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Screening for gestational diabetes[1]

Executive Summary

[1] Translation of the executive summary of the final report "Screening auf Gestationsdiabetes" (Version 1.1; Status: 25.08.2009). 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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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 impaired glucose tolerance to manifest diabetes mellitus.

Gestational diabetes is viewed by many professional associations as a disorder that should be diagnosed and treated, and which should be systematically identified through general screening. A possible justification for screening is based on the premise that diagnosis and intervention will reduce the risk of complications during pregnancy and birth for mother and baby. The list of potential maternal risks and complications from severe impaired glucose tolerance includes, for example, increased rate of Caesarean sections, pre-eclampsia and injuries during delivery. The list of risks to the baby includes, for example, birth trauma, acute respiratory distress syndrome, and metabolic disorders that require intervention.

Studies that test the complete screening chain on sufficiently large groups of pregnant women would provide the best basis for answering the question of whether screening for gestational diabetes has a benefit. They should also include pregnant women whose screening test produced a “normal” result. If there is a lack of suitable studies for the complete screening chain, a hierarchical assessment of the individual screening steps “diagnosis” and “therapy” can be useful.

Based on these premises, the main aim of this report was to assess the benefit of screening for impaired glucose tolerance during pregnancy with regard to patient-relevant outcomes. Further sub-goals were to assess:

(2) the efficacy of therapies,

(3) the relationship between the results of an oral glucose tolerance test (oGTT) and maternal/baby outcomes, and

(4) the comparability of the women included in the studies with regard to these last two sub-goals.

Methods

For the purpose of this investigation, systematic searches were made for studies on the partial research questions (MEDLINE, EMBASE, Cochrane and other databases). The results on patient-relevant outcomes and defined surrogate parameters were extracted and assessed in summary.

The sub-goal 1 "screening" primarily involved randomized controlled trials (RCTs) of unselected pregnant women. Non-randomized controlled trials (nRCTs) could be drawn on, if the problem of possible structural inequality (unfair comparison) was adequately addressed and comparable side effects from the collectives were available. The same conditions on study types applied to sub-goal 2 "therapy". Studies were to target pregnant women who had been diagnosed with impaired glucose tolerance under clinical circumstances resembling a screening setting. Sub-goal 3 "relationship" primarily involved prospective cohort studies of pregnant women with no known diabetes mellitus, in which the results of the oGTT remained blinded throughout the pregnancy.

The following outcomes in particular were used for this investigation, as they permitted patient-relevant outcomes to be assessed. Maternal results: mortality, type of birth, birth complications (e.g. shoulder dystocia), pre-eclampsia/eclampsia. Baby results: perinatal and neonatal mortality, birth trauma, diagnostic and therapeutic measures that extend beyond what is usual, admission to intensive care, adverse events. Macrosomia/birth weight was not a patient-relevant outcome; it was considered a surrogate parameter of unclear validity.

Results

The core question of this report could not be answered. For sub-goal 1 "screening", no studies could be found in which screening for gestational diabetes was compared with no screening. Although 2 nRCTs were identified, in each of which 2 screening strategies were compared with each other, none of the screening strategies used in the studies provided proof of benefit compared to no screening. Due to their design and analysis characteristics, both studies had a high risk of bias. Therefore, it was not possible to ascertain with sufficient certainty of results whether there was an effect from one of the screening strategies. The complete assessment for sub-goal 1 therefore produced no proof of benefit or harm from screening for gestational diabetes for any of the patient-relevant outcomes. All further results from this report must be viewed with this reservation.

To assess the benefit of therapies (sub-goal 2), a total of 25 trials (17 RCTs, 8 nRCTs) were analysed in 2 groups. One RCT with low risk of bias (Crowther 2005) reported a reduction in perinatal complications through a GDM-specific therapy. These results were evaluated as an indication of benefit. However, the amount of benefit remained unclear. There was an indication of benefit from a GDM-specific therapy for the patient-relevant outcome, shoulder dystocia.

Harm from a GDM-specific therapy was not explicitly investigated in the trials and consequently not reported either.

To evaluate the relationship between the results of an oral glucose tolerance test and maternal or baby outcomes (sub-goal 3), 3 cohort studies were included. In 2 out of the 3 studies that could be included for this sub-goal and which displayed low risk of bias, the natural relationship between the results of an oGTT in a screening setting of pregnant women and the maternal and baby outcome was described in detail. Rising blood sugar levels in the oGTT had a statistically significant association with the following patient-relevant outcomes: first Caesarean section, shoulder dystocia and/or birth trauma, pre-eclampsia, and admission to neonatal intensive care. In addition, there were statistically significant associations with the following outcomes of unclear patient-relevance: hyperbilirubinaemia and neonatal hypoglycaemia. Finally, there were statistically significant associations with the surrogate outcomes, large-for-gestational-age (LGA) and premature birth.

Sub-goal 4 “transferability”: the studies identified for sub-goals 2 and 3 did not meet the basic requirements for a transfer of results. It therefore remains unclear whether the effects found in sub-goal 2 “therapy” can be transferred to other populations. This means that the benefit of a therapy can only be assumed for a population, defined by the combination of screening strategy (combination GCT [glucose challenge test]/oGTT) and inclusion and exclusion criteria described in sub-goal 2.

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

A direct conclusion on the benefit and harm of screening was not possible. However, there was an indication of benefit from a GDM-specific therapy with regard to the reduction in perinatal complications. 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 as it was included in the relevant therapy studies.

Conclusions

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.

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

The full report (in German) is available on www.iqwig.de