AACC Abstract Submission

Independent validation of the use of point-of-care (POC) lactate in addition to POC pH for the clinical determination of foetal distress and associated surgical intervention

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Abstract

Background:

The amendments to NICE Clinical Guideline 190 have led to the utilization of lactate concentration for the determination of fetal hypoxia from an intrapartum fetal blood sample (FBS). FBS sampling allows the maternity team to determine if caesarian section is necessary, or continue with vaginal delivery. Lactate assay is revolutionary in cases where FBS pH assay is inappropriate; or the sample is inadequate and of a poor quality (BHRUT has a 59% success rate). This study aims to independently validate the use of POC lactate in addition to POC pH for the clinical determination of foetal distress and associated surgical intervention; correlating cord blood and FBS lactate with pH.

Methods:

Phase 1: The analytical performance of 2 POC lactate methods were compared to the Olympus AU2700 (Siemens Healthcare Diagnostics Inc): StatStrip Lactate from Nova Biomedical and RL500 from Siemens Healthcare Diagnostics Inc. Accuracy and decision making criteria were assessed with freshly taken adult arterial and venous blood gas samples (n = 45), validating the performance of the StatStrip lactate against the AU2700 lactate, and RL500 lactate and pH values. Correlation coefficients (R^2) were determined using regression analysis; the Wilcoxon sign rank test and Students *t*-test were used for ANOVA, and Bland-Altman plots were used for data plotting.

Phase 2: Accuracy and decision making criteria were assessed with freshly taken arterial and venous umbilical cord bloods and FBS (incomplete as of April 2016), validating the performance of the StatStrip POC lactate against the Siemens RL1240 (Siemens Healthcare Diagnostics Inc) pH values.

Results:

Although both POC methods showed good correlation with the reference method for arterial and venous blood (r = 0.98 and 0.97 respectively), the StatStrip and RL500 showed a significant negative bias when compared to the AU2700 (mean bias -0.33mmol/L, p<0.0001, 95% CL 0.51-6.30 and mean bias 0.08mmol/L, p 0.034, 95% Cl 0.7 – 7.78 respectively). The POC methods show good correlation to one another (r = 0.97) although a significant negative bias is still observed with StatStrip method (mean bias -0.38mmol/L, p<0.0001). The study will investigate potential pre-analytical factors having an impact on this performance to verify the suitability of the POC lactate for clinical decision making for FBS lactates.

Conclusion:

The clinical utility of POC lactate for the intrapartum care of women has both financial and managerial implications for the labour ward. The independent validation of POC devices and locally derived reference ranges are vital for the correct management of caesarean section indicated by fetal distress. The variation and systemic bias of POC devices indicate that the NICE classification of FBS results (1.10.14) should not be determined as a definitive source of reference. The study shall continue to include both cord blood and FBS cohort specimens to characterise lactate measurement, which is relatively new to obstetrics.