IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Working Paper – Update of Commission No. S07-01

Search update for report S07-01 – Screening for gestational diabetes[1]

Executive Summary

[1] Translation of the executive summary of the working paper "Aktualisierungsrecherche zum Bericht S07-01 – Screening auf Gestationsdiabetes" (Version 1.0; Status: 25.03.2010). Please note that 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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Institute for Quality and Efficiency in Health Care
Dillenburger Str. 27
51105 Cologne
Germany

Tel.: +49-221/35685-0
Fax: +49-221/35685-1
berichte@iqwig.de
www.iqwig.de

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Executive summary

Research question

Gestational diabetes (GDM: gestational diabetes mellitus) is generally understood to mean any impaired glucose tolerance (IGT) first occurring or diagnosed during pregnancy. This glucose metabolic disorder can occur in varying degrees of severity, ranging from mild IGT to manifest diabetes mellitus.

The relevance of the diagnosis "gestational diabetes" and its association with pregnancy and birth risks, as well as the existing uncertainties in this context, are presented in detail in the final report "Screening for gestational diabetes" (Commission S07-01). During the work on the commission, an ongoing study (Landon et al) on sub-goal 2 ("therapies") was identified, which provided a realistic chance of reducing existing uncertainties in the final report. At the time of the publication of the final report, the results of this study had only been presented as an abstract at scientific conferences, but were not available as a full-text publication, so that the study could not be included in the assessment up to July 2009.

In the meantime the study by Landon et al has been published. The present working paper describes the effects of this study on the results and conclusions of final report S07-01.

The aims are:

- the update of the literature searches described in the final report S07-01 for the sub-goals 1 and 2. Compared to the final report, the search was limited to fewer databases (MEDLINE, EMBASE, Cochrane), and, for sub-goal 2, to randomized studies that could be allocated to study pool A.
- the extraction of results of the studies identified.
- an estimation of the effects on the conclusions of final report S07-01.

Methods

For the present investigation, a systematic search was performed for studies on the sub-goals of the research question. The results on patient-relevant outcomes and defined surrogate parameters were extracted and assessed in summary.

The detailed aims, methods, project process, and results of project S07-01 are described in the final report, which was published in August 2009. As in the final report, the sub-goal 1 "screening" primarily involved randomized controlled trials (RCTs) of unselected pregnant women. Non-randomized controlled trials (nRCTs) could be drawn upon if the problem of

possible structural inequality ("unfair comparison") was adequately addressed and comparable additional conditions existed between the study populations. In contrast to the final report, for sub-goal 2 ("therapies") only RCTs were considered in which a blood-glucose lowering intervention or another intervention targeted towards optimizing obstetric management was compared to an approach without such an intervention (usual care). The study pool investigating the comparison of treatments with differing intensities was not updated. These restrictions were based on the fact that the results of study pool A were already based on RCTs, and that only additional RCTs would have had the potential to modify these results.

For the present working paper, in accordance with the methods of project S07-01, particular consideration was given to the following outcomes, which allowed the assessment of patient-relevant outcomes.

- Maternal outcomes: mortality, type of delivery, birth complications (e.g. shoulder dystocia), and pre-eclampsia/eclampsia.
- Infant outcomes: perinatal and neonatal mortality, birth trauma, diagnostic and therapeutic measures extending beyond what is usual, admission to intensive care, and adverse events.

Macrosomia/birth weight was not a patient-relevant outcome, but a surrogate parameter of unclear validity.

Results

The core question of commission S07-01 could not be conclusively answered in this working paper. For the sub-goal 1 "screening", studies could still not be identified in which screening for gestational diabetes was compared with no screening. The assessment of sub-goal 1 therefore still concluded that no proof of the benefit or harm from screening for gestational diabetes was available for any patient-relevant outcome.

For the assessment of the benefit of therapies (sub-goal 2), one new study (Landon 2009) could be included in study pool A. The assessment of the 5 RCTs in the updated study pool A showed the following findings for the comparison between GDM-specific therapies and usual care: in the overall consideration of results, Crowther 2005 is still evaluated as an indication of a benefit regarding "serious perinatal complications". However, the extent of the benefit remains unclear. For the outcome "shoulder dystocia", proof is now available of a benefit from GDM-specific therapy. For the outcome "pre-eclampsia", an indication of a benefit is available, based on Landon 2009.

Meta-analyses showed a statistically significant lower proportion of macrosomic / "large-for-gestational-age" (LGA) infants as a result of GDM-specific therapy.

Harm caused by GDM-specific therapy was not explicitly investigated in the studies and consequently not reported. A meta-analysis of "small-for-gestational-age" infants showed no statistically significant difference.

Even if an indication of a benefit from GDM-specific therapy exists, it does not necessarily follow that there is an indication of a benefit from screening. The following aspects of potential harm were considered: time and effort needed for the test, adverse events from oGTT, detrimental psychological effects, false-negative test results, and effects of risk compensation. Overall, on the basis of these considerations a potential for harm from screening for gestational diabetes was inferred. However, the potential risks from screening for women with a negative oGTT were not evaluated as serious.

Direct conclusions as to the benefit and harm of screening were still not possible. However, there was proof of a benefit from GDM-specific therapy with regard to the reduction of the rate of shoulder dystocia; for the broader combined outcome of perinatal complications, the prior conclusion ("indication of a benefit") remained unchanged. An indication was indirectly deduced from this that screening for gestational diabetes leads to a reduction in perinatal complications. This deduction is based on the assumption that screening leads to the identification of a population like the one included in the relevant therapy studies.

Assessment of the effects on the conclusions of final report S07-01

The conclusions of final report S07-01 were as follows:

"There is an indication of benefit from a therapy specific to gestational diabetes. No direct proof or indications exist of a benefit or harm from screening for gestational diabetes, since no suitable screening studies were identified. Nevertheless, an indication can be indirectly deduced that screening for gestational diabetes leads to a reduction in perinatal complications."

The results of the present working paper would lead to the following change in the conclusions of final report S07-01 (changes in italics).

There is *proof* of a benefit from a therapy specific to gestational diabetes. No direct proof or indications exist of a benefit or harm from screening for gestational diabetes, since no suitable screening studies were identified.

Nevertheless, an indication can be indirectly deduced that screening for gestational diabetes leads to a reduction in perinatal complications.

Keywords: impaired glucose tolerance, gestational diabetes, screening, IGT, GIGT [gestational impaired glucose tolerance], oGTT, glucose challenge test, glucose tolerance test, systematic review

The full German-language working paper is available under
http://www.iqwig.de/download/Arbeitspapier_Aktualisierungsrecherche_Screening_auf_Gestationsdiabetes.pdf

The list of references, including the studies cited in this document, is on pp. 67-70.