Ned Tijdschr Klin Chem Labgeneesk 2015; 40: 215-217

POC-lactate: evaluation of strip and cassette versus routine results

R. van HORSSEN[1] T.N. SCHUURMAN[2], M.J.M. de GROOT[1] and B.S. JAKOBS[1]

Blood lactate is an indicator for metabolic acidosis and a marker for immediate intervention. Here we cross-compared two point-of-care (POC) lactate analysers with routine results: the StatStrip-Lactate and the iSTAT-1 versus the ABL-735. We also performed precision analysis. We found good correlations between the three analysers and also the precision met the validation criteria, except for pO_2 and pCO_2 measured with the iSTAT-1. Differences and bias were acceptable for clinical practice. The most up-to-date validation criteria were used and the pro's and con's of strip versus cassette analysers were evaluated.

In critically ill patients, lactate levels correlate well with disease state, have prognostic value and can be used for monitoring (1). POC-lactate devices represent an attractive and quick tool for the Emergency Department (ED), but analytical performance and costs-benefits ratios should be taken into account.
Similarly, at the department of Obstetrics, measurement of fetal lactate can lead to immediate intervention, since it is a direct indicator of fetal acidosis during labour. Lactate is measured, along with pH, in fetal scalp blood, sampled from the unborn by making a small incision. Major drawback of full blood analysis (including pH), compared to only lactate measurement with a strip-analyser, is the amount of sample needed (40 – 90 µl). This amount is often not available, resulting in high failure rates, of up to 23% (2). Lactate is responsible for metabolic acidosis and can be measured in a very small volume (1 µl) so it represents an attractive alternative for full blood gas analysis (3). Recent literature revealed that for patients with metabolic acidosis, biological variability of lactate is about half of that of healthy individuals, which evidently is important for validation of lactate POC devices (4). We compared a strip and a cassette device to routine blood gas results and with each other.

Methods

A total of 151 samples were used, of which 66 were from umbilical cords and 85 from the ED and Critical Care. We used surplus, de-identified samples and patients who refused the reuse of their blood were excluded. We compared the ABL-735 (Radiometer), StatStrip Lactate (Nova Biomedical) and iSTAT-1 (CG4+ cassettes, including pH, pCO_2, pO_2, BE, HCO_3^-, sO_2 and lactate, Abbott). Samples were measured routinely on the ABL-735. Simultaneously, lactate levels were analysed on the StatStrip (1 µl) and for samples that contained sufficient material, full blood gas was measured on the iSTAT-1 (90 µl). Analytical performance of the POC devices was assessed by measuring control material according to the CLSI:EP5A Complex Precision Protocol. Results were analysed with EP-Evaluator (Version 10.3, Rhoads): Alternate Method Comparison (CLSI:EP9A), Multiple Instrument Comparison (comparing three analysers, using the median of the three analysers as target) and Complex Precision (CLSI:EP5A). To compare two methods and calculate the correlation coefficients (R), Passing-Bablok regression analysis was done.

Results

A good correlation was achieved, but when using the strict allowable error (13.6%, which is the analytical imprecision), as suggested in recent literature (4), some samples located just out of the allowable area (Figure 1A). Comparing the ABL-735 versus the StatStrip showed a mean (± SD) of all included samples of 5.22 (± 3.22) and 4.94 (± 3.18) respectively and a correlation coefficient (R) of 0.9861 (Figure 1B) with a slope (Confidence Interval) of 0.967 (0.938 – 1.000). Cross-comparing the iSTAT-CG4+ to the StatStrip, showed a mean of 5.25 (± 3.03) and 4.89 (± 3.04) respectively, with R=0.9782 (Figure 1C) with a slope of 0.941 (0.903 – 0.984). In the subset of umbilical cords, the same cross-comparisons were made and shown as inserts in Figure 1. For 66 umbilical cords, comparing the StatStrip with the ABL-735 a mean of 5.35 (± 2.24) and 4.97 (± 2.16) was found with R=0.9737, with a slope of 0.937 (0.917 – 1.028), see Figure 1B, insert. For 54 umbilical cord samples in the cross-comparison of the StatStrip with the iSTAT-CG4+, we found a mean of 5.07 (± 2.15) and 5.83 (± 2.36) respectively and R=0.9774, with a slope of 0.917 (0.863 – 0.981), see Figure 1C, insert. The iSTAT-CG4+ will be the device of choice for the ED, therefore we showed these samples as insert in Figure 1D compared with the ABL-735. For the other blood gas parameters measured with the iSTAT-CG4+ cassette, good correlations were achieved, with a very small spreading of pH values, while for pCO_2 and pO_2, the spreading was too high (data not shown).

