FETAL SCALP LACTATE RESEARCH STUDY
COMPARISON OF TWO POINT OF CARE METERS

Presentation to Healthy Mothers, Healthy Babies Conference
Perinatal Services BC
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Disclosure

- This study has received in-kind support from Nova Biomedical in the form of equipment (meters, test strips, and quality control solutions).

- Potential for conflict(s) of interest:
  - None
Funding Acknowledgement

- This study has been funded by the Women’s Health Research Institute (WHRI) in the form of a Nursing Research Grant
Purpose & Objectives

Purpose:

To describe an interdisciplinary research project that provides leading-edge information on a new clinical practice change in the use of fetal scalp lactate testing

Objectives:

To discuss the evidence base for using lactate to assess for fetal acidemia

To discuss the research methods used to compare two scalp lactate meters

To present the preliminary results of our findings
Fetal Health Assessment

- Electronic Fetal Monitoring (EFM) has poor predictive value of true fetal compromise

- Laboratory Tests:
  - pH
  - Lactate

- Blood Sample Types
  - Fetal scalp blood
  - Cord blood
A fetal scalp blood pH does not differentiate between respiratory and metabolic acidosis.
Respiratory Acidosis

- Respiratory acidosis is generally transitory
- It is an acute process caused by a build up of carbon dioxide in the blood.
- It quickly resolves when blood flow resumes and does not result in long term sequelae for the newborn

- Example: Cord compression
Metabolic Acidosis

- Metabolic acidosis results from prolonged hypoxemia and is associated with poor longer term neonatal outcomes.
- Lactic acid accumulates in the fetus deprived of oxygen due to anaerobic cellular metabolism.
- Accumulation of lactic acid is characterized by decreased pH (increased hydrogen ions), increased base deficit and increased lactate levels.
- Example: Poor placental perfusion.
Mixed Acidosis

- Results from a combination of both respiratory and metabolic acidosis

- It may have more than one etiology, such as a placental as well as an umbilical origin (e.g. utero-placental insufficiency [metabolic] as well as cord occlusion resulting from oligohydramnios and uterine contractions in labour [respiratory])
Cord Gases

The SOGC recommendations for Umbilical Cord Blood Gases:

- Ideally, cord blood sampling of both umbilical arterial and umbilical venous blood is recommended for ALL births, for quality assurance and improvement purposes. If only one sample is possible, it should preferably be arterial. (III-B)

- When risk factors for adverse perinatal outcome exist, or when intervention for fetal indications occurs, sampling of arterial and venous cord gases is strongly recommended. (I-insufficient evidence.)
Lactate

- A metabolite in anaerobic metabolism; reflects tissue hypoxia.
- Many studies have shown that lactate analysis has similar or better predictive properties compared with pH analysis in identifying fetal status.
- An RCT comparing analyses of fetal scalp blood pH and scalp lactate showed no differences in intrapartum management of suspected fetal compromise or in neonatal outcome.
Background

In the SOGC’s (2007) Fetal Health Surveillance Guidelines, fetal scalp lactate testing was not recommended as a clinical practice change due to a need to conduct larger scale studies.

CURRENTLY:
New evidence in 2008 supports the use of lactate testing.

In 2011 BC Women’s Hospital adopted fetal scalp lactate testing in our delivery suite as an assessment for the presence of fetal acidemia in the event of an atypical or abnormal tracing.
# Lactate vs. pH Testing

<table>
<thead>
<tr>
<th>Lactate</th>
<th>pH</th>
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<tbody>
<tr>
<td>Differentiate between metabolic and</td>
<td>Identifies presence of acidosis but does not</td>
</tr>
<tr>
<td>respiratory acidosis in fetus</td>
<td>differentiate</td>
</tr>
<tr>
<td>Small blood sample (less than 5 µl)</td>
<td>Large blood sample (85 µl)</td>
</tr>
<tr>
<td>Less than 1 min for results</td>
<td>Approximately 30 minutes for results</td>
</tr>
<tr>
<td>Point of care testing (at bedside)</td>
<td>Sample sent to lab to process</td>
</tr>
<tr>
<td>Technically easier to obtain results</td>
<td>Clotting can occur due to time delays, so no</td>
</tr>
<tr>
<td></td>
<td>results obtained</td>
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![Lactate testing equipment](image1.png)

![pH testing equipment](image2.png)
Many studies compared pH to Lactate

- No significant differences were found between lactate and pH in predicting perinatal outcome
- Scalp lactate was as good a predictor as scalp pH, with the advantages of being easier, cheaper and with a lower rate of technical failure
Evidence


- Large scale randomized controlled trial (RCT). Women with a gestational age over 34 weeks who had clinical indications for fetal blood sampling. 1496 women had standard pH analysis which was compared an equal number (1496) who had scalp lactate analysis.

- Analyzing fetal scalp blood by either scalp pH or lactate resulted in no differences in intrapartum management of suspected fetal compromise or in neonatal outcome.

- There was a higher failure rate with assessment of scalp pH (155 or 10.4%) due to clotting of specimens and inability to obtain results, compared to 18 (1.2%) with the lactate procedure.

- Study data collected using the Lactate Pro meter
Fetal Scalp Blood Lactate Sampling: BCWH Policy

- **Indications:**
  - Gestational age > 34 weeks
  - Cephalic presentation
  - Ruptured membranes
  - Cervix dilation at least 3 cm

- **Contraindications:**
  - Family history of hemophilia
  - Malpresentation
  - Maternal infection (i.e. HIV, active genital herpes, severe chorioamnionitis, Hepatitis B/C
  - Suspected bleeding disorders
Lactate Pro: Decision-Making Algorithm

- RN receives blood in the collection tube from physician and performs lactate testing at bedside.
- Action based on lactate result; duplicate testing indicated if results not in keeping with clinical picture.
- RN records results on partogram and fetal scalp lactate record.
- If repeat testing is required, cover kit with a sterile drape to be reused with next testing.

