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Evaluation of neonatal bilirubin method on GEM 5000 blood gas analyzer

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Introduction

The aim of this research was to compare the analytical performances of the neonatal bilirubin method on the GEM 5000 blood gas analyzer to central lab analyzer. This point-of-care testing (POCT) device can determinate neonatal bilirubin, making it potentially valuable for use in neonate care units. Neonatal jaundice is a common finding in neonates but severe hyperbilirubinemia could have considerable impact on morbidity, requiring phototherapy or exchange transfusion to reduce plasma bilirubin concentrations.

Material and Methods

We paired 223 patient samples for intermethod comparisons between POCT method and routine laboratory method (Cobas, Roche). We secondly paired 125 patient samples between POCT method and new routine laboratory method (Alinity, Abbott). Whole blood heel stick capillary samples for POCT were sampled along with venipuncture serum samples for central lab. The experiment was carried out over a period of several months. Agreement between the two methods was assessed by Concordance correlation coefficient (CCC) and Passing-Bablok regression.

Statistical analysis:

MedCalc software, version 12.7.7.0 (Oostende, Belgium) was used to perform statistical analysis.

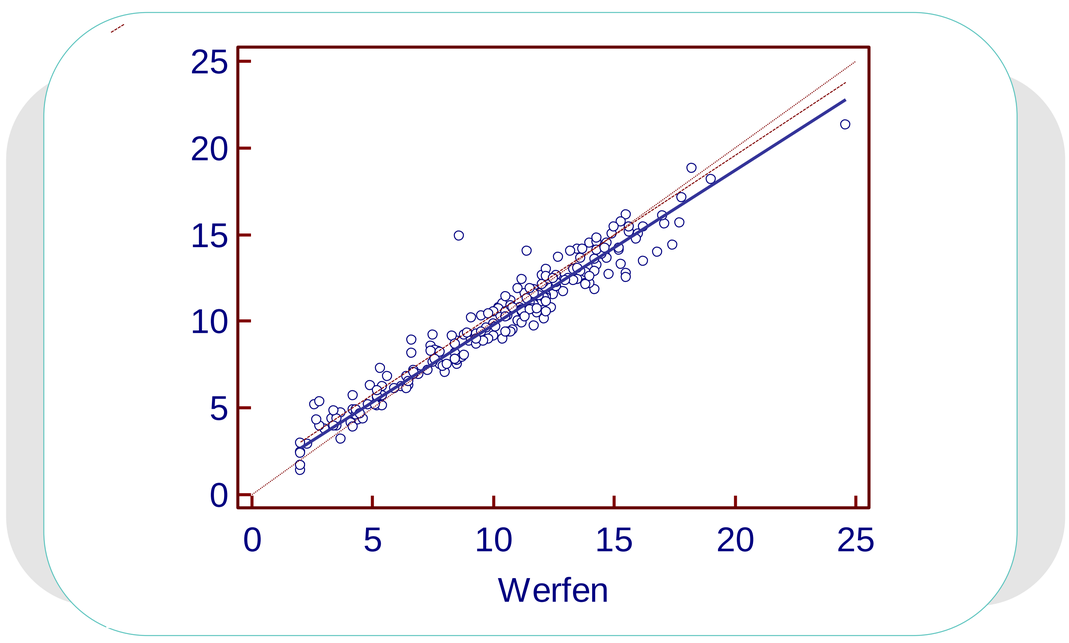

Figure 1 Correlation between GEM 5000 (Werfen) and central laboratory total serum bilirubin (mg/dL) measured with Cobas (Roche). Passing and Bablok regression.

