

Non-invasive estimation of haemoglobin in pregnancy using pulse Co-oximetry

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Background

- Anaemia complicating pregnancy is common and remains an important cause of maternal mortality worldwide.
- Availability of a test that does not require blood collection equipment and robust laboratory services is particularly attractive in resource-poor settings such as low-income countries.
- Another benefit is that it can avoid repeated pricks for hemoglobin estimation, thus improving patient experience and decrease the burden on the NHS laboratories.
- Non-invasive estimation of haemoglobin is possible with pulse co-oximetry. A commercial device is available (Massimo Pronto pulse co-oximeter).
- This technology uses a finger probe, and a blood sample is not necessary.
- The pulse co-oximetry technology uses circulation through skin capillaries, which is known to change in pregnancy.
- Therefore, specific validation in pregnant population is important.

Objective

Our study aimed to investigate the accuracy of a non-invasive device to measure haemoglobin and compare it with the laboratory gold standard in pregnant women, and to assess if cutaneous pulse co-oximetry results are influenced by skin pigmentation.

Design

It was a prospective study involving the clinical investigation of a medical device.

Methodology

- Women attending the day assessment unit for the pre-operative assessment before a scheduled Caesarean section were invited to participate.
- Haemoglobin (Hb) estimation was performed using a non-invasive point-of-care device (Massimo Pronto pulse co-oximeter).
- Venous blood sample was collected and sent to the laboratory for Full Blood Count.
- The skin pigmentation was classified using the Fitzpatrick scale.
- Bias and 95% limits of agreement were examined for pulse Co-oximeter and laboratory Haemoglobin estimation.
- Variability of accuracy of the pulse Co-oximeter device was assessed in the six Fitzpatrick scales of skin tone.

Results

A total of 122 women were recruited for the study. Twelve of these women (9.8%) had haemoglobin values of less than 105 g/L.

Figure 1- Correlation between Hb estimation by pulse co-oximetry and laboratory Hb estimation with past performance. The Pronto device showed a significant positive bias. The mean difference was 23.4g/L (SD: 11.97).

