



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:

PubMed, CINAHL, Embase, and Scopus
(2007-2017)

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= $([\text{blood glucose meter results} - \text{plasma glucose value}] / \text{plasma glucose}) \times 100$
- ❖ 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

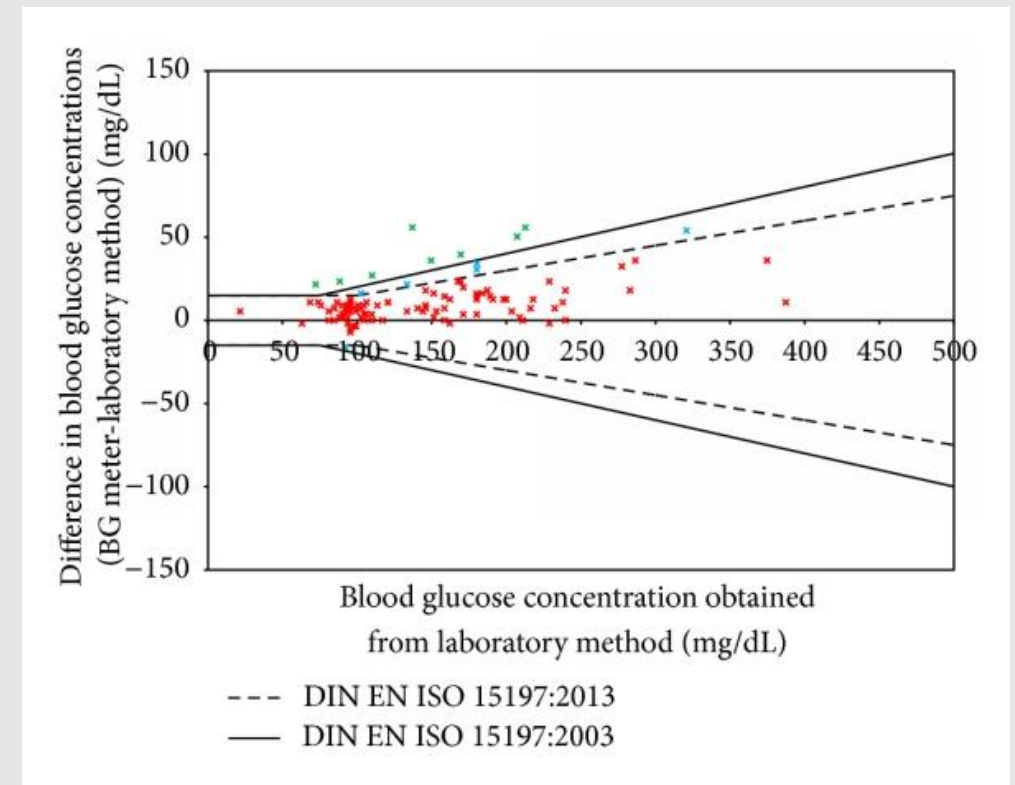
Studies included: 4

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 < 5.6 mmol/l (100 mg/dl); within $\pm 15\%$ for ≥ 5.6 mmol/l



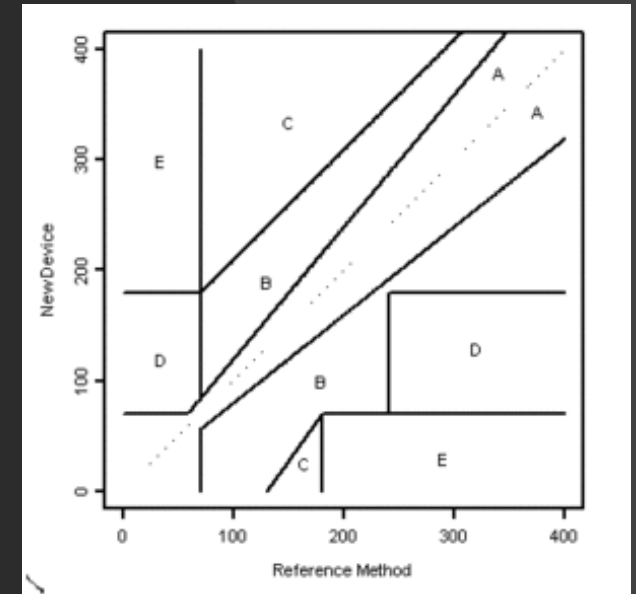
Results: Hematocrit influence

3 devices; Optium, Optium Xceed
20 s, Optium Xceed 5 s were
sensitive to hct changes

Results: Clinical accuracy

| Author/ Year | Devices | Assessment method | Zone A (%) | Zone B (%) | Zone C (%) | Zone D (%) | Zone E (%) |
|-----------------------|---------------------|------------------------|---------------|---------------|---------------|---------------|---------------|
| Dhatt et al 2011 | Accu-Chek Active | Error Grid Analysis | 99.4 | 0.6 | 0 | 0 | 0 |
| Kong et al 2010 | Elite | Clarke Error Grid | 93.5 | 6.3 | 0 | 0.2 | 0 |
| | Accu-Chek | Clarke Error Grid | 93.2 | 5.8 | 0 | 1.0 | 0 |
| | Advantage II | | | | | | |
| | CareSens | Clarke Error Grid | 92.1 | 7.2 | 0 | 0.7 | 0 |
| | Optium | Clarke Error Grid | 88.7 | 9.4 | 0 | 1.9 | 0 |
| Parwaiz et al 2014 | FreeStyle Lite | Clarke Error Grid | 99 | 0 | 0 | 1 | 0 |
| | Accu-Chek | Clarke Error Grid | 97 | 1 | 0 | 2 | 0 |
| | Performa | | | | | | |
| | FreeStyle Lite | Consensus Grid | 100 | 0 | 0 | 0 | 0 |
| Perera et al 2011 | Accu-Chek | Consensus Grid | 99 | 1 | 0 | 0 | 0 |
| | Performa | | | | | | |
| | All 4 meters | Adjusted Clarke's | | | | >50 | 0 |

Clarke Error Grid



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

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

Conclusion



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