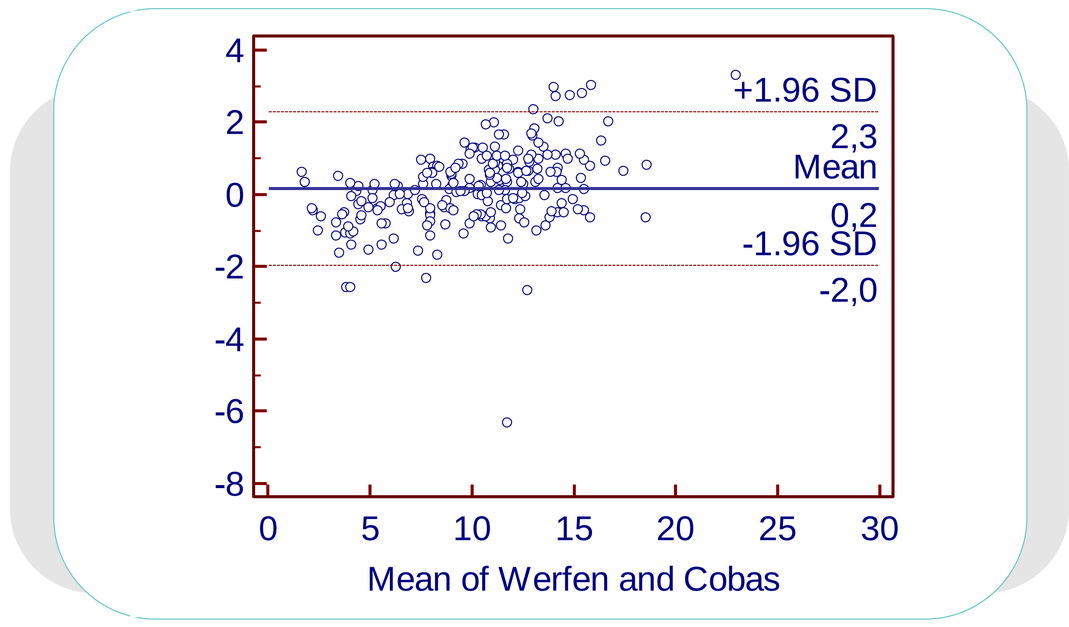

Figure 2 : Bland-Altman plot of GEM 5000 (Werfen) and central laboratory total serum bilirubin (mg/dL) measured with Cobas (Roche). Mean difference (solid line) ± 2SD (dashed line) is shown.

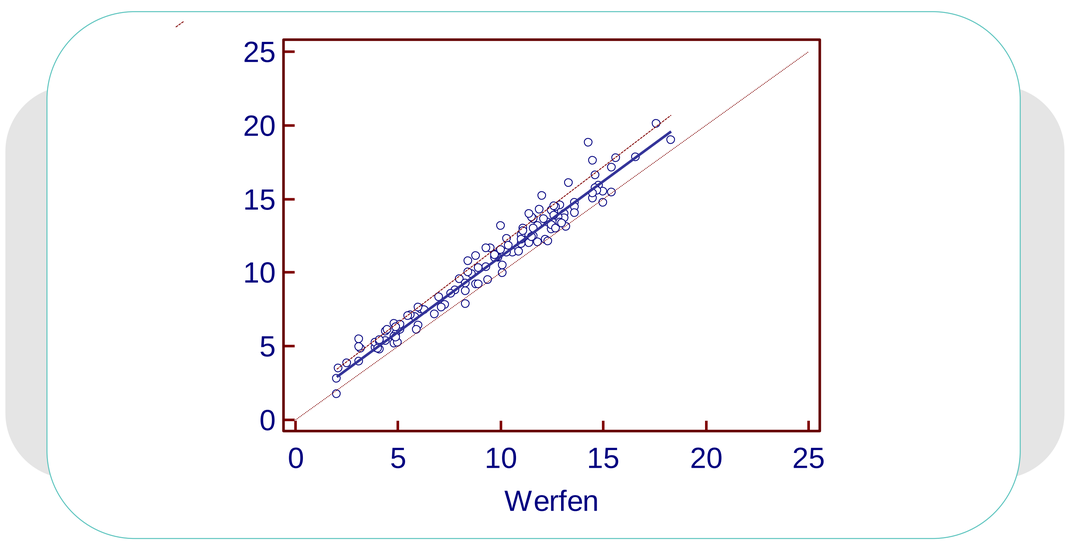

Figure 3 : Correlation between GEM 5000 (Werfen)and central laboratory total serum bilirubin (mg/dL) measured with Alinity (Abbott). Passing and Bablok regression.

