Technical Performance of Lactate Biosensors and a Test-Strip Device during Labour

Präzision und Richtigkeit von Laktatbiosensoren im Kreißsaaleinsatz

Authors A. K. Luttkus[1], C. Fotopoulou[2], J. Sehouli[2], J. Stupin[3], J. W. Dudenhausen[3]

Affiliations
[1] Frauenklinik und Perinatalzentrum, Ev. Krankenhaus Bielefeld in Bethel, Bielefeld, Germany
[2] Department of Gynecology, Charité, Medical University of Berlin, Berlin, Germany
[3] Department of Obstetrics, Charité, Medical University of Berlin, Berlin, Germany

Key words
- fetal lactate
- fetal hypoxia
- fetal blood sampling
- lactate biosensors

Schlüsselwörter
- fetales Laktat
- fetale Hypoxie
- Fetalblutanalyse
- Laktatbiosensoren

received 26.05.2009
accepted 21.09.2009
after revision

Bibliography
DOI http://dx.doi.org/10.1055/s-0030-1249641
Z Geburtsh Neonatol 2010; 214: 62–67

ISSN 0948-2393

Correspondence
Andreas K. Luttkus, MD, PhD
Frauenklinik und Perinatalzentrum
Ev. Krankenhaus Bielefeld in Bethel
Burgsteig 13
33617 Bielefeld
Germany
Tel.: +49/521/772 78251
Fax: +49/521/772 78252
andreas.luttkus@evkb.de

Abstract

Introduction: Lactate in fetal blood has a high diagnostic power to detect fetal compromise due to hypoxia, as lactate allows an estimation of duration and intensity of metabolic acidemia. Biosensor technology allows an instantaneous diagnosis of fetal compromise in the delivery room. The goal of the current investigation is to define the preanalytical and analytical biases of this technology under routine conditions in a labour ward in comparison to test-strip technology, which allows measurement of lactate alone.

Material and Methods: Three lactate biosensors (RapidLab 865, Siemens Medical Solutions Diagnostics, Bad Nauheim, Germany; Radiometer ABL625 and ABL 700, Radiometer Copenhagen, Denmark) and one test-strip device (Lactate Pro™, Oxford Instruments, UK) were evaluated regarding precision in serial and repetitive measurements in over 1350 samples of fetal whole blood. The coefficient of variation (CV) and the standard deviation (SD) were calculated. The average value of all three biosensors was defined as an artificial reference value (refval). Blood tonometry was performed in order to test the quality of respiratory parameters and to simulate conditions of fetal hypoxia (pO_2: 10 and 20 mmHg).

Results: The precision of serial measurements of all biosensors indicated a coefficient of variation (CV) between 1.55 and 3.16 % with an SD from 0.042 to 0.053 mmol/L. The test-strip device (Lactate Pro™) mounted to 0.117 mmol/L and 3.99 % (SD, CV). When compared to our reference value (refval) ABL 625 showed the closest correlation of −0.1 %, while Siemens RapidLab 865 showed an overestimation of +8.9 %, ABL700 an underestimation of −6.2 % and Lactate Pro™ of −3.7 %.

Conclusion: For routine use all tested biosensors show sufficient precision. The test-strip device shows a slightly higher standard deviation. A direct comparison of measured lactate values

Zusammenfassung

Einführung: Laktat im Fetalblut hat eine hohe diagnostische Aussagekraft für die Gefährdung durch Sauerstoffmangel, da Laktat eine Einschätzung der Dauer und der Intensität der metabolischen Azidosen ermöglicht. Mit moderner Biosensor-Technologie ist eine unmittelbare Messung von fetalem Laktat im Kreißsaal möglich. Ziel der vorliegenden Untersuchung ist, die analytischen und präanalytischen Fehlerquellen von drei gängigen Laktatbiosensoren und einer Teststreifenmethode aufzuzeigen.

Material und Methode: Drei Lactat-Biosensoren (RapidLab 865, Siemens Medical Solutions Diagnostics, Bad Nauheim, Deutschland; Radiometer ABL 625 und ABL 700, Radiometer Kopenhagen, Dänemark) und ein Teststreifen-System (Laktat Pro™, Oxford Instruments, UK) wurden hinsichtlich der Präzision von Messungen in Serie und Doppelmessungen an über 1350 fetalen Vollblutproben evaluiert. Der Variationskoeffizient (CV) und die Standardabweichung (SD) wurden berechnet. Da kein allgemein akzeptierter Goldstandard für die Richtigkeit der Laktatmessung besteht, wurde der Mittelwert aller drei Biosensoren als Referenzwert herangezogen. Das Fetalblut wurde auf einen Sauerstoffpartialdruck von 10 und 20 mmHg tonometriert, um die Qualität der respiratorischen Parameter zu testen und die Konditionen eines fetalen Sauerstoffmangels zu simulieren.

