandlungsstrategien bei Patienten mit essenzieller Hypertonie: Kochsalzreduktion” (Version 1.0; Status: 18.06.2009). 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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# **Benefit assessment of non-drug treatment strategies in patients with hypertension: reduction in salt intake**

## **Executive summary**

### **Background**

The main treatments available for essential hypertension are blood pressure-lowering drugs, known as antihypertensive drugs, and 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.

In the present rapid report (A05-21B), the benefit of reduced salt intake is assessed as a non-drug treatment strategy in patients with essential hypertension.

### **Research question**

The aim of this investigation was to assess the benefit of interventions for reducing salt intake compared to interventions that are not intended to reduce salt intake in patients with essential hypertension with reference to patient-relevant outcomes and criteria used in blood pressure control.

### **Methods**

The research question was addressed using secondary literature, i.e. systematic reviews. Current papers were consulted that summarized and evaluated the results of primary studies in a systematic, transparent and reproducible manner.

These reviews were identified by a systematic literature search: MEDLINE, EMBASE and Cochrane databases were searched up till December 2008. Reviews published from 1997 onwards were considered.

The investigation included systematic reviews of randomized controlled trials of at least 4 weeks' duration of adult patients with essential hypertension. The intervention to be tested in these trials was a measure for reducing salt intake, and the intended salt intake in the intervention group was lower than in the control group. Excluded were systematic reviews and HTA reports in which the reduction in salt intake as a primary intervention was compared to another antihypertensive treatment as a primary intervention (e.g. reduced salt intake versus diet or versus blood pressure-lowering drugs).

The investigation applied predefined outcomes that enabled patient-relevant outcomes to be evaluated: all-cause mortality, cardiovascular morbidity and mortality, hospital stays, terminal renal failure, (in)capacity for work, health-related quality of life, patient satisfaction and adverse events. In addition to the patient-relevant outcomes, surrogates were also recorded, in

this instance particularly the duration and extent of change in blood pressure, as well as the discontinuation of or reduction in antihypertensive medication.

The methodological quality of the systematic reviews was evaluated using Oxman and Guyatt's quality index. Studies were included if they scored at least 5 out of 7 possible points when assessed by 2 reviewers independently of each other.

The robustness of the report's results on the basis of secondary literature was checked by evaluating a random sample of the primary studies included in the reviews and conducting a targeted update search of primary studies for the period following the last search date of the included systematic reviews. This confirmed sufficient robustness within the scope of this methodology.

## Results

A total of 1491 potentially relevant reviews published since 1997 were identified from the database search. After titles and abstracts were screened by 2 reviewers, 46 potentially relevant secondary publications remained, one of which was a duplicate. The next stage of selection was performed on a full-text basis. After screening and assessing the full text, 12 references were considered to be relevant, 7 of which were also assessed as being of high methodological quality according to Oxman and Guyatt's index. These publications were classified according to 4 groups of authors, each with 1 main publication.

The results are based on analyses of a total of 62 randomized controlled trials.

Overall, it could not be assumed that the methodological quality of all primary studies was unreservedly sufficient.

No primary study was identified where the primary objective was to investigate the reduction in salt intake as an intervention in order to prevent late complications such as all-cause mortality and cardiovascular mortality or morbidity. In relation to these outcomes, it is therefore not possible, due to insufficient data, to evaluate the potential benefit of a reduction in salt intake as an antihypertensive treatment in patients with essential hypertension.

In relation to blood pressure, all analyses showed a blood pressure-lowering effect in hypertensive patients through reduced salt intake when compared to a control treatment. The extent of the effect varied among the reviews.

Over an intervention period of up to 12 months, the analyses showed a significant advantage with regard to mean systolic blood pressure reduction ranging from 3.6 to 8.0 mmHg. For the same intervention period, a significant advantage with regard to mean diastolic blood pressure reduction ranging from 1.9 to 2.8 mmHg was only found in 3 reviews. In the fourth publication, an advantage was also observed (difference of 4.7 mmHg compared to control treatment), but there was no statistical significance.

These data primarily apply to analyses of patients without concomitant antihypertensive drug treatment (3 reviews; 1 review put untreated and treated patients together in the presentation of results).

In their analyses, none of the reviews considered only studies that included hypertensive patients with concomitant antihypertensive drug treatment nor was there a separate analysis of patients treated with antihypertensive drugs in any review. Therefore, it is not possible from the given data to draw a conclusion concerning a potentially extra effect of reducing salt intake in addition to an antihypertensive drug treatment.

No precise conclusions can be drawn from the available studies on the sustainability of a blood pressure-lowering effect over time. The authors of one review reported that the significant advantage from restricting salt, based on results of studies with a duration of 2 to 12 months, could no longer be verified when the analysis was then restricted to studies with a minimum duration of 6 months. Moreover, they found a negative correlation between the number of study participants and the effect on diastolic blood pressure, i.e. smaller studies revealed a greater reduction in diastolic blood pressure than those with greater numbers of patients.

## **Conclusions**

A benefit or harm from a salt-reduced diet in patients with high blood pressure has not yet been proven with regard to patient-relevant outcomes based on randomized controlled trials.

The systematic reviews included in this report are based on randomized controlled trials mainly of short duration. The results of these reviews prove a blood pressure-lowering effect through reducing salt intake in patients with essential hypertension.

The full report (in German) is available on <http://www.iqwig.de/index.581.html>