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Full Length Research Paper

Assessment of the analytical quality of the electrolyte analyzer i-Smart 30 PRO for the measurement of serum electrolytes

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ABSTRACT

The i-Smart 30 PRO electrolyte analyzer is an electrochemical analyzer used to measure the concentrations of sodium, potassium and chlorides in various biological fluids. The aim of this study was to assess the analytical quality of the electrolyte analyzer i-Smart 30 PRO and validate its use for electrolytes testings at the Laboratory of Clinical Biochemistry and Toxicology, National Teaching Hospital Hubert Koutoukou MAGA. Samples received routinely for sodium, potassium and chlorides testings were runned on the electrolyte analyzers i-Smart 30 PRO and ILyte used as the gold standard. The sodium, potassium and chlorides serum concentrations were biased with significant differences. However more than 95% of the testings results were within the 95% limits of agreement. The i-Smart 30 PRO electrolyte analyzer could validly replace the ILyte analyzer for the measurements of these electrolytes concentrations in serum.

Keywords: Electrolytes, testings, analyzer, validation, i-Smart 30 PRO, ILyte.

INTRODUCTION

The electrolytes assay is one of the most important emergency testing (Zhang et al., 2015, Arya et al., 2014, Yılmaz et al., 2016). It allows determining the concentrations of electrolytes (sodium, potassium, chlorides, etc.) in different biological liquids. Among the numerous laboratory techniques that can be used to measure the serum concentrations of these electrolytes, the most common are automated to reduce the workload and based on the electrochemical principle (Yılmaz et al., 2016, Pant et al., 2017, Geffrй et al., 2006).

The Laboratory of Clinical Biochemistry and Toxicology of the National Teaching Hospital Hubert Koutoukou MAGA in Cotonou, has recently acquired the i-Smart 30 PRO (i-Sens; Korea) electrolytes analyzer. It is a fast analyzer, requiring a small volume of sample with an integrated autonomy generator of two hours. However, prior to its implementation, it was important to assess its analytical performance compared to the ILyte analyzer (Diamond diagnostics; USA) in use since several years in the laboratory.

The aim of this study was to assess the analytical quality of the i-Smart 30 PRO analyzer and validate its use at the Laboratory of Clinical Biochemistry and Toxicology of the National Teaching Hospital Hubert Koutoukou MAGA in Cotonou.

METHODS

Study Setting and Period

This study has been conducted at the Laboratory of Clinical Biochemistry and Toxicology. It is the reference laboratory in Benin for Clinical Biochemistry and

Toxicology testings. The study was conducted from February to June 2017, after the analyzer acquisition by the laboratory.

Study Samples

All the blood samples were collected from inpatients, in dry tubes containing a separating gel. The samples were centrifuged at 3.500 rpm for 10 minutes for serum isolation. The testings have been performed on 60 µl of serum.

Electrolytes Testings

Before starting the testings, the both analyzers were calibrated with the calibrators provided by their manufacturers. All the internal quality controls were performed with i-Smart Electrolyte Quality Control reagents. It is a set of three levels control reagents with low, medium and high electrolytes concentrations. The quality controls were carried out before the testings and then after each series of ten samples. The first electrolyte testing on the sera was performed with the ILyte analyzer. The sera were then refrigerated between 2-8°C until the second testing by another laboratory technician. Each laboratory technician reported the results of his testings on a different bench-top file.

Data Collection

To maintain the confidentiality of the results, each laboratory technician transmitted his bench-top report directly to the secretary for the record of the results into a MS Excel 2010 file. At the end of the study, the data file was sent to the statistician for analysis.

Statistical Analysis

The data were analyzed by the XLSTAT 2017 Software. The results of both electrolytes analyzers were assessed by a numerical and graphical approaches (Design, Medica et al. 2017; Zaki et al. 2013; Freund 2016; Journois 2004; Fuhrman & Chouaid 2004). The correlation was assessed by the Passing-Bablok linear regression and the concordance by the Bland-Altman graphical test (Freund, 2016). The Cusum test was used to judge the linearity. Any difference associated with a p-value less than 0.05 was considered as statistically significant.

RESULTS

A total of two hundred fifty-two samples were used to determine the serum levels of sodium, potassium and chlorides. Of the samples tested for sodium, seventy-one were outside the range of 140-150 mmol/l, lower in sixty-five and higher in six. Likewise, they were seventy-six outside the range of 3.5-5 mmol/l for potassium, sixty-four samples below and twelve above. They were forty-four values outside the range of 95-105 mmlo/l for chlorides, eighteen below and twenty-six above.

The measurements results of the electrolytes serum levels are summarized in the