Ergebnisse: Der Variationskoeffizient der seriellen Messungen der Biosensoren lag zwischen 1,55 und 3,16 % mit einer Standardvariation von 0,042 bis 0,053 mmol/L. Das Teststreifensystem (Laktat Pro™) erreichte eine Standardabweichung von 0,117 mmol/L und einen Variationskoeffizienten von 3,99 %. Der Vergleich zum Referenzwert zeigte beim Biosensor ABL 625 (Radiometer) die engste Korrelation von −0,1 %. Wo hingegen Siemens Rapid Lab 865 eine Überbe-

from the various devices needs to be interpreted with caution as each method detects different lactate concentrations. Furthermore, the 40 min process of tonometry led to an increase of SD and coefficient of variation in all devices. This results in the important preanalytical finding that the precision of replicated measurements worsens significantly with time. The clinician should be aware of the type of analyser used and of preanalytical biases before making clinical decisions on the basis of lactate values.

wertung von +8,9%, ABL 700 eine Unterbewertung von −6,2% und Laktat Pro™ von −7,3% lieferten.

Schlussfolgerung: Für die klinische Routine zeigten alle Biosensoren eine befriedigende Präzision. Die Teststreifenmethode hatte eine diskret höhere Standardabweichung. Der direkte Vergleich von Laktatwerten verschiedener Geräte ist kritisch, da jedes Gerät leicht divergierende Laktatkonzentrationen detektiert. Mit zunehmendem Zeitintervall steigen sowohl die Standardabweichung als auch der Variationskoeffizient aller Geräte an. Der Kliniker sollte sich bewusst sein über den „Normalbereich" des verwendeten Sensorsystems und über die präanalytischen Fehlerquellen, bevor klinische Entscheidungen auf der Basis von Laktatwerten gefällt werden.

Introduction

Biosensors measure fetal lactate as a direct metabolite of anaerobic glycolysis. The pathophysiology of fetal metabolic acidemia [1,2] and its relevance for long-term neurological impairment has been well known for many decades [3]. The technical equipment, however, to measure lactate concentration within minutes in the delivery room using only small quantities of whole fetal blood has been available for a relatively short time [4,5].

The acid-base balance at birth measured in umbilical cord artery and vein blood has long been considered as a quality control for the management of delivery [6]. Moreover, in many countries obstetricians use fetal scalp blood samples in order to determine fetal state [7,8] after abnormal fetal heart rate patterns have occurred. The additional information about lactate concentration increases the value of fetal scalp blood sampling, since the metabolic amount of acidemia is additionally measured. Long-term neurological consequences for the newborn are much more severe after metabolic acidemia compared to those after respiratory acidemia. Some clinicians use test-strip lactate devices as an alternative to pH measurements by blood gas analysers to monitor fetal well-being. In particular, the advantage of handheld devices requiring only small sample volumes must be pointed out [2,9].

Pre-analytical, analytical and physiological biases concerning lactate as a diagnostic tool are as yet not perfectly understood. Among clinical chemists no consensus has been reached on defining a reference method to measure lactate [10].

The aim of our investigation is to evaluate different methods and devices for lactate measurement in fetal blood in a routine clinical setting during labour. Tonometry was performed to simulate fetal oxygenation levels during labour and to test the blood gas analysers with regard to the accuracy of saturation measurements [11]. We evaluated clinically relevant differences in measurement standards among the different devices as well as significant errors induced by preanalytical factors.

Methods

Three different blood gas analysers with integrated biosensors and one test-strip method to measure lactate in whole blood were evaluated concerning precision, systemic and standard deviation and reliability to ensure comparable standards (Siemens-RapidLab 865, Medical Solutions Diagnostics Bad-Nauheim, Germany; Radiometer ABL625 and ABL700, Radiometer Copenhagen/Denmark). All measurements started immediately after umbilical blood had been taken without adding flouride.

Since the activity of lactate oxidase on the biosensor limits its lifetime, we performed a daily quality control. The valid concentration range of the lactate biosensors lies between 0 and 30 mmol/L, whereas the range of the test-strip method lies between 0.8 and 23.3 mmol/L.

