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L-methionine in patients with neurogenic bladder disorders¹

Executive Summary

¹ Translation of the executive summary of the final report “L-Methionin bei Patienten mit neurogenen Blasenstörungen” (Version 1.0; Status: 11.05.2010). 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

In its letter of 22 December 2004, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess L-methionine in the treatment of patients with neurogenic bladder disorders. After a temporary deferment of the commission, new priorities were set at the G-BA on 14 April 2009.

Research question

The aim of this research was to assess the benefit of treatment with L-methionine in patients with neurogenic bladder disorders versus another drug- or non-drug intervention or versus placebo. The focus of the assessment was on patient-relevant outcomes. The interventions had to be used with the aim of preventing or treating urinary tract infections (UTIs) or urinary stones (phosphate stones).

Methods

The assessment was conducted on the basis of randomized controlled trials (RCTs) on the research question outlined above. For this purpose, a systematic search for literature (coverage up to September 2009) was conducted in the databases MEDLINE, EMBASE, BIOSIS, as well as in the Cochrane databases (the specialist databases Cochrane Database of Systematic Reviews [Cochrane Reviews], Database of Abstracts of Reviews of Effects [Other Reviews], and Health Technology Assessment Database [Technology Assessments]). Reference lists of relevant secondary publications (systematic reviews, HTA reports) were also screened. In addition, trial registries, publicly accessible regulatory documents, and comments to the G-BA were scanned, and the manufacturer of L-methionine was asked to provide relevant published and unpublished studies.

RCTs were included that investigated patients with neurogenic bladder disorders and used L-methionine according to the valid approval status in Germany. Potential comparator interventions were drug- or non-drug therapies used in patients with neurogenic bladder disorders, either to prevent or treat UTIs or urinary stones (phosphate stones), or to optimize the effect of antibiotics with an optimum impact in acidic urine. Other comparators were placebo interventions. There was no restriction of study duration. The literature screening was performed by 2 reviewers independently of one another. After assessing the risk of bias, the results of the studies included were analysed.

Results

One placebo-controlled study was identified for the assessment of L-methionine. No studies with active comparator treatments were found.

In the study included, the outcomes UTIs and adverse events were investigated; however, information relevant to the benefit assessment was only available for adverse events. No data were available for the following outcomes: overall mortality, other complications due to the neurogenic bladder disorder, inpatient treatment, health-related quality of life, activities of daily living and active social life, invested time and effort related to the disease or intervention, and treatment satisfaction.

Urinary tract infections

In the study included, for the diagnosis of a UTI either a urine bacterial count (UBC) of 10^6 /ml was required or a UBC of 10^5 /ml in patients with accompanying clinical symptoms. The UTI outcome was therefore a combined outcome. In clinical practice guidelines, an increased UBC alone is not necessarily seen as relevant and requiring treatment. Only the existence of accompanying clinical symptoms or additional findings constitutes the need for therapy and therefore the relevance to patients. For this reason, this component of the combined outcome and thereby the whole combined outcome of the study included were assessed as not being patient-relevant. A separate analysis for the second component of the outcome, i.e. patients who also had clinical symptoms, was not available. Overall it was therefore not clear from the study included whether L-methionine decreases the recurrence rate for patient-relevant UTIs.

Treatment-related adverse effects

The available information on adverse events in the study included was not fully clear. According to the publication, a total of 5 patients experienced at least one adverse event. On the basis of this information and information from a query to the authors, we assumed that 3 patients in the L-methionine group and 2 in the placebo group experienced an adverse event ($p = 0.706$). No serious adverse events or discontinuations due to adverse events occurred in the study.

Conclusion

There is no proof of benefit or harm from L-methionine in the treatment of patients with neurogenic bladder disorders, neither for the prevention or treatment of UTIs or urinary stones (phosphate stones), nor for the optimization of the effects of antibiotics with an optimum impact in acidic urine.

Key words: methionine, L-methionine, urine acidification, neurogenic bladder disorder, urinary tract infection, benefit assessment, systematic review