IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Screening for asymptomatic bacteriuria within the framework of the German maternity guidelines, under special consideration of test methods[1]

Executive Summary

[1] Translation of the executive summary of the final report *Screening auf asymptomatische Bakteriurie im Rahmen der Mutterschafts-Richtlinien unter besonderer Berücksichtigung der Testmethoden* (Version 1.0; Status: 19 February 2015). 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.

The responsibility for the contents of the report lies solely with IQWiG.

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IQWiG thanks the external experts for their collaboration in the project.

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[2] Due to legal data protection regulations, employees have the right not to be named.

Executive summary

On 20 August 2013, the Federal Joint Committee (G-BA) wrote to the Institute for Quality and Efficiency in Health Care (IQWiG) to commission the benefit assessment of screening for asymptomatic bacteriuria (ASB) in pregnant women, under special consideration of the test methods applied.

Research question

The goal of this research was to assess the patient-relevant benefit of universal screening for ASB in pregnant women. The research question was divided into several subgoals.

In subgoal A, the benefit of screening for ASB was to be examined, especially the type of screening described in the German maternity guidelines, that is, screening by means of a urine sediment test as a triage test before a urine culture.

If the evidence found on subgoal A was insufficient to assess the patient-relevant benefit of screening versus no screening, in subgoal B those studies were to be examined that investigated the benefit and harm of treatment for ASB versus no treatment in pregnant women with ASB that had been detected in screening.

If subgoal A or B showed a benefit, it was planned in subgoal C to examine which test method showed the highest diagnostic or prognostic accuracy.

Methods

For subgoal A, randomized controlled trials (RCTs) and, if appropriate, non-randomized intervention studies with concurrent control groups (controlled clinical trials, CCTs) were to be included. For subgoal B, RCTs and CCTs were included. For subgoal C, prospective cohort studies were to be included in which pregnant women with unknown bacteriuria status were to be investigated with at least 2 test methods, which were then to be put in relation to the clinical course of upper and lower tract urinary infections (UTIs), (prognostic studies).

A systematic literature search was performed in the following databases: MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials (Clinical Trials). In addition, in parallel to the search for relevant primary studies, a search for relevant systematic reviews was conducted in the databases MEDLINE and EMBASE as well as in the databases Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (Other Reviews), and the Health Technology Assessment Database (Technology Assessments). The last search related to subgoals A and B was conducted on 21 October 2014. The search related to subgoal C was superfluous.

Systematic reviews and publicly available trial registries were also searched. In addition, documents sent by the G-BA and publications that had been provided in the hearing procedure for the preliminary report plan were screened. Furthermore, the authors of a

publication on the study protocol were contacted and asked to provide so far unpublished data.

The selection of relevant studies from the above sources was performed by 2 reviewers independently of each other.

Data were extracted into standardized tables. To evaluate the certainty of results, the risk of bias at study and outcome level was assessed and rated as low or high respectively. The results of the individual studies were described, organized by outcomes. If the studies were comparable regarding the research question and relevant characteristics, the individual results were to be pooled quantitatively by means of meta-analyses.

Results

A total of 3 studies (3 RCTs) were identified as relevant for the research question of the present benefit assessment. The 3 studies referred to treatment for ASB (subgoal B). They investigated antibiotic treatment versus no treatment or placebo in pregnant women with ASB. One study each contained data on the patient-relevant outcomes “pyelonephritis”, “lower UTI”, and “neonatal morbidity”, and 2 studies contained data on adverse events.

No study contained information on the main characteristics of the study populations, which makes the interpretation of results considerably more difficult. In addition, due to the missing information it was not possible to assess comparability with the characteristics of pregnant women today.

In one study, the results for the outcome “pyelonephritis” showed a statistically significant reduction of events under antibiotic treatment, which leads to the conclusion that there is a hint of an effect with regard to this outcome. The majority of the study population participated in a preceding study, for which the pregnant women were hospitalized and received no fluids for 24 hours. These measures do not conform to current guideline recommendations and create a situation that differs substantially from the normal healthcare situation today and can thus potentially influence the effects observed. Primarily for this reason, the study results were regarded to be non-applicable to the current healthcare situation. For the benefit assessment of antibiotic treatment versus no treatment in pregnant women with ASB, this thus leads to the conclusion that there is no hint, indication or proof that such treatment reduces the occurrence of pyelonephritis.

In another study, the results for the outcome “lower UTI” showed a statistically significant reduction of events under antibiotic treatment versus no treatment in pregnant women with ASB; this would lead to the conclusion that there is a hint of an effect. However, on the basis of the information provided in the study, it remains unclear whether 2 different procedures were used to identify the women included, and how they were used (i.e. which combination of tests and which cut-off values were applied). It is thus not possible to relate the observed effects to a specific diagnostic strategy. Due to the unclear applicability, for the benefit

assessment this leads to the conclusion that there is no hint, indication, or proof of a reduction in the occurrence of lower UTIs.

Information on the outcome “neonatal morbidity” (for the outcome “kernicterus”) was available in one study. Information on the outcome “adverse events” was available for several events (vomiting, skin rash/pruritus, photosensitivity, and discontinuation due to adverse events). However, on the basis of the information provided in the publication (no case of kernicterus, one case of vomiting in the intervention group, and no further adverse events), the effect of antibiotic treatment with regard to these outcomes could not be determined. For the benefit assessment this leads to the conclusion that there is no hint, indication or proof of a benefit or harm from antibiotic treatment versus no treatment with regard to neonatal morbidity and adverse events.

Conclusion

The patient-relevant benefit or harm of screening for ASB in pregnant women (subgoal A) is unclear due to a lack of studies.

The patient-relevant benefit or harm of antibiotic treatment of ASB in pregnant women (subgoal B) is not proven, as the evidence base is unsuitable with regard to the current healthcare situation of pregnant women.

Due to the unclear patient-relevant benefit of screening or treatment for ASB in pregnant women, the prognostic accuracy of the available test methods for detection of ASB (subgoal C) was not investigated.

Keywords: mass screening, bacteriuria, pregnancy, benefit assessment, systematic review

The full report (German version) is published under

https://www.iqwig.de/de/projekte-ergebnisse/projekte/nichtmedikamentoese-verfahren/s13-02-screening-auf-asymptomatische-bakteriurie-im-rahmen-der-mutterschaftsrichtlinien-unter-besonderer-berucksichtigung-der-testmethoden.3700.html