No quality control measurements are currently available for the test-strip method; however, before any new package of test strips, containing 25 pieces, was used, a calibration process was performed.

Device description

Precision within-run

For the evaluation of the precision within-run, a series of ten replicates from one identical blood sample was measured by a single device without any time delay. For this purpose we used a 10 mL heparinised syringe of umbilical vein blood. The sample was first stored for 30 min in the ice drawer to decelerate or even interrupt the metabolism. Between the different analyses the syringe was replaced in the ice drawer. The average time interval between the individual measurements amounted to two minutes. The standard deviation of the precision in series (s) and the variation coefficient were then determined out of the 10 measured values.

Precision of replicates

The values of the first measurement per device and per series of measurements were compared with the average values of the repetitive measurements. The bias of the differences was calculated as follows:

Bias (diff) = average value (1st measurement) – average value (repetitive measurement).

Accuracy of the measurement

Since no reference method currently exists as gold standard for lactate in the test-strip method, in our study we determined the average lactate value of the three blood gas analysers, Siemens 865, ABL625 and ABL700 as reference. Lactate Pro™ was not included into the reference value, since it consists of a different kind of sensors and the number of measurements was far fewer compared to the blood gas analysers. Information on the biased error of the results of measurement of a device is given by the $Bias_{(syst)}$, i.e., the difference between the average value of test equipment and the average value of the reference device:

Table 1 Precision of series of ten lactate replicates. Mean ξ, standard deviation $SD_{(series)}$ and coefficient of variation $CV_{(series)}$ were determined using one umbilical vein sample for each analyser.

No.	Siemens 865	Lactate Pro™	ABL 625	ABL 700	
1	1.87	3.0	2.7	1.5	mmol/L
2	1.89	2.8	2.7	1.5	mmol/L
3	1.86	3.0	2.7	1.5	mmol/L
4	1.90	3.0	2.7	1.5	mmol/L
5	1.88	2.9	2.7	1.5	mmol/L
6	1.89	2.7	2.7	1.5	mmol/L
7	1.92	3.1	2.7	1.5	mmol/L
8	1.97	3.0	2.7	1.6	mmol/L
9	2.00	2.9	2.8	1.6	mmol/L
10	2.00	3.0	2.8	1.6	mmol/L
ξ	1.92	2.94	2.72	1.53	mmol/L
$SD_{(series)}$	0.053	0.117	0.042	0.048	mmol/L
$CV_{(series)}$	275	3.99	1.55	3.16	%

$Bias_{(syst)}$ = average value of the test equipment – average value of the reference.

The biased error is indicated as follows derived from the reference value:

Systematic error (%) = $Bias_{(syst)} \times 100$/Average of the 3 blood gas analysers

Quality of data

Under the following circumstances lactate measurements were not included into the current evaluation.

- Time delay more than 10 min between the first and second measurement, regardless if it affected native (n = 25) or tonometered (n = 34) blood.
- Any error messages displayed on the devices, for example, due to insufficient blood volume, detected disturbing substances or calibration errors.

A total number of 78 measurements had to be excluded from the evaluation for these reasons.

The number of valid results of lactate concentration was 1 392. The series of measurements No. 1 included 483 valid results, the series of measurements No. 2a included 471 valid values and series of measurements No. 2b included 438 valid values. The biosensors Siemens 865, ABL625 and ABL700 measured overall 1 000 valid lactate values (n = 348, 394 and 381, respectively), while the Lactate Pro™ performed 269 valid measurements.

Statistics

The Wilcoxon-test for paired samples was applied for the statistical significance of the differences between first and second measurement and between test equipment and reference value. Statistical significance was assumed with a probability of error smaller than 5% ($p < 0.05$).

Results

Precision within-run in a series of ten replicates

The standard deviation SD (series) ranged between 0.042; 0.048; 0.058 mmol/L for the biosensors ABL625, ABL700, Siemens 865, respectively, and 3.99 mmol/L for the test-strip Lactate Pro™. The coefficient of CV from ten sequential replicates amounted to 1.55%, 3.16% and 2.75% for the biosensors ABL625, ABL700, and Siemens 865, respectively. Lactate Pro™ achieved a CV of 3.99%. Repetitive measurements showed good precision of the biosensors (< 3.5%) and a precision for the test-strip method of 6% (**Table 1**). The negative bias is due to the fact that lactate increases during the maximum 10 min-period between the first and the repetitive measurement. Furthermore, the standard deviation of the differences SD (diff) and the variation coefficients of the differences CV (diff) increase between series one (1) and two (2a + b). The differences between the first and second measurements are all statistically significant ($p < 0.05$).