### If the Lactate result is... | Action
--- | ---
Less than (<) 4.2 mmol/L | Normal, no action required
4.2-4.8 mmol/L | Continue to monitor EFM
Greater than (>) 4.8 mmol/L | Repeat lactate testing within 30 minutes
| Delivery is indicated
Discontinuation of Lactate Pro...

In September 2012, Arkray stopped manufacturing the Lactate Pro Meter
Moving Forward

- The extensive research to date on fetal scalp lactate testing and clinical action levels has primarily involved the Lactate Pro.

- Fortunately another POCT device was recently approved by Health Canada...

- Clinical cut-offs for the Nova StatStrip Lactate have yet to be determined, making it necessary to do research to compare the Lactate Pro and the newer POCT lactate device.
New Meter: Nova StatStrip

- **Benefits:**
  - Requires 0.6 µl of blood
  - Results obtained in 12 seconds
  - Test strips are not sensitive to exposure to oxygen and are not hematocrit dependant
  - Test data is stored in internal memory
  - Touch screen
Key Collaborators

- Clinical Educators
- Lab Medicine
- Perinatal Medicine
  - PI: Melanie Basso, RN, Senior Practice Leader
  - Obstetricians
  - Nurses
  - Residents
  - Clinical Educators
  - Obstetricians
  - Student Nurses/Research Assistants
PHASE I

(Comparison of the two meters to the GEM Premier 4000)
Study Phase I

- Lactate Pro and the Nova StatStrip evaluated in the laboratory
  - Linearity and precision determined for each type of device
  - The two meters were compared to the GEM Premier 4000, the gold standard laboratory analyzer using venous, arterial, and capillary residual whole blood samples.
Study Phase I: Results

Comparison of Lactate Meters versus Laboratory Method (GEM4000)
Summary of Phase I

- The Nova Lactate meter performs well in a laboratory setting
- The Nova Lactate meter performs in a near perfect correlation with the GEM Premier 4000
PHASE II

(Comparison of the two meters on fetal scalp blood)
Study Phase II

- Scalp lactate is measured using the Lactate Pro meter for women in labour with atypical or abnormal fetal heart rate.

- Fetal scalp blood from the same sample is used to conduct a comparison test using the Nova Stat Strip device.

- Lactate Pro results dictates clinical decision making.

- Aiming for 350 samples (200-250 patients) over a 1 year period.
  - 320 normal lactate results
  - 15 - 20 moderate lactate results
  - 15 - 20 high lactate results
Study Phase II: Preliminary Results

NOVA LAC (new) vs Lactate Pro (current)
Fetal Scalp Whole Blood samples
September 17 - January 13 2014

Lactate Pro vs NOVA LAC

\[ y = 1.0266x + 0.023 \]

\[ R^2 = 0.8523 \]

Fetal Scalp Lactate Comparisons n = 67
< 4.2 n=59  4.2-4.8 n= 3  > 4.8 n=5

Lactate Pro vs Nova LAC combined

Linear (Lactate Pro vs Nova LAC combined)
Additional Findings

- Samples contaminated with amniotic fluid tend to read false high
  - Must re-test with new sample
- Research on lactate levels in amniotic fluid will be conducted in the lab
Case Study

- 31 yr old G1 at 39+4
- Arrives to LDR in active labour
- 0905 – at 5cm EFM showed “decelerations to 80 bpm with slow recovery to 160 bpm, with minimum variability”
- 0927 – Lactate result: 2.2 mmol/L
- 1226 – at 10 cm EFM showed “moderate variability, no accelerations, repetitive complicated variable decelerations”
- 1240 – Lactate result: 4.3 mmol/L
Case Study Continued

- Active pushing
- 1256 – SVD
- Female, 2970 g
- APGARS
  - 1 min: 9 and 5min: 9
- Lab results:
  - Arterial pH: 7.07
  - Arterial Base Deficit: 11.8
  - Venous pH: 7.29
  - Venous Base Deficit: 8.8
## Research Team Members

<table>
<thead>
<tr>
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<tr>
<td><strong>Melanie Basso, RN, MSN, PNC(C)</strong></td>
<td>Senior Perinatal Practice Leader-Team Leader</td>
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<td><strong>Ivy Fernando, RN, BSN, PNC(C)</strong></td>
<td>Perinatal Clinical Educator</td>
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<td><strong>Dr. Catherine Halstead, MD, FRCPC</strong></td>
<td>Laboratory Experts in Biochemistry</td>
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<td><strong>Dr. Benjamin Jung, PhD, CACB</strong></td>
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<td><strong>Dr. Li Wang, MD, FRCPC</strong></td>
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<td><strong>Dr. Ellen Giesbrecht, MD, FRCSC</strong></td>
<td>Department Head of Obstetrics and Senior Medical Director</td>
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<td><strong>Erin Broughton, Langara SN</strong></td>
<td>Research Assistants</td>
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<td><strong>Jillian Saunders, Langara SN</strong></td>
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Lactate testing is a valid tool for assessing fetal acidemia

The current point of care lactate testing meter clinical cut-offs are being evaluated for application to a new point of care meter

Preliminary data so far shows strong correlation in the normal range – more data required in the moderate and high ranges

Future research into scalp lactate results in second stage is needed
Special Thanks To…

- The Canadian Association of Perinatal and Women’s Health Nurses
- Labour and Delivery staff at BC Women’s Hospital
- Women’s Health Research Institute
- Students from Langara College School of Nursing
- Nova Biomedical


Questions or Comments
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