Department of Clinical Chemistry and Haematology[1] and Department of Obstetrics and Gynaecology[2], Elisabeth-TweeSteden Hospital, Tilburg, The Netherlands

Correspondentie: R. van Horssen, Elisabeth-TweeSteden Hospital, Laboratory for Clinical Chemistry and Haematology
E-mail: r.horssen@elisabeth.nl

The analytical precision for both POC devices was determined by comparing the measured CV with the CV provided by the company, the desirable CV and the Total Allowable Error (www.westgard.com). In addition, we calculated the bias, compared to the reference method: ABL-735. For lactate, we found a small negative bias (-5.3%) for the StatStrip and a small positive bias (1.6%) for the iSTAT-CG4+ compared to the ABL-735. For the other parameters in the iSTAT-CG4+ there was no noteworthy bias for pH and pCO_2, while for pO_2 the bias was -6.6%. All measured CVs were within the TEa, but for pCO_2 and pO_2 the CV was higher than the Analytical Imprecision. Data on precision and bias are presented in Table 1.

Discussion

In literature there is growing evidence that lactate can replace pH to predict metabolic fetal acidosis (5). POC strip-instruments have short analysis time and, importantly, use small volumes. Drawback of a strip analyser is that only lactate is measured while still many gynaecologists prefer also a pH value. The POC device that meets these criteria, the iSTAT-CG4+, can measure a full blood gas but, 90 µl of sample is

