SOGC CLINICAL PRACTICE GUIDELINE

No. 309, July 2014 (Replaces No. 123, February 2003)

Prenatal Invasive Procedures in Women With Hepatitis B, Hepatitis C, and/or Human Immunodeficiency Virus Infections

This guideline has been prepared by the Genetics Committee, reviewed by the Infectious Disease Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To review the risk of in utero infection through prenatal invasive procedures in women with hepatitis B, hepatitis C, and/or human immunodeficiency virus (HIV) infections.

Outcomes: Fetal and neonatal morbidity and mortality.

Evidence: Published literature was retrieved through searches of Medline, CINAHL, and the Cochrane Library using appropriate controlled vocabulary (amniocentesis, chorionic villus sampling, cordocentesis, fetal and neonatal infection) and key words (hepatitis B, hepatitis C, HIV). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies from 2002 to 2012 published in English or French. (Studies from 1966 to 2002 were previously reviewed in Clinical Practice Guideline No. 123.) Searches were updated on a regular basis and incorporated in the guideline to February 2014.

Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (Table).

Recommendations

 For women infected with hepatitis B, hepatitis C, and/or human immunodeficiency virus, the use of non-invasive methods of prenatal risk assessment is recommended, using tests with high sensitivity and low false-positive rates, such as serum screening combined (or not) with nuchal translucency, anatomic ultrasound, and non-invasive molecular prenatal testing. (III-B)

Key Words: Pregnancy, genetics, amniocentesis, chorionic villus sampling, viral hepatitis, human immunodeficiency virus, prenatal diagnosis

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Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment*

- Evidence obtained from at least one properly randomized controlled trial
- II-1: Evidence from well-designed controlled trials without randomization
- II-2: Evidence from well-designed cohort (prospective or retrospective) or case—control studies, preferably from more than one centre or research group
- II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

- Classification of recommendations+
- A. There is good evidence to recommend the clinical preventive action
- B. There is fair evidence to recommend the clinical preventive action
- C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- D. There is fair evidence to recommend against the clinical preventive action
- E. There is good evidence to recommend against the clinical preventive action
- There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

- For women infected with hepatitis B, hepatitis C, and/or human immunodeficiency virus undergoing an amniocentesis, every effort should be made to avoid inserting the needle through, or very close to, the placenta. (II-2B)
- Little information is available on other prenatal diagnostic and therapeutic invasive procedures; the risks and benefits of such procedures should therefore be assessed prior to their use. (III-C)
- 4. The rate of neonatal hepatitis B infection attributable to amniocentesis ranges up to 1.4% in newborns of mothers positive for hepatitis B surface antigen. However, the rate of neonatal infection attributable to amniocentesis in newborns of mothers with a positive hepatitis B e antigen status may be as high as 16%. Although there is no statistically significant difference between the rates of infection in newborns exposed to amniocentesis or not exposed to amniocentesis in these two maternal populations, knowledge of the mother's hepatitis B e antigen status may be valuable in counselling women about the risks associated with amniocentesis. (II-2A)
- Amniocentesis in women infected with hepatitis C does not appear
 to significantly increase the risk of vertical transmission, but
 women should be counselled that very few studies have properly
 addressed this possibility (II-2C). More research on this topic is
 recommended. (III-L)
- Amniocentesis in women infected with human immunodeficiency virus on combination antiretroviral therapy does not appear to significantly increase the risk of vertical transmission, particularly if the viral load is undetectable, but women should be counselled that data on this issue is limited. (II-2B)
- 7. For women not on combined antiretroviral therapy, the risk of vertical transmission is increased by performing an amniocentesis. When possible, combined antiretroviral therapy should be initiated and the procedure postponed until the viral load is undetectable. Other case management should be individualized in consultation with infectious diseases specialists and obstetricians. (III-B)

INTRODUCTION

These guidelines are designed to address the risks of in utero infection (vertical transmission) through prenatal invasive procedures in women infected with hepatitis B, hepatitis C, and/or HIV so that obstetric care providers may better counsel these women about their options.

ASSESSMENT OF RISK AND AMNIOCENTESIS

For women infected with hepatitis B, hepatitis C, or HIV, the addition of non-invasive methods of prenatal risk screening, such as serum screening combined (or not) with nuchal translucency, and anatomic ultrasound, provide the best risk assessment possible to properly inform women of their risk of chromosomal anomalies. The best available test should be used to keep the false-positive rate to a minimum. None of these infections seems to be associated with a significant increase in vertical transmission when amniocentesis is performed in the settings described below. The use of NIPT using cell-free DNA technology could be based on the same indications as in women without these chronic infections.

Women whose risk of vertical transmission is significantly higher than in those not exposed to an invasive procedure (such as HIV-infected women not on cART) should be considered for NIPT prior to any confirmatory invasive testing, after being counselled on the benefits and limitations of the test. NIPT provides higher sensitivity (close to 100%) and a lower false-positive rate (around 1%) when screening for trisomy 13, 18, or 21 in a high-risk population than the most frequently used screening

^{*}The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.³⁵

[†]Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.³⁵

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