Compared to the reference value, the Siemens 865 presented higher lactate values (95% confidence interval: +0.28 to +0.38 mmol/L). However, the values measured by Lactate Pro™ and ABL700, deviated from the reference value into lower concentration ranges.

Concentration-dependent bias

To investigate whether the biased error was dependent on the lactate concentration and to display the relationship of the test equipment results to the reference value, deviation diagrams were employed (**Figs. 1–3**). Only fetal whole blood was analysed. In **Figs. 1–3**, which show the results for the series of measurements No. 1, the abscissa represents the reference values (= average value of all three blood gas analysers) and the ordinate the difference between the lactate concentrations measured by the respective test equipment and the corresponding reference values. The slope of the central of the regression line (middle line) gives information about any correlation of the systematic errors in the lactate concentration. The dashed line through point zero of the ordinate represents an imaginary line when no differences between test device and reference value would exist. The position of the squares in reference to the regression line marks the dispersion of differences. The 95% confidence interval is represented by the outer straight lines.

Since we calculated the deviations of the lactate measurements of each device from the reference value computed as the average value of all three blood gas analysers, we also wanted to describe the difference of the devices to one another. We achieved this by a simple comparison in pairs: we compared the average values from the series of measurements No. 1. Differences were noted between Lactate Pro™ and Siemens 865 (bias = −0.68 mmol/L) as well as between ABL700 and Siemens 865 (bias = −0.58 mmol/L). Lactate Pro™ presented, correlated to the concentrations measured by Siemens 865, around 16.8% lower values. ABL700 underestimated the concentrations compared to those measured by Siemens 865 by 14.4%. Compared to Siemens 865, ABL625 detected approximately 0.24 mmol/L lower lactate concentrations, which correlates to a relative difference of 5.9%. Lactate Pro™ and ABL700 indicated overall lower values than ABL625 (bias = −0.44 or 0.34 mmol/L). They showed hereby, compared to the ABL625 results, proportional deviations as high as 11.6% and 9%. Only a small difference was noted between lactate concentrations measured by Lactate Pro™ and ABL700 (bias = −0.1 mmol/l); the relative deviation amounted to 2.9%.

Discussion

The method of fetal scalp blood sampling during labour allows a safe and instantaneous control of the fetal oxygenation status [12]. Combined with continuous fetal heart rate monitoring, FBA

