

ORIGINAL ARTICLE

Accuracy of bilirubin on the Siemens RAPIDPoint 500 blood gas analyser: A data mining study

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Aim: Blood gas analysers which can measure bilirubin in whole blood are commonly available in neonatal intensive care units; however, the accuracy of these measurements is not well established. We sought to determine accuracy of whole blood bilirubin on the Siemens RAPIDPoint 500 blood gas analyser with reference to formal laboratory total serum bilirubin on the Ortho Vitros 5600.

Methods: A method comparison of the bilirubin results from the blood gas analysers compared with the chemistry analysers was performed by data mining of results obtained as part of routine patient care. Results were included if patients underwent bilirubin testing by blood gas analyser and formal TSB, with both samples being collected within 20 min. Retrospective laboratory data was collected over a 28-month period, 1 January 2019 to 1 May 2021.

Results: 449 eligible sample pairs were included. A Bland-Altman plot was generated to identify systematic differences between the methods. A mean bias of $-11 \mu\text{mol/L}$ was observed with 95% limits from $-60 \mu\text{mol/L}$ to $38 \mu\text{mol/L}$. Some blood gas bilirubin results were up to $70 \mu\text{mol/L}$ lower than formal TSB measurements around the clinically significant concentration range of 200 to $300 \mu\text{mol/L}$.

Conclusion: Clinicians need to be aware of potential differences between the results from their blood gas analysers compared to formal TSB results. Sole reliance on blood gas bilirubin results which underestimate TSB may lead to under-recognition of neonatal jaundice that meets treatment thresholds. Formal measurement of TSB should be sought to inform decisions regarding treatment of neonatal jaundice.

Key words: bilirubin; blood gas analyser; neonatal jaundice; point of care testing.

What is already known on this topic

- 1 Neonatal jaundice treatment thresholds are based on the measurement of total serum bilirubin.
- 2 Bilirubin measurements are commonly performed using whole blood samples on blood gas analysers; however, it is unknown how these results compare with total serum bilirubin.

What this paper adds

- 1 Comparison data are presented for bilirubin as measured by the Siemens RAPIDPoint 500 blood gas analyser, with reference to total serum bilirubin as measured by the Ortho Vitros 5600.
- 2 We propose an approach to the interpretation of bilirubin measurements by the Siemens RAPIDPoint 500 blood gas analyser.

Guidelines for neonatal jaundice typically address the interpretation of transcutaneous bilirubin (TcB) and total serum bilirubin (TSB) which are formally measured on laboratory chemistry analysers.^{1,2} TSB is considered to be the gold standard for neonatal jaundice treatment decisions and its measurement is advised if TcB results are $\geq 250 \mu\text{mol/L}$.^{1,2} Some guidelines also recommend confirmation with TSB if a TcB result is within range of the treatment threshold for gestational age, for example within $50 \mu\text{mol/L}$.²

In contrast, there is rarely guidance provided on the use of whole blood bilirubin measurements on blood gas instruments despite these being available on many commercial instruments within neonatal and paediatric wards,³ and previous studies concluding that the blood gas instruments assessed were acceptable for use in neonates.^{4,5}

There is limited awareness amongst clinicians of the potential analytical differences between point of care test blood gas instrument bilirubin results in whole blood and TSB results obtained from chemistry analysers located in central laboratories. For example, depending on the instrument manufacturer, there may be good agreement between the methods at lower concentrations, with significant bias at higher concentrations.⁴ Depending on the manufacturer, the blood gas instrument may require activation of a specific correction for fetal haemoglobin, prior to use in neonates.³

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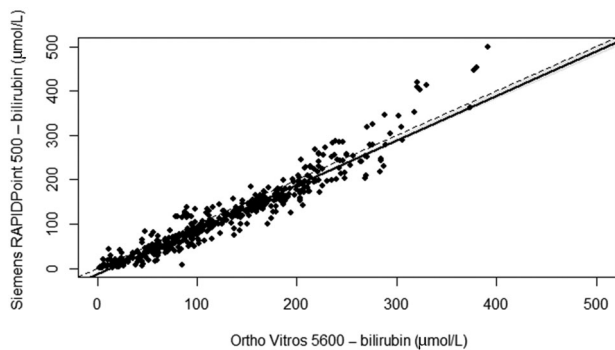


Fig. 1 Bilirubin comparison by Siemens RAPIDPoint 500 versus Ortho Vitros 5600, $n = 449$.