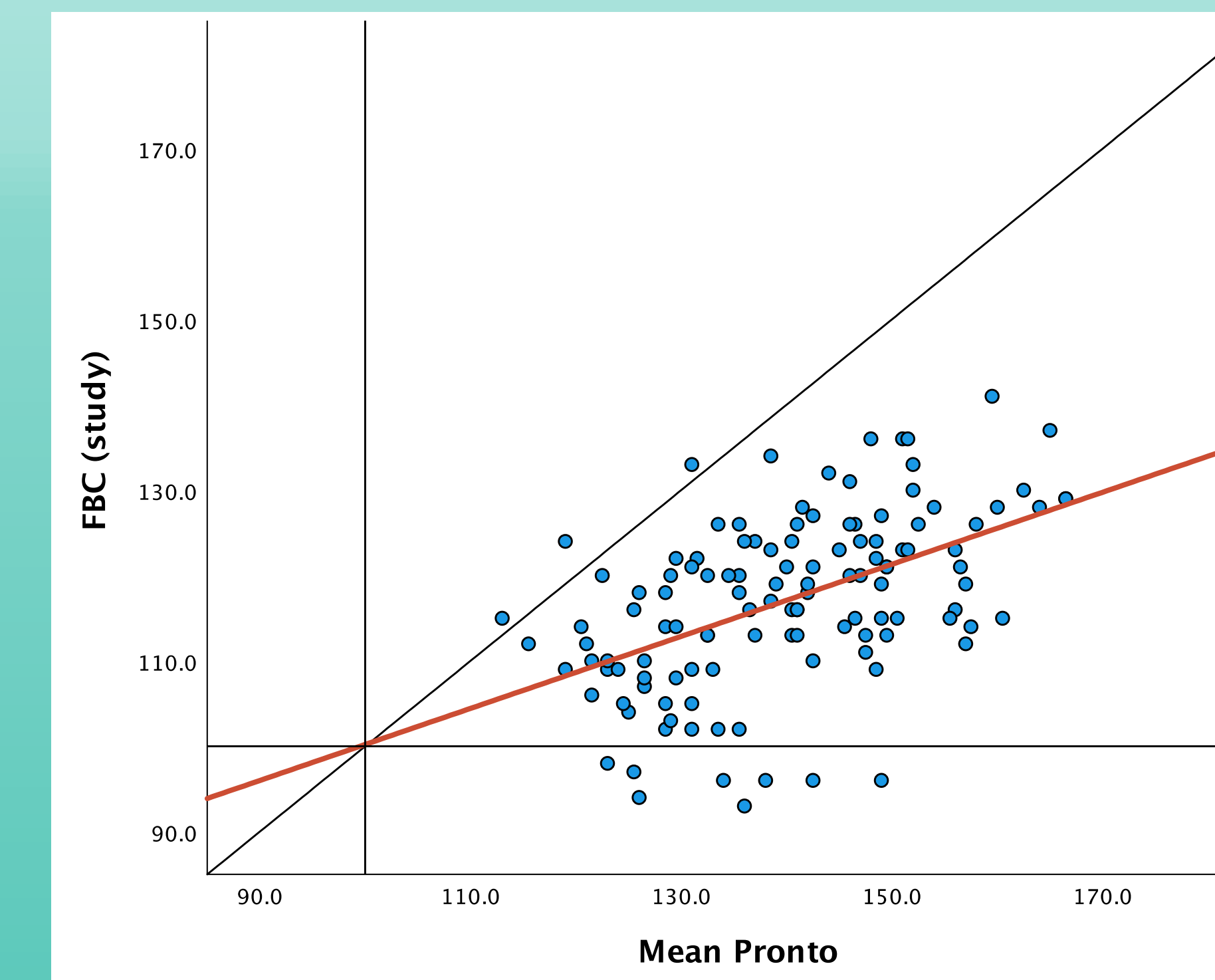
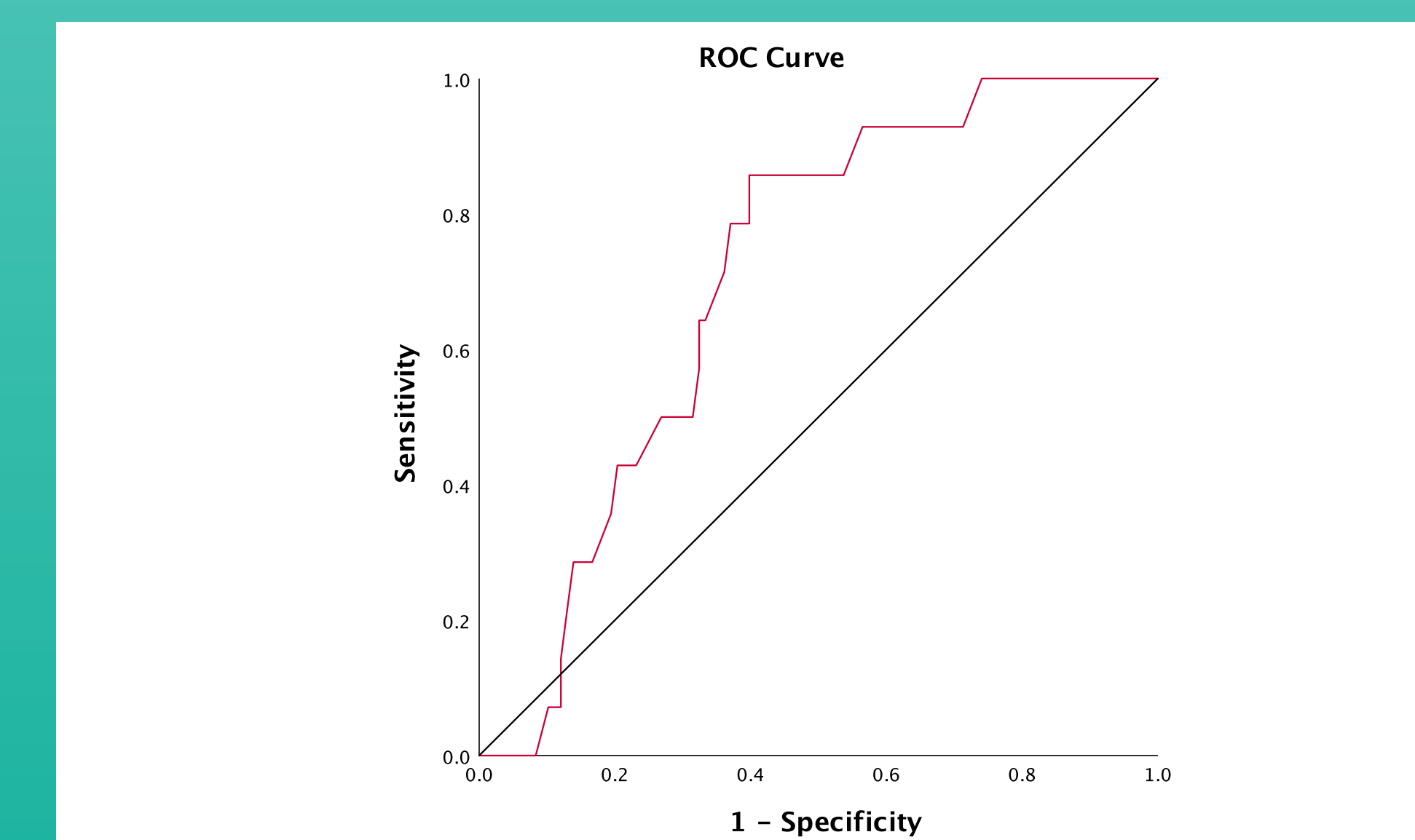


Figure 2- The area under the ROC curve was 0.705 (95% CI: 0.817 – 0.593, p = 0.013) for the detection of anaemia



The 95% limits of agreement between the Pronto device and the laboratory estimation were -0.06 to 46.9 gm/L. The difference between the two methods was unrelated to the skin pigmentation.

Conclusion

- The non-invasive point-of-care device (Massimo Pronto pulse co-oximeter) over-estimates the Hb readings in pregnant women and a correction is needed to estimate the real Hb value.
- The accuracy is not affected by skin pigmentation.
- As the area under the ROC curve for the detection of anaemia in pregnancy was statistically significant, the point of care device shows promise as an alternative to laboratory estimation as a screening test for anaemia in pregnancy.

References

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