

L-methionine in patients with neurogenic bladder disorders: neither benefit nor harm proven

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It is unclear whether patients with neurogenic bladder disorders benefit from the drug L-methionine. The only study currently available provides neither proof of benefit nor proof of harm. This is the result of a report published by the German Institute for Quality and Efficiency in Health Care (IQWiG) on 12 July 2010.

The normal function of the bladder is to ensure the storage of urine and its controlled and coordinated excretion. This coordinating activity is regulated by the nervous system. If this system is damaged and the connection between bladder and nervous system totally or partially interrupted, this is referred to as a "neurogenic bladder disorder".

The patients affected often perceive little or no urge to void urine and are either unable to begin voiding or cannot stop the bladder from passing urine (incontinence). This may lead, among other things, to recurrent [urinary tract infections](#) (UTIs). This is due to the fact that after the bladder has been emptied a small amount of urine always remains, promoting the formation of urinary stones (phosphate stones) and bladder infections, which may spread to the kidneys. In addition, urine may accumulate permanently in the kidneys. For these reasons, patients with neurogenic bladder disorders often have a reduced quality of life and an increased risk of [kidney damage](#).

L-methionine lowers the pH of the urine

Drug treatment is often targeted towards the muscles involved in the storage of urine and the emptying of the bladder. The agent L-methionine, which has been on the market for some 30 years, has a different mode of action, achieving its effect by the acidification of urine. The lower pH aims to prevent [bacterial growth](#) and the adherence of bacteria to the bladder wall, thus contributing to the healing of existing UTIs and the prevention of new ones. In addition, it aims to prevent the formation of urinary stones and improve the effects of antibiotics with an optimum impact in acidic urine.

Study only included 89 patients

The IQWiG researchers searched for studies in which one group of patients with neurogenic bladder disorders received L-methionine and the comparator group received either a different drug or non-drug therapy or placebo. The aim of the interventions had to be the treatment or prevention of UTIs or urinary stones or the optimization of the effects of antibiotics. The participants had to be randomly allocated to treatment groups. There were no restrictions regarding study duration.

The literature search showed that only one study including a total of 89 patients with paraplegia fulfilled these criteria. In this study L-methionine was compared to placebo. Unfortunately, important aspects pertaining to the design and conduct of the study remained unclear in the publication. In the opinion of the IQWiG researchers, the results of the study are therefore highly susceptible to bias. The sponsor of the study, who was also the manufacturer of the L-methionine agent, did not provide additional information requested by IQWiG.

Data on urinary tract infections are not informative

The study did not provide data on most outcomes such as mortality,

hospital stays, other complications caused by the neurogenic bladder disorder, or quality of life. Only data on adverse events and UTIs were collected and reported.

Similarly high rates of adverse events occurred in both treatment groups, so that there is no proof that L-methionine causes harm.

In the study, UTIs were summarized in two outcomes: 1) patients who only had an increased urine bacterial count (UBC), and 2) patients with both a specific UBC and accompanying clinical symptoms, such as fever. However, according to clinical practice guidelines, an increased UBC alone is not relevant and therefore does not require treatment. An increased UBC only becomes a patient-relevant outcome in combination with clinical symptoms. In IQWiG's opinion the results are not informative, as the study did not provide a separate analysis for the group with symptoms. Therefore no proof of a benefit of L-methionine exists with regard to UTIs.

Procedure of report production

IQWiG published the preliminary results, the preliminary report, at the end of February 2010 and interested persons and parties were invited to submit comments. When the commenting procedure ended, the preliminary report was revised and sent as a final report to the contracting agency, the Federal Joint Committee, in mid-May 2010. Documentation of the written comments and the minutes of the oral debate are published in a separate document simultaneously with the final report. The report was produced in collaboration with external experts.

Provided by Institute for Quality and Efficiency in Health Care

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