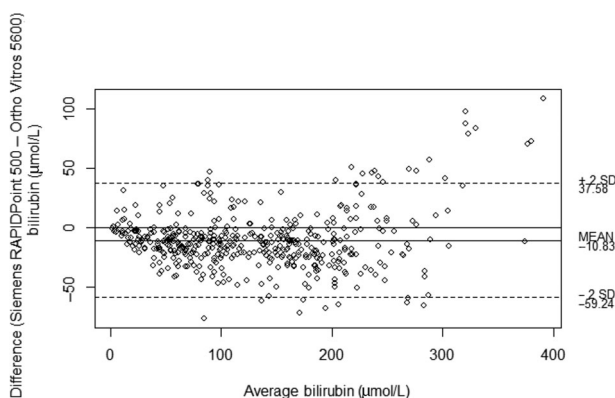


Fig. 2 Bland-Altman difference plot for bilirubin by Siemens RAPIDPoint 500 versus Ortho Vitros 5600, $n = 449$.

Methods

Measurement of whole blood total bilirubin on blood gas analysers usually involves a direct spectrophotometric method, where sample absorbance at multiple different wavelengths is related back to the bilirubin concentration in the whole blood sample via an algorithm. The corresponding serum bilirubin concentration is subsequently calculated by correcting for the sample haematocrit. In our institution, the Children's Hospital at Westmead, Siemens RAPIDPoint 500 blood gas analysers are used within the Neonatal Intensive Care Unit. Formal TSB measurements are performed by the central laboratory using BuBc slides on Ortho VITROS 5600 chemistry analysers. The method principle is based on dual-wavelength reflectance spectrophotometry following sample migration through a multilayered slide and the binding of bilirubin to a cationic mordant.

Using a data mining approach, we performed a method comparison of the bilirubin results from the blood gas analysers compared with the chemistry analysers using results obtained as part of routine patient care. Ethics approval was granted by the Sydney Children's Hospitals Network Human Research Ethics Committee. Results were included in the method comparison if patients underwent bilirubin testing by blood gas analyser and formal TSB, with both samples being collected within 20 min.

Retrospective laboratory data was collected over a 28-month period, 1 January 2019 to 1 May 2021. Data analysis was performed using R programming language.

Results

We identified 449 eligible sample pairs. There was overall good agreement of whole blood bilirubin results from the RAPIDPoint 500 blood gas analyser with formal TSB results from the Ortho Vitros 5600 (Fig. 1). A Bland-Altman plot was generated to identify systematic differences between the methods (Fig. 2). A mean bias of $-11 \mu\text{mol/L}$ was observed with 95% limits from -60 to $38 \mu\text{mol/L}$. Subgroup analysis of neonates less than 2 weeks of age showed a similar correlation, with a mean bias of $-18 \mu\text{mol/L}$ with 95% limits from -54 to $18 \mu\text{mol/L}$.

Discussions

Clinicians with access to blood gas bilirubin in their neonatal wards need to be aware of potential differences between the results from their blood gas analysers compared to formal TSB results. Of note, some blood gas bilirubin results were up to $70 \mu\text{mol/L}$ lower than formal TSB measurements around the clinically significant concentration range of $200\text{--}300 \mu\text{mol/L}$. This highlights the need for effective communication between clinicians and the laboratory, which must ensure that blood gas instruments are fit for the intended clinical purpose. Quality assurance activities should include ongoing monitoring of the correlation between blood gas bilirubin and TSB results to ensure any differences are small and stable over time.

Conclusion

Sole reliance on blood gas bilirubin results which underestimate TSB may lead to under-recognition of neonatal jaundice that meets treatment thresholds. Formal measurement of TSB should be sought to inform decisions regarding the treatment of neonatal jaundice. Furthermore, to better support clinicians, we recommend that neonatal jaundice guidelines be revised to recognise the availability of bilirubin measurements by blood gas analysers and provide an approach to interpretation. As with the use of TcB, clinical sensitivity is desirable over specificity for neonatal jaundice requiring intervention due to the potentially serious consequences of missing the condition. A proposed risk mitigation strategy is to recommend that blood gas bilirubin results approaching the decision limit for gestational age be confirmed by a formal laboratory TSB measurement, analogous to the current approach for interpreting TcB results.²

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Inside the fishbowl by Amarra (Aokoe) Yarisse (age 16) from "A Pop of Colour" competition, Children's Hospital at Westmead Art Youth Program