Technical accuracy of glucose meters in pregnancy: a systematic review

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Introduction

❖ Accuracy of glucose meters is of major concern
❖ Hemodilution during pregnancy → reduced hematocrit (hct) level
❖ Low hct levels overestimate glucose concentration → positive bias
❖ Purpose of the review: to summarize accuracy profile of glucose meters in pregnancy
Methods

**Database search:**

**Inclusion criteria:**
- Studies performed in pregnancy
- For any clinical outcome

**Exclusion criteria:**
- Published prior to 2007
- Animal studies
- Studies outside pregnant population
- Published in non-English languages
Outcome measures

- Mean difference with 95% limits of agreement
- Mean percentage bias = \left( \frac{\text{blood glucose meter results} - \text{plasma glucose value}}{\text{plasma glucose}} \right) \times 100
- Imprecision (CV (Coefficient of variation))
- Mean total analytical error (\% bias + 1.96 CV)
- Hematocrit influence
- Meters that fulfilled ISO 15197:2003 or 2013 recommendations
- Meters that met clinical accuracy criteria
Results

Number of studies identified: 355
Studies included: 4
Number of glucose meters evaluated: 10

- Accu-Chek ® Active (Roche Diagnostics GmbH, Mannheim, Germany)
- Ascensia EliteF (Bayer Health care, Elkhart, IN, USA)
- Accu-Chek Advantage II (Roche Diagnostics Corp., Indianapolis, IN, USA)
- CareSens 505B (iSENS, Seoul, South Korea)
- Optium (MediSense, Abbott Laboratories, Abbot Park, Bedford, MA, USA)
- Freestyle Lite (Abbott Diabetes Care Inc., Alameda, CA, USA)
- Performa (Accu-Chek Performa, Roche Diagnostics, Mannheim, Germany)
- Accu-Chek Advantage II (Roche Diagnostics, Mannheim, Germany)
- Optium Xceed 20 s (Abbott Diabetes Care, Alameda, CA, USA)
- Accu-Chek Performa (Roche Diagnostics)
- Optium Xceed 5 s (Abbott Diabetes Care)
- FreeStyle Lite (Abbott Diabetes Care)
- Stat-Strip (Nova Biomedical, Waltham, MA, USA)
Results: Glucose meter Bias

- Mean difference: -0.33 to 0.725 mmol/l
- Roche Accu-Chek Active: lowest mean bias (-0.2%)
- No meters showed a total analytical error <5%
- Most glucose meters had CV<5%

Example: Bland Altman Tool
Results: Glucose meter accuracy

❖ 2 studies used ISO 15197:2003 criteria
❖ Accu-Chek Active, Freestyle lite, Accu-Chek Performa met the ISO 2003 criteria
❖ No studies evaluated meters by ISO 2013 criteria

ISO 2003 Criteria: 95% samples, within 0.83mmol/l (15mg/dl) for plasma glucose ≤4.2 mmol/L (75 mg/dl); within 20% for >4.2 mmol/L
ISO 2013 Criteria: 95% samples, within ±0.83 mmol/l (15mg/dl) for plasma glucose < 5.6mmol/l (100 mg/dl); within ±15% for ≥ 5.6mmol/l
Results: Hematocrit influence

3 devices; Optium, Optium Xceed 20 s, Optium Xceed 5 s were sensitive to hct changes
# Results: Clinical accuracy

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Devices</th>
<th>Assessment method</th>
<th>Zone A (%)</th>
<th>Zone B (%)</th>
<th>Zone C (%)</th>
<th>Zone D (%)</th>
<th>Zone E (%)</th>
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</thead>
<tbody>
<tr>
<td>Dhatt et al 2011</td>
<td>Accu-Chek Active Chek</td>
<td>Error Grid Analysis</td>
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<td>Kong et al 2010</td>
<td>Elite Clarke Error Grid</td>
<td>Clarke Error Grid</td>
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<td>CareSens</td>
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<td>Parwaiz et al 2014</td>
<td>FreeStyle Lite</td>
<td>Clarke Error Grid</td>
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<td>Perera et al 2011</td>
<td>All 4 meters</td>
<td>Adjusted Clarke’s</td>
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</tr>
</tbody>
</table>

- Zone A: Clinically accurate
- Zone B: Benign errors
- Zone C: Overcorrection
- Zone D: Dangerous failure to detect & treat
- Zone E: Erroneous treatment, Serious errors
Conclusion

Performance of meters varied during pregnancy

Majority of meters showing positive bias, a few negative bias

Performance goal during pregnancy: Total error of <5%; bias and impression <2%

Meters with automatic corrections for hct interference should be encouraged for use in pregnancy

A uniform standard for the analytical performance of meters is needed
Acknowledgment

Prof. David Simmons
Western Sydney University