Clinical evaluation of Statstrip® Lactate for use in fetal scalp blood sampling

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Insight in:

- Fetal acid-base during labour
- Statstrip Lactate in addition to pH in fetal scalp blood sampling
- Two year follow up clinical practice
Fetal monitoring during labour

Cardiotocography (CTG)

Fetal heart rate

Contractions
Cerebral palsy

CP prevalence (black bars) and the CS rate (dark gray bars) in developed countries

Clark & Hankins, AJOG 2003
Fetal monitoring during labour

• Normal CTG excludes hypoxia/acidosis

• Abnormal CTG has high false positive rate (at least 50%)

➢ Unnecessary operative intervention
Fetal monitoring during labour

Table 8 and Fig. 4. The current blood pH values in the fetal circulation during the individual birth segments.

<table>
<thead>
<tr>
<th></th>
<th>$E_{1-3}$</th>
<th>$E_{6-8}$</th>
<th>$E_{10-12}$</th>
<th>BB</th>
<th>BA</th>
<th>NV</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper limit of normal range</td>
<td>7.40</td>
<td>7.46</td>
<td>7.42</td>
<td>7.40</td>
<td>7.42</td>
<td>7.45</td>
<td>7.40</td>
</tr>
<tr>
<td>Middle values</td>
<td>7.31</td>
<td>7.33</td>
<td>7.31</td>
<td>7.30</td>
<td>7.28</td>
<td>7.30</td>
<td>7.25</td>
</tr>
<tr>
<td>Lower limit of normal range</td>
<td>7.23</td>
<td><strong>7.19</strong></td>
<td><strong>7.21</strong></td>
<td>7.21</td>
<td>7.14</td>
<td>7.15</td>
<td>7.09</td>
</tr>
</tbody>
</table>
Reduction placental perfusion

Reduction gas exchange

CO₂ accumulation

Respiratory acidosis

Reduction O₂ saturation

Hypoxia

Anaerobic metabolism

Lactic acid accumulation

Metabolic acidosis

Fall in pH
pH

- pH
  - Large amount of blood (30-50 µL)
  - Failure rates 10-20%
  - Large sampling to result interval
  - Respiratory or metabolic acidosis?

- Base deficit
  - Calculated value
  - Variable adult algorithms
  - Sensitive to error
  - No cut-off values available
Lactate

- Lactate
  - Measured end product of anaerobe glycolysis
  - 5 µL blood needed
  - Results within 60 seconds (Point of Care)
  - Success rate 99%

- RCT (Lactate Pro vs pH)

  ➢ No difference in mode of delivery and neonatal outcome
## More ODFD in lactate group*

<table>
<thead>
<tr>
<th>Cut-off (n)</th>
<th>Fetal scalp blood pH (n=508)</th>
<th>Fetal scalp blood lactate (n=684)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 7.25 (281)</td>
<td>7.25-7.21 (91)</td>
<td>&lt; 7.21 (135)</td>
</tr>
<tr>
<td>7 (3)</td>
<td>3 (3)</td>
<td>10 (7)</td>
</tr>
<tr>
<td>ODFD (%)</td>
<td>81 (29)</td>
<td>58 (63)</td>
</tr>
</tbody>
</table>

*Operative delivery for fetal distress

FBS < 60 minutes of delivery

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Wiberg-Itzel et al. BMJ 2008
Discrepancies

N = 486

Heinis et al. AOGS 2011
Discrepancies

- Low pH with normal lactate
  - Transient impairment of CO2 exchange (cord compression)
  - Early stage of a fast developing acidosis

- Normal pH with high lactate
  - Slow clearance of lactate and normalization of pH after hypoxic insult
  - Early stage of a slowly developing acidosis
  - Factors other than hypoxia
    - Contamination amniotic fluid
    - Limited local perfusion (caput formation)

- Beta mimetic drugs, glucose, maternal hyperventilation and catecholamine concentrations

Liljeström et al. AOGS 2011
Discrepancies

Evaluation of the discrepancy between pH and lactate in combined fetal scalp blood sampling

• N=241

• 55% discrepancies with combined testing

• Lactate more often abnormal than pH

• Fewer intervention abnormal combined test vs single test (53 vs 95%)
Cut-off values

• Measure both pH and lactate
• Abolish failure rates
• Lactate with POCT device
• Cut-off values for each device
• Statstrip lactate designed for clinical use
Lactate Pro vs Statstrip Lactate

FBS n=37

Heinis et al. CCLM 2011
Cut-off values

• Analysis of FBS and cord blood samples on RapidLab (n=486)

• Lactate cut-off values for metabolic acidosis at birth*
  • Absence: 5.4 mmol/L
  • Presence: 6.6 mmol/L

➤ From Rapidlab to Statstrip >> 5.7 and 7.0 mmol/L

*Cord artery pH < 7.00 and BD ≥ 12 mmol/l
In summary

• FBS essential for excluding fetal acidosis
• pH high failure rate
• Lactate low failure rate
• Low pH (different pathways) >> Discrepancies common
• Statstrip Lactate (SSL) performed better than Lactate Pro
• Cut-off values SSL 5.7 and 7.0 mmol/L

➢ Evaluation SSL in clinical setting
Objective

• To analyze SSL for its use in FBS in a clinical setting:
  • To evaluate the agreement between SSL, lactate (RLL) and pH (RLpH)
  • To test the validity of the previously established SSL cut-off values.
Methods

- Parallel sampling
  - Statstrip lactate (SSL)
  - Rapidlab lactate (RLL) and pH (RLpH)

