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**Benefit assessment of non-drug  
treatment strategies in patients  
with essential hypertension:  
reduction in alcohol  
consumption<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: Reduktion des Alkoholkonsums” (Version 1.0; Status: 25.07.2011). 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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## **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 various non-drug interventions within the framework of antihypertensive therapy.

## **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 reducing alcohol consumption versus no such intervention as a non-drug treatment strategy 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). The systematic reviews were screened for further relevant studies. The literature search covered the period up to 10.03.2011.

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

The highest priority in the report was to answer the question as to the benefit of the test intervention regarding morbidity and mortality. Specifically, the following patient-relevant 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, and all adverse events. In addition, the surrogate outcome “duration and extent of changes in blood pressure” was investigated.

## **Results**

Two relevant RCTs were identified: 1 study was conducted in France and 1 in the United States, each lasting 2 years. A total of 129 and 266 (mainly male) patients with hypertension having a high intake of alcohol (about 6 to 7 alcoholic beverages per day) were included. Patients with alcohol dependency were excluded or, as in the French study, it was assumed

that most participants were not dependent on alcohol. In the French study, the intervention comprised a programme for reducing alcohol consumption conducted within the framework of occupational medical care. An attempt was made to normalize participants' liver enzyme levels (gamma-GT), which were elevated at the time of inclusion in the study. The US study was primarily a long-term cognitive behavioural training programme with psychodynamic and social components. Through this intervention, individual consumption was to be either halved or reduced to less than 28g/day. In both studies specially trained staff supervised the implementation of the interventions or corresponding training programmes were conducted. Complete alcohol abstinence was not the aim of the intervention in either study.

In the French study, alcohol consumption in the test group did not decrease statistically significantly greater than in the control group, whereas in the US study, the participants in the test group drank about 1.4 alcoholic beverages less per day at the end of the study than those in the control group.

All results on outcomes relevant to the report were regarded as carrying a potentially high risk of bias. The RCTs included did not provide data or provided only insufficient data on the following patient-relevant outcomes: all-cause mortality, cardiovascular mortality and morbidity, end-stage renal disease, health-related quality of life, and adverse events. Consequently, an assessment of the potential benefit or harm of a non-drug treatment strategy for reducing alcohol consumption in patients with essential hypertension was not possible.

In the US study, the reduction observed in alcohol consumption was not accompanied by a statistically significant decrease in systolic or diastolic blood pressure in hypertensive patients. Even though no statistically significant reduction in alcohol consumption was achieved in the French study, compared with the control group, a statistically significant decrease in systolic blood pressure was found; however, this did not apply to diastolic blood pressure. In both studies no relevant or statistically significant group differences regarding changes in antihypertensive medication were noted. A meta-analytical evaluation of results was dispensed with in each case, as the information required for this purpose was lacking.

Thus only one study showed a statistically significant effect on the lowering of systolic blood pressure, which, however, carried a potentially high risk of bias. A statistically significant effect on the lowering of diastolic blood pressure was not reported in any study. Therefore, for an intervention targeted towards reducing alcohol consumption in hypertensive patients, no proof is available overall of a lowering effect on systolic or diastolic blood pressure, or an effect on changes in antihypertensive medication. Likewise, the data provide no indication of such an effect.

With regard to an impact on cardiovascular secondary diseases as a complication of hypertension, the current information basis does not provide proof of a benefit of interventions for reducing alcohol consumption within the framework of antihypertensive treatment. However, of course this does not affect the fact that excessive alcohol consumption

or high-risk drinking behaviour is associated with considerable potential for causing harm at an individual, but also at a societal level. In this regard, the fundamental benefit of treatment of alcohol dependency or high-risk drinking behaviour is not questioned by the result of the present report.

### **Conclusions**

No studies are available that provide data for a benefit assessment of an intervention for reducing alcohol consumption 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). No effect on changes in antihypertensive medication or in systolic or diastolic blood pressure is proven, nor do the data provide any indication of such effects.

With regard to the patient-relevant outcomes investigated, no benefit in terms of a direct impact on the underlying disease by an intervention for reducing alcohol consumption in hypertensive patients is proven.

The fundamental benefit (i.e. the benefit independent of antihypertensive therapy) of treatment of alcohol dependency or high-risk drinking behaviour is by no means called into question by the results of the present report.

**Keywords:** hypertension, alcohol drinking, benefit assessment, systematic review

*The full rapid report (German version) is published under [www.iqwig.de](http://www.iqwig.de)*