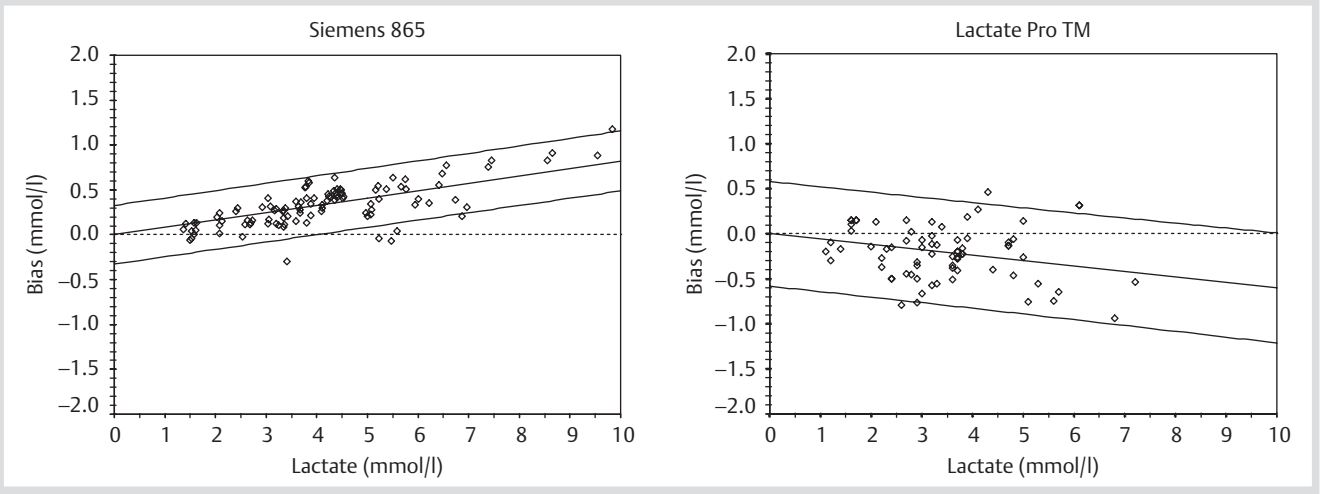

Fig. 1 Biased error and dispersion of the *Bias*$_{(syst)}$ of Siemens 865 and Lactate Pro™ in the series of measurements No. 1. The 95 % confidence interval as measured by the dispersion and is represented by the two outer straight lines. The deviation diagram for Lactate Pro™ shows a negative upward gradient of the involution straight line, which however compared with Siemens 865 is less pronounced. With a lactate concentration of 3 mmol/L the Bias$_{(syst)}$ amounts to 0.18 mmol/L; with a concentration of 6 mmol/L it amounts to 0.36 mmol/L. The 95 % confidence interval is broad, which suggests a large dispersion of the differences.

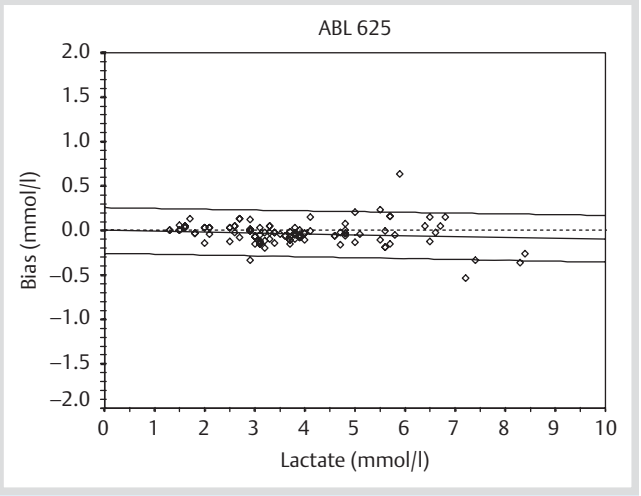

Fig. 2 Biased error and dispersion of the *Bias*$_{(syst)}$ for ABL 625 in the series of measurements No. 1. The involution straight line of ABL 625 runs along the zero line. No biased error is to be expected. The dispersion is small; the two outer lines of the 95 % confidence interval show that the differences with a probability of 95 % are situated within the range 0.25 to +0.25.

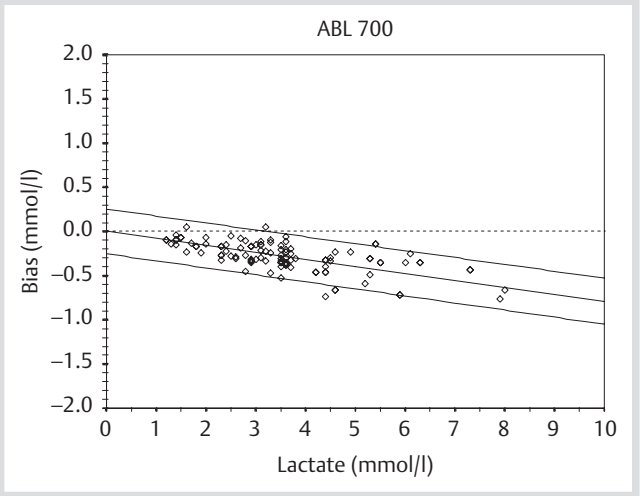

Fig. 3 Biased error and dispersion of the Bias$_{(syst)}$ for ABL 700 in series of measurements No. 1. While the 95 % CI of the device ABL 700 is just as narrow as that of the device ABL 625, a clearly recognisable negative upward gradient of the ABL 700 involution straight line trends downwards in contrast to that of the ABL 625 device. Within the concentration range of 3 mmol/L the Bias$_{(syst)}$ amounts to 0.24 mmol/L and the lower delimitation of the confidence interval is situated at 0.50 mmol/L. These negative differences increase with rising lactate concentration: At a lactate value of 6 mmol/L the Bias$_{(syst)}$ already amounts to 0.48 mmol/L, and the 95 % confidence interval is downward limited by the value 0.75 mmol/L.

constitutes currently the gold standard in cases at risk for hypoxia in many countries [12, 13]. This established monitoring pattern results in a lower perinatal mortality and leads to a reduced number of unnecessary operative interventions by objectifying fetal distress [14]. Although fetal blood sampling remains the standard for further investigation of non-reassuring cardiotocograph (CTG) traces, it is still a poor predictor of fetal outcome [15]. Scalp lactate has been shown to be as good a predictor as scalp pH, with the advantages of being easier, inexpensive and with a lower rate of technical failures [15, 16]. Retrospective data suggest that lactate determinations in fetal scalp blood are equivalent to pH for predicting severe neonatal morbidity [15–19]. Before their implementation in clinical routine can be promoted, the technical performance of the lactate biosensors should be studied.

