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Title **Using Fetal Fibronectin to Diagnose PreTerm Labor**

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Aim

To evaluate the accuracy and safety of using the TLi™ System (Adeza Biomedical Corporation, Sunnyvale, CA, USA) as a point-of-care test for rapid detection of cervicovaginal fetal fibronectin (fFN) to diagnose preterm labor in symptomatic women.

Conclusions and results

The reviewed evidence confirms that the principal usefulness of the TLi System (referred to here as the rapid fFN assay) lies in its high negative predictive value. The absence of fetal fibronectin in cervicovaginal secretions of symptomatic women is a powerful predictor of the absence of progressive delivery within the next 7 to 10 days. However, the positive predictive value of the rapid fFN assay is a poor predictor of subsequent progressive preterm delivery/birth in symptomatic women with preterm labor, and the clinical importance of a positive test result remains unclear.

Knowledge of a negative rapid fFN assay result may supplement clinical judgment in predicting "false" preterm labor with more accuracy than clinical criteria alone. However, the hypothesis that using the rapid fFN assay will alter clinical management (eg, avoid overdiagnosis and unnecessary intervention) and ultimately improve patient outcomes and reduce healthcare costs remains unproven. Evidence from good-quality randomized controlled trials (RCTs) suggests these effects may be negligible, raising the question of whether the rapid fFN assay offers significant benefit beyond that of good clinical assessment and judgment.

Recommendations

Initial and ongoing education of clinical and laboratory staff, and regular audits of clinical practice, are necessary to ensure optimal use of the rapid fFN assay. Samples must be collected according to manufacturer recommendations and contraindications to specimen collection rigorously observed.

As the rapid fFN assay becomes widely available in Canada, clear protocols and a standardized clinical pathway are needed to guide clinicians in using the results to manage preterm labor in symptomatic women. Implementing the rapid fFN assay may inadvertently increase the use of interventions to prevent preterm delivery/birth if clinicians are unwilling to change their practices on the basis of its results.

Methods

All relevant systematic reviews and RCTs, published in English or French, were identified by systematically searching the Cochrane Library, the Centre for Reviews and Dissemination databases (National Health Service Economic Evaluation Database, HTA, Database of Abstracts of Review of Effects), PubMed, EMBASE, CINAHL, Web of Science, websites of various HTA agencies, research registers, evidence-based resources, and practice guideline clearinghouses from January 1995 to April 2007. Two reviewers, using appraisal tools developed by the Critical Appraisal Skills Programme (UK), independently assessed the methodological quality of the studies.

Further research/reviews required

Information from rapid fFN assay helps resolve uncertainty about whether to transport a woman in preterm labor from a level 1 or 2 healthcare center to a level 2 or 3 center. However, current evidence from good-quality RCTs only addressed the impact of the rapid fFN assay in level 2 and 3 hospitals where admission (or transfer) for care would occur. Further well-designed research is needed to assess the clinical and economic impact of using the test in level 1 hospitals.

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