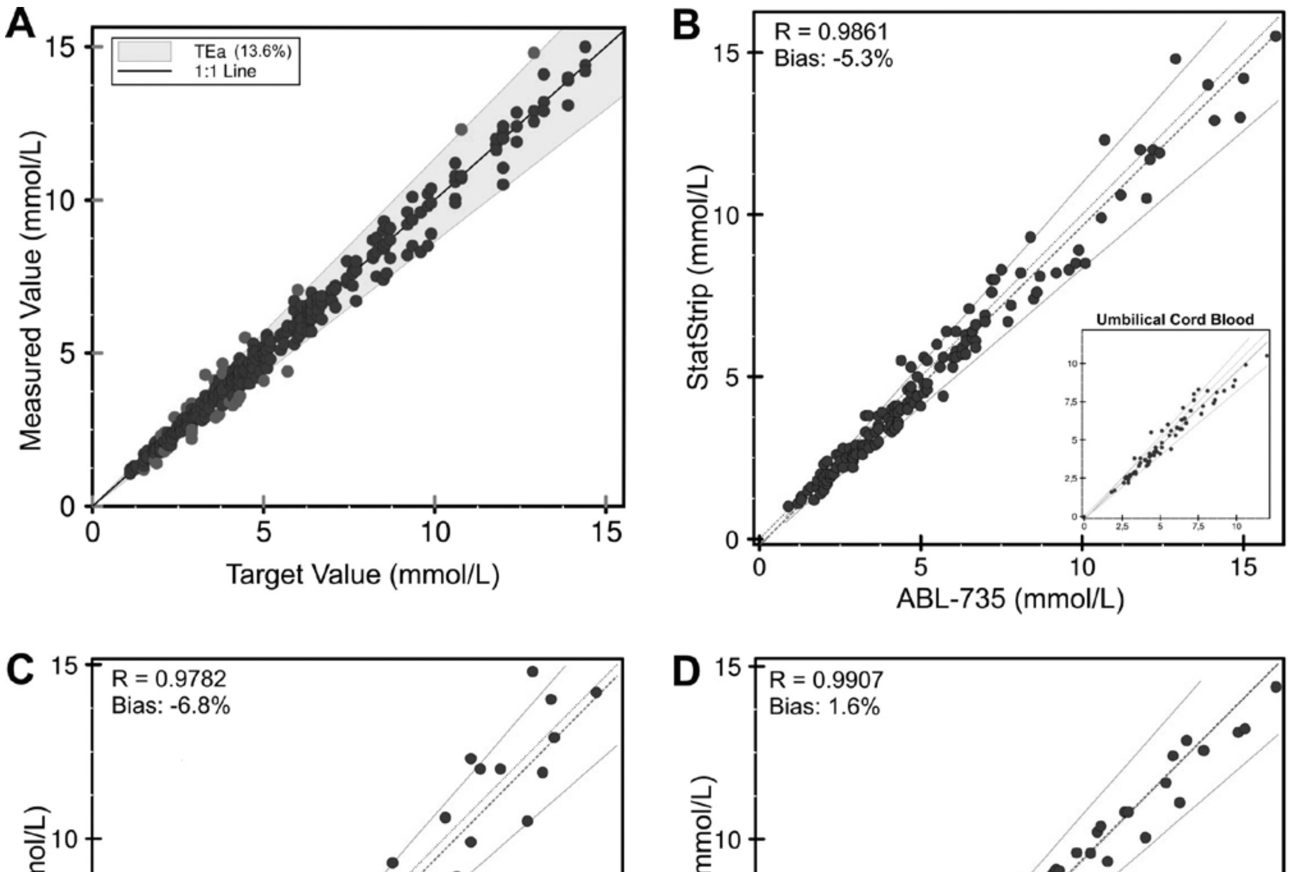

Figure 1. Cross-comparison of POC-lactate measurements with routine results. A) Multi Instrument Comparison comparing all lactate results measured on three instruments (Measured Value) to the Target Value (median of three measurements). We used 13.6% as TEa because we measured patients with lactic acidosis. B) Method comparison for lactate measured on the StatStrip versus the ABL-735 for all samples. Insert shows the subset of samples from umbilical cords. C) Method comparison for lactate measured on the StatStrip versus the iSTAT-CG4+ for all samples. Insert shows the subset of samples from umbilical cords. D) Method comparison for lactate measured on the iSTAT-CG4+ versus the ABL-735 for all samples. Insert shows the subset of samples from the ED and Critical Care.

Table 1. Quality specifications of the StatStrip-Lactate and iSTAT-CG4+ devices

	Desirable analytical CV[a]	Total Allowable Error (TEa)[a]	CV (Company)	CV (Measured)	Bias (*vs* ABL-735)
StatStrip-Lactate	13.6	30.4	9.1	5.5	-5.3
iSTAT-CG4+					
Lactate	13.6	30.4	3.7	1.1	1.6
pH	1.8	3.9	0.1	0.1	-0.01
pCO_2	2.4	5.7	2.5	3.4	0.7
pO_2	4.8	8.0	4.8	6.3	-6.6

[a]Analytical Imprecision and TEa according to www.westgard.com

needed. Next to these practical issues, the analytical performance of the POC analysers must meet up-to-date quality requirements.

The analytical performance of the StatStrip was good, both for the comparison to routine results as for the precision analysis. Although a negative bias exists, this is acceptable for clinical practice. The analytical performance of the iSTAT-CG4+ was good, especially for lactate and pH. For pCO_2 and pO_2 the correlation with the ABL-735 was good, while the CV of the precision measurements was too high. The clinical consequences of this imprecision are limited. Based on the analytical precision, we conclude that both the StatStrip and the iSTAT are suitable for use in the clinic. For lactate, as recently published, the biological variability is strongly dependent on the patient population (4). We implemented this tighter allowable error and found for both POC devices that this new target was met.

References

1. Bakker J, Nijsten MW, Jansen TC. Clinical use of lactate monitoring in critically ill patients. Ann Intensive Care. 2013; 3: 12.
2. Reif P, Lakovschek I, Tappauf C, Haas J, Lang U, Scholl W. Validation of a point-of-care (POC) lactate testing device for fetal scalp blood sampling during labor: clinical considerations, practicalities and realities. Clin Chem Lab Med. 2014; 52: 825-833.
3. Heinis AM, Spaanderman ME, Gunnewiek JM, Lotgering FK. Scalp blood lactate for intra-partum assessment of fetal metabolic acidosis. Acta Obstet Gynecol Scand. 2011; 90: 1107-1114.
4. Versluys KA, Redel S, Kunst AN, et al. Tighter precision target required for lactate testing in patients with lactic acidosis. Clin Chem Lab Med. 2014; 52: 809-813.
5. Ridenour RV, Gada RP, Brost BC, Karon BS. Comparison and validation of point of care lactate meters as a replacement for fetal pH measurement. Clin Biochem. 2008; 41: 1461-1465.