Lactate, produced by anaerobic glycolysis under conditions of tissue hypoxia, is a specific indicator for acidotic metabolism and fetal distress [16–23]. Since metabolic acidemia is responsible for fetal compromise [3], a diagnostic parameter to detect it would be optimal for fetal surveillance. Lactate measurements have been evaluated in intrapartum fetal surveillance for more than 30 years. However, it was not reliable. Handheld, microvolume devices were launched during the 1990s that lactate became a clinical option [16–23]. Biosensor devices allow measure-

Table 2 Precision of replicates in native and tonometered fetal whole blood samples. The best precision of double measurements is indicated by the device ABL 625 with a variation coefficient of 2.4% in series No. 1 of measurements. The precision of Lactate Pro™ appears to be reduced.

	$Bias_{(Diff)}$ [mmol/L]	$SD_{(Diff)}$ [mmol/L]	$CV_{(Diff)}$ [%]	N
Series No. 1 (without time delay in native blood)				
Siemens 865	−0.11	0.14	3.5	54
LacPro™	−0.08	0.20	6.0	43
ABL 625	−0.04	0.09	2.4	69
ABL 700	−0.03	0.12	3.5	66
Series No. 2a (after 40 min of tonometry, PO_2 = 20 mmHg)				
Siemens 865	−0.53	0.33	5.9	58
LacPro™	−0.33	0.35	7.3	45
ABL 625	−0.34	0.19	3.6	60
ABL 700	−0.31	0.23	4.9	63
Series No. 2b (after 40 min of tonometry, PO_2 = 10 mmHg)				
Siemens 865	−0.49	0.40	6.9	54
LacPro™	−0.40	0.54	10.4	39
ABL 625	−0.48	0.35	6.1	56
ABL 700	−0.52	0.76	14.6	58

Table 3 Systematic error of lactate measurement; the mean value of the three biosensors Siemens 865, ABL 625 and ABL 700 functions as reference. Evaluation of measurement deviation showed that the Siemens 865 detected systemically higher values of lactate with a relative deviation of 8.9%.

	$Bias_{(syst)}$ [mmol/L]	95%CI of $Bias_{(syst)}$ [mmol/L]	Systematic error [%]	N (pairs)
Series No. 1 (without time delay, native blood)				
Siemens 865	+0.33	+0.28 to +0.38	+8.9	116
LacPro™	−0.13	−0.18 to −0.08	−3.7	85
ABL 625	<0.005*	−0.03 to +0.02	−0.1	117
ABL 700	−0.23	−0.27 to −0.20	−6.2	115
Series No. 2a (after 40 min of tonometry, PO_2 = 20 mmHg)				
Siemens 865	+0.41	+0.30 to +0.51	+7.6	114
LacPro™	−0.38	−0.49 to −0.27	−7.2	90
ABL 625	+0.12	+0.07 to +0.18	+2.3	113
ABL 700	−0.24	−0.29 to −0.18	−4.6	108
Series No. 2b (after 40 min of tonometry, PO_2 = 10 mmHg)				
Siemens 865	+0.29	+0.12 to +0.45	+5.0	109
LacPro™	−0.48	−0.65 to −0.31	−8.2	80
ABL 625	+0.27	+0.18 to +0.36	+4.6	111
ABL 700	−0.22	−0.30 to −0.14	−3.9	102

$Bias_{(syst)}$ = mean of test device) − mean of reference; systematic error = $Bias_{(syst)}$ × 100/mean of reference; CI = confidence interval; + = deviation to higher concentration; − = deviation to lower concentration

* No statistical significance

ments of fetal lactate as a direct metabolite of anaerobic glycolysis within seconds in the labour room.

Due to the continuous glycolysis, in vitro lactate depends on the metabolic activity of the erythrocytes [24, 25]. Therefore, the clinical consequence of the various methods and mediums being applied for lactate measurement is that no standardised lactate reference values are currently available [17, 19–23].

Precision of replicates

The duration of tonometry which ranged up to 40 min may have caused a certain degree of hemolysis and vaporisation [25]. Still, this cannot properly explain why the repetitive measurements from identical tonometered samples showed such clinically relevant differences.

The highest precision of repetitive measurements in all three series was shown by the biosensor ABL625. At the measurements in native whole fetal blood (series No. 1) Siemens 865 and ABL700 also reached a high precision, showing a CV of merely 3.5%. In contrast to the biosensors, the test-strip method showed a relative low precision with a CV as high as 6.0%. After 40 min of tonometry the precision was marked by a decrease. The measurements of series No. 2b (PO_2 = 10 mmHg) generated distinctly higher coefficients of variation (CV) than the measurements of series No. 2a (PO_2 = 20 mmHg) (**Table 2**).

The biases of differences were continuously negative and the differences between first and second measurements were statistically significant ($p < 0.05$). Accordingly, the concentration of lactate rose within a maximum of 10 min in series No. 1 and a maximum of 15 min in series No. 2a and 2b as follows: in series No. 1 lactate rose between 0.9% (ABL700) and 2.7% (Siemens865). After tonometry lacate rose at least by 6.5% (ABL700, series No. 2a) and at the most by 9.9% (ABL700, series No. 2b).

Accuracy of the measurements

Due to the lack of a reference method as "gold standard" for the measurement of lactate, the mean of the three biosensors Siemens 865, ABL625 and ABL700 was defined to function as reference value for our study. Therefore it would not be correct to use the term "accuracy" and one should rather speak of "systematic errors". The systematic error was, as already reported, calculated in relation to the reference value:

Systematic error SE (%) = $Bias_{(syst)}$ × 100/mean of the three biosensors.

Regarding the measurements in native blood (series No. 1), no statistically significant difference was noted between the results of the biosensor ABL625 and the reference value. The other devices indicated, however, statistically significant systematic errors: the Siemens 865 detected systematically higher lactate concentrations and thus showed the highest deviation from the reference value (SE = +8.9%) compared to the other devices; Lactate Pro™ and ABL700 detected systematically lower lactate concentrations (SE = −3.7% and −6.2%, respectively) (**Table 3**).

In the series of measurements after tonometry to 20 mmHg (No. 2a), similar values were obtained: the Siemens 865 showed the largest (7.6%) while the ABL625 showed the smallest systematic error (2.3%).

While the systematic error of Lactate Pro™ and ABL625 rose from series No. 1 to series No. 2b, the systematic errors of Siemens865 and ABL700 showed the opposite trend and decreased towards series No. 2b. Lactate Pro™ indicated the largest systematic error (−8.2%) and ABL700 the smallest one (−3.9%) (**Table 3**).

Scatter plots are suitable to indicate whether a systematic error depends on the lactate concentration. The scatter plots (**Figs. 1–3**) show the results of the measurements in native whole blood (series of measurements No. 1).

We conclude that, for routine use, all tested biosensors (Siemens 865, ABL625 and ABL700) show sufficient precision. The test-strip device Lactate Pro™ presented a slightly higher standard deviation than the biosensors. A direct comparison of measured lactate concentrations by the various devices appears problematic since each method detects different lactate concentrations and no established reference value can be defined. These results should be considered when it comes to any comparison of data calculated by different devices. The 40 min duration time of the

tonometry process led to an increase of SD and coefficient of variation in all devices. The important preanalytical finding derived here is that the precision of the replicated measurements worsens significantly with time while the blood gases are rather being stabilised.

Financial Disclosure

Siemens Medical Solutions Diagnostics, Radiometer Copenhagen and Oxford Instruments provided the technical equipment.