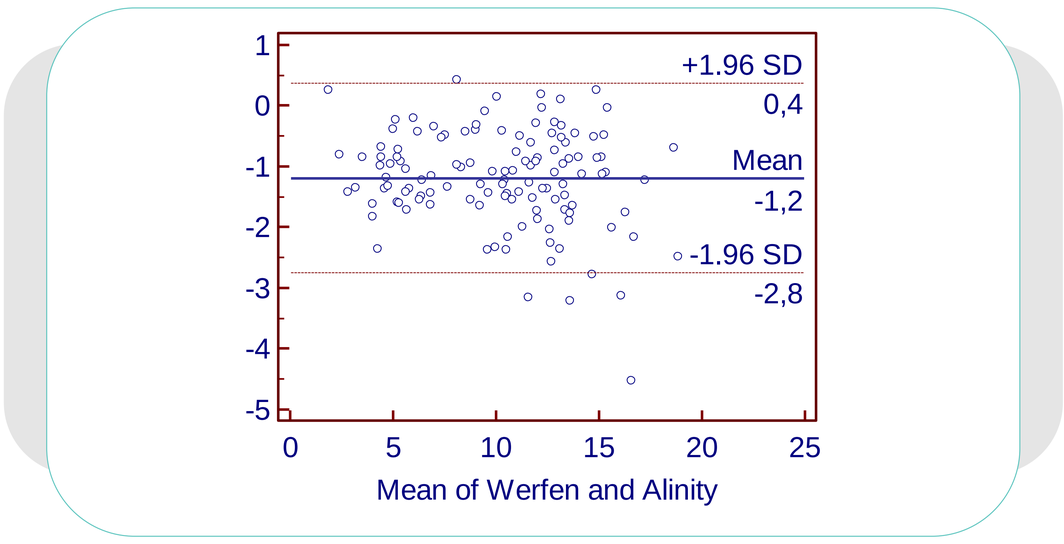

Figure 4 : Bland-Altman plot of GEM 5000 (Werfen and central laboratory total serum bilirubin (mg/dL) measured with Alinity (Abbott). Mean difference (solid line) ± 2SD (dashed line) is shown.

Results

The correlation between Cobas (y) and GEM (x) was y = 0,89 (95% CI 0,61 to 1,19) + 0,89x (95% CI 0,86 to 0,92) Passing-Bablok equation. Correlation coefficient was 0,967 (95% CI 0,957 to 0,974), CCC was 0,996 (95% CI 0,949 to 0,968) and Bias correction factor C_b (accuracy) was 0,992. The correlation between Alinity (y) and GEM (x) was y = 0,89 (95% CI 0,65 to 1,29) + 1,02x (95% CI 0,98 to 1,06). Correlation coefficient was 0,948 (95% CI 0,927 to 0,963), CCC was 0,9 (95% CI 0,865 to 0,926) and Bias correction factor C_b (accuracy) was 0,95. A proportional bias of 11 % is observed between POCT and Cobas, POCT method overestimating bilirubin compared to central lab. Conversely, a proportional bias of 2% is observed between POCT and Alinity, Alinity method overestimating bilirubin compared to POCT. A systematic bias of about 0,9 mg/dL is observed with both Cobas and Alinity method.

Conclusions

POCT allowed using small neonatal whole blood samples, reducing net blood volume taken and provides results in less than a minute. The results of GEM 5000 for bilirubin showed good correlation with the Cobas analyzer but a significant proportional bias (slope 0,897). A good correlation with the Alinity was also observed with a slight proportional bias (slope 1.019). This discrepancy could be explained by matrix (serum versus whole blood). Data regarding the differences between capillary and venous Total Serum Bilirubin (TSB) are divergent, whole blood being higher or lower than venous sample according to studies. American Academy of Pediatrics guidelines are based on TSB results. Nevertheless, they consider capillary sample as acceptable and do not recommend to confirm high capillary result by venous sample, because it will delay the initiation of the treatment. These guidelines do not take into account the lack of standardization between methods within TBS and between TBS and capillary methods. Lack of standardisation provides bilirubin results that could result in unnecessary cares. Pediatricians should be aware of this difficulty.

References

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