- Agreement:
  - Regression analysis
  - Bland-Altman analysis

- Success rate

- Discrepancies
SSL vs RLL

$R^2 = 0.742$

$N = 142$
SSL vs RLL (Bland-Altman)

N=143
SSL vs RLpH

\[ R^2 = 0.204 \]

N=191
Success rates

- SSL 93%
- RLpH 77%
- RLL 57%
In summary

• StatStrip® Lactate
  • Excellent agreement with laboratory lactate
  • Higher success rate
  • Accurate information on fetal status
  • 5% discrepancies

➢ Combined testing of lactate (SSL) and pH
Combined testing

- pH fails >> clinical management on SSL only

<table>
<thead>
<tr>
<th>FBS result</th>
<th>Normal</th>
<th>Borderline</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>&gt; 7.25</td>
<td>7.20 - 7.25</td>
<td>&lt; 7.20</td>
</tr>
<tr>
<td>Lactate (mmol/L)</td>
<td>&lt; 5.7</td>
<td>5.7 - 7.0</td>
<td>&gt; 7.0</td>
</tr>
</tbody>
</table>

- Borderline: repeat FBS within 30 minutes
- Abnormal: expedite delivery
- Discrepant: senior consultancy >> repeat FBS or deliver
Two year follow up (2014-2016)

- 426 FBS samples (from 259 women)
- 69 (16%) RLpH failed >> SSL result
- 11 (3%) SSL failed >> RLpH (n=5)
  - Overall FBS success rate 99%

➢ Major improvement
Discrepancies

<table>
<thead>
<tr>
<th>pH</th>
<th>SSL</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Abnormal#</td>
</tr>
<tr>
<td>Normal</td>
<td>296</td>
<td>13</td>
</tr>
<tr>
<td>Abnormal*</td>
<td>17</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>313</td>
<td>17</td>
</tr>
</tbody>
</table>

*pH < 7.20
# SSL > 7.0 mmol/L
Two year follow up

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cohort I (1 year)</th>
<th>Cohort II (2 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries</td>
<td>1589 N (%)</td>
<td>3054 N (%)</td>
</tr>
<tr>
<td>Women with FBS</td>
<td>139 (9)</td>
<td>259 (8)</td>
</tr>
<tr>
<td>Spontaneous vaginal</td>
<td>52 (37)</td>
<td>127 (49)</td>
</tr>
<tr>
<td>Ventouse</td>
<td>52 (37)</td>
<td>71 (27)</td>
</tr>
<tr>
<td>C-section</td>
<td>35 (25)</td>
<td>61 (24)</td>
</tr>
<tr>
<td>ODFD#</td>
<td>44 (32)</td>
<td>83 (32)</td>
</tr>
<tr>
<td>Metabolic acidosis at birth*</td>
<td>4 (3)</td>
<td>10 (4)</td>
</tr>
</tbody>
</table>

*Operative delivery for fetal distress

*Cord artery pH < 7.00 and BD ≥ 12 mmol/l
Key message

• Statstrip Lactate in FBS
  • Reliable test for current cut-off values
  • Failure rate almost nil
  • Statstrip Lactate in addition to pH
## Discrepancies

<table>
<thead>
<tr>
<th>Case Interval</th>
<th>FBS delivery (min)</th>
<th>SSL (mmol/l)</th>
<th>RLL (mmol/l)</th>
<th>RLpH</th>
<th>Mode of delivery</th>
<th>ODFD*</th>
<th>UA pH</th>
<th>UA BD (mmol/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSL ≥ 7.0. pH &gt; 7.20</td>
<td>1 46</td>
<td>8.5</td>
<td>7.8</td>
<td>7.24</td>
<td>CS</td>
<td>-</td>
<td>7.18</td>
<td>7.9</td>
</tr>
<tr>
<td></td>
<td>2 66</td>
<td>9.0</td>
<td>6.7</td>
<td>7.37</td>
<td>VE</td>
<td>-</td>
<td>7.28</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>3 20</td>
<td>8.4</td>
<td>4.7</td>
<td>7.22</td>
<td>SV</td>
<td>-</td>
<td>7.22</td>
<td>6.6</td>
</tr>
<tr>
<td></td>
<td>4 303</td>
<td>8.4</td>
<td>NA</td>
<td>7.38</td>
<td>VE</td>
<td>+</td>
<td>7.28</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>5 255</td>
<td>7.1</td>
<td>7.6</td>
<td>7.39</td>
<td>VE</td>
<td>+</td>
<td>7.15</td>
<td>11.5</td>
</tr>
<tr>
<td>SSL &lt; 7.0. pH ≤ 7.20</td>
<td>6 11</td>
<td>6.3</td>
<td>NA</td>
<td>7.13</td>
<td>VE</td>
<td>+</td>
<td>7.09</td>
<td>12.6</td>
</tr>
<tr>
<td></td>
<td>7 25</td>
<td>6.0</td>
<td>6.4</td>
<td>7.16</td>
<td>VE</td>
<td>+</td>
<td>7.12</td>
<td>8.3</td>
</tr>
<tr>
<td></td>
<td>8 25</td>
<td>5.8</td>
<td>5.3</td>
<td>7.18</td>
<td>VE</td>
<td>+</td>
<td>7.23</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td>9 26</td>
<td>3.8</td>
<td>4.8</td>
<td>7.08</td>
<td>VE</td>
<td>+</td>
<td>6.95</td>
<td>21.0</td>
</tr>
<tr>
<td></td>
<td>10 19</td>
<td>6.6</td>
<td>NA</td>
<td>7.16</td>
<td>VE</td>
<td>+</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

* Operative delivery for fetal distress, UA: umbilical artery, BD: Base deficit