References

1 *Eguiluz A*, *López Bernal A*, *McPherson K et al.* The use of intrapartum fetal blood lactate measurements for the early diagnosis of fetal distress. Am J Obstet Gynecol 1983; 147: 949–954
2 *Borruto F*, *Comparetto C*, *Wegher E et al.* Screening of foetal distress by assessment of umbilical cord lactate. Clin Exp Obstet Gynecol 2006; 33: 219–222
3 *Low JA*, *Pancham SR*, *Worthington D et al.* Acid-base, lactate, and pyruvate characteristics of the normal obstertric patient and fetus during the intrapartum period. Am J Obstet Gynecol 1974; 120: 862–867
4 *Friedmann W*, *Luttkus A*, *Qian XH et al.* Lactate and glucose determination using biosensors in umbilical cord blood. Z Geburtshilfe Neonatol 1997; 201: 11–14
5 *Kost GJ*, *Nguyen TH*, *Tang Z.* Whole-blood glucose and lactate. Trilayer biosensors, drug interference, metabolism, and practice guidelines. Arch Pathol Lab Med 2000; 124: 1128–1134
6 *Victory R*, *Penava D*, *Da Silva O et al.* Umbilical cord pH and base excess values in relation to adverse outcome events for infants delivering at term. Am J Obstet Gynecol 2004; 191: 2021–2028
7 *Saling E.* Fetal scalp blood analysis. J PeriNat Med 1981; 9: 165–177
8 *Borruto F*, *Comparetto C*, *Treisser A.* Prevention of cerebral palsy during labour: role of foetal lactate. Arch Gynecol Obstet 2007, Dec 11 [Epub ahead of print]
9 *Ramanah R*, *Martin A*, *Riethmuller D et al.* Value of fetal scalp lactate sampling during labour: a comparative study with scalp pH. Gynecol Obstet Fertil 2005; 33: 107–112
10 *Detry B*, *Nullens W*, *Cao ML et al.* Assessment of the lactate biosensor methodology. Eur Respir J 1998; 11: 183–187
11 *Porath M*, *Sinha P*, *Dudenhausen JW et al.* Systematic instrumental errors between oxygen saturation analysers in fetal blood during deep hypoxemia. Clin Chim Acta 2001; 307: 151–157
12 *Morel O*, *Richard F*, *Thiébaugeorges O et al.* Fetal scalp pH: Practical value during labour. Gynecol Obstet Fertil 2007; 35: 1148–1154
13 *Trochez RD*, *Sibanda T*, *Sharma R et al.* Fetal monitoring in labor: are accelerations good enough? J Matern Fetal Neonatal Med 2005; 18: 349–352
14 *van den Berg P*, *Schmidt S*, *Gesche J et al.* Fetal distress and the condition of the newborn using cardiotocography and fetal blood analysis during labour. Br J Obstet Gynaecol 1987; 94: 72–75
15 *Allen RM*, *Bowling FG*, *Oats JJ.* Determining the fetal scalp lactate level that indicates the need for intervention in labour. Aust N Z J Obstet Gynaecol 2004; 44: 549–552
16 *Nordstrom L.* Fetal scalp and cord blood lactate. Best Pract Res Clin Obstet Gynaecol 2004; 18: 467–476
17 *Nordstrom L*, *Chua S*, *Roy A et al.* Quality assessment of two lactate test strip methods suitable for obstetric use. J PeriNat Med 1998; 26: 83–88
18 *Nordstrom L*, *Chua S*, *Roy A et al.* Lactate, lactate/pyruvate ratio and catecholamine interrelations in cord blood at delivery in complicated pregnancies. Early Hum Dev 1998; 52: 87–94
19 *Nordstrom L*, *Ingemarsson I*, *Kublickas M et al.* Scalp blood lactate: a new test strip method for monitoring fetal well-being in labor. Br J Obstet Gynaecol 1995; 102: 894–899
20 *Nordstrom L*, *Ingemarsson I*, *Persson B et al.* Lactate in fetal scalp blood and umbilical artery blood measured during normal labor with a test strip method. Acta Obstet Gynecol Scand 1994; 73: 250–254
21 *Nordstrom L*, *Persson B*, *Shimojo N et al.* Fetal scalp and umbilical artery blood lactate measured with a new test strip method. Br J Obstet Gynaecol 1992; 99: 307–309
22 *Nordstrom L*, *Ingemarsson I*, *Westgren M.* Fetal monitoring with lactate. Baillieres Clin Obstet Gynaecol 1996; 10: 225–242
23 *Nordstrom L*, *Malcus P*, *Chua S et al.* Lactate and acid base balance at delivery in relation to cardiotocography and T/Qrs ratios in the second stage of labor. Eur J Obstet Gynecol-Reprod Biol 1998; 76: 157–160
24 *Picker SM*, *Radojska SM*, *Gathof BS.* In vitro quality of red blood cells (RBCs) collected by multicomponent apheresis compared to manually collected RBCs during 49 days of storage. Transfusion 2007; 47: 687–696
25 *Toffaletti J*, *Hammes ME*, *Gray R et al.* Lactate measured in diluted and undiluted whole blood and plasma: Comparison of methods and effect of hematocrit. Clin Chem 1992; 38: 2430–2434