TITLE: Fetal Scalp Lactate Testing to Reduce Caesarean Sections: A Review of the Clinical and Cost-Effectiveness

DATE: 09 December 2008

CONTEXT AND POLICY ISSUES:

Fetal well-being during the third trimester is monitored using cardiotocography (also called electronic fetal monitoring), a non-invasive technique, which records the fetal heart beat and uterine contractions. A normal result indicates the fetus is getting enough oxygen. Abnormal fetal heart rate is indicative of fetal distress; additional testing is required to determine if the baby is healthy enough to continue labor or if forceps delivery or caesarean section might be indicated.

Fetal scalp pH testing is a vaginal procedure performed when a woman is in active labor and has abnormal cardiotocography result to determine if the baby is getting enough oxygen. The test is performed to obtain information about fetal acid-base balance (blood pH). When the cervix of the mother is dilated at least 3 to 4 centimeters, a plastic cone is placed in the vagina and fit snugly against the scalp of the fetus. The scalp of the fetus is cleansed and pierced, and a small blood sample (30-50 μl) is taken for examination. The blood is collected in a thin tube, which is either sent to the hospital laboratory or analyzed by a machine in the labor and delivery department. The results should be available within minutes.

Lactate is a metabolite in anaerobic metabolism and reflects the lack of oxygen in the tissues. Fetal scalp lactate testing is used to determine the lactate level in the blood from the fetus’s scalp during labor. Higher lactate levels indicate fetal distress due to lack of oxygen. The test has been shown to be as predictive as the fetal scalp pH testing with added benefits. It requires less blood (5 μl), fewer scalp incisions, less time, and has a lower sampling failure rate compared with the pH testing.

There is a typical interest in the clinical and cost-effectiveness of the fetal scalp lactate testing in order to develop a policy of implementing the test in a jurisdiction.
RESEARCH QUESTIONS:

1. What is the clinical effectiveness of fetal scalp lactate testing for fetuses with an abnormal heart rate to reduce unnecessary caesarean sections?

2. What is the cost-effectiveness of fetal scalp lactate testing for fetuses with an abnormal heart rate to reduce unnecessary caesarean sections?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Database results include articles published between 2003 and December 2008, and are limited to English language publications only. No filters were applied to limit the retrieval by study type.

SUMMARY OF FINDINGS:

One randomized controlled trial, one prospective study, and two guidelines were identified.

Clinical effectiveness

The randomized controlled multicentre trial by Wiberg-Itzel et al. (2008) compared the pH and lactate analyses of fetal scalp blood in the clinical management of intrapartum fetal distress to prevent severe acidaemia at birth. The participants were women with a singleton pregnancy, cephalic presentation, gestational age ≥34 weeks, and clinical indication for fetal scalp blood sampling. The population (n=3007) was randomly assigned to the pH group (n=1503) and lactate group (n=1504). The cut-off levels were pH <7.21 and lactate >4.8 mmol/L. The outcome measures were metabolic acidaemia, pH <7.0 in cord artery blood, Apgar scores, and operative deliveries (caesarian sections) for fetal distress. [The Apgar score is a recording of the physical health of a newborn infant, determined after examination of the adequacy of respiration, heart action, muscle tone, skin color and reflexes. Total numerical score is 10].

Comparing between lactate group and pH group, the results showed that there was no significant difference in metabolic acidaemia [relative risk (RR) 0.91, 95% confidence interval (CI) 0.61 - 1.36], or in pH<7.0 (RR = 0.84, CI: 0.47 - 1.50) in the lactate and pH groups. There was also no difference in Apgar scores (RR = 1.15, CI: 0.76 - 1.75) or operative deliveries for fetal distress (RR = 1.02, CI: 0.93 - 1.11). However, significantly more protocol violations occurred for pH estimation (10.4%) than for lactate estimation (1.2%), mainly due to failed sampling. The time taken to perform sampling was not recorded.

Thus, there were no significant differences in rate of acidaemia at birth after use of lactate analysis or pH analysis to determine hypoxia during labor. Fewer sampling failures occurred with lactate testing.

The prospective study by Allen et al. (2004) determined the fetal scalp lactate cut-off level to ensure the satisfactory outcomes for both babies and mothers. One hundred and forty women in labor, with non-reassuring fetal heart rate traces, were tested using fetal blood scalp sampling. Decision to intervene in labor was based on clinical assessment and predetermined cut-off lactate levels. Main outcomes were Apgar scores, cord arterial pH, meconium stained liquor, and intensive care admission.
Two-graph receiver operating characteristic (TG-ROC) analyses for all main outcome variables were plotted. The intersection of the sensitivity and specificity curves showed that a scalp lactate level above 4.2 mmol/L was optimal for predicting adverse neonatal outcomes. Thus, a cut-off fetal scalp lactate level of >4.2 mmol/L was useful, in combination with clinical assessment, in identifying women in labor who need intervention.

Guidelines

A guideline from the Society of Obstetricians and Gynecologists of Canada in 2007 was identified. The guideline was developed based on comprehensive review of randomized controlled trials between January 1996 and March 2007. One of its recommendations (#17) stated that “Intrapartum scalp lactate testing is not recommended for routine use at this time”. [Quality III (“opinion of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees”’), Classification C (conflicting evidence; unable to make recommendation but decision making could be influenced by other factors)

The test is not recommended because there is a likelihood of falsely elevated lactate levels due to poor scalp perfusion derived from extensive caput or prolonged second stage.

The intrapartum care guideline issued by the National Institute for Health and Clinical Excellence in 2007 recommended that fetal scalp sampling for pH testing should be used when the fetal heart trace was pathological. The guideline did not mention fetal scalp lactate testing.

Cost-effectiveness

No cost-effectiveness studies were identified.

Limitations

This review was undertaken with limited information. Interpretation should be done with caution. Of the two studies identified, there was only one RCT comparing the clinical effectiveness between the pH and lactate testing. The other was an observational study, which determined the fetal scalp lactate cut-off level. A Canadian guideline on fetal health surveillance developed based on the evidence derived from randomized controlled trials between January 1996 and March 2007, does not recommend routine use scalp lactate testing.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Lactate testing appears to be comparable with pH estimation for fetal scalp sampling with some advantages including fewer sampling failures, shorter time of estimation, and smaller sampling volume. As with pH testing, the fetal scalp lactate testing is still an invasive technology that bears some risks including continued bleeding from the puncture site, infection, and bruising of the baby's scalp. No recommendation for the use of fetal scalp lactate testing during labor was found in the identified guidelines. The limited available evidence should be considered when deciding whether to use fetal scalp lactate testing to determine fetal distress.

Prepared by:
Khai Tran, MSc, PhD, Research Officer
Jessie Cunningham, M.I.St., Information Specialist
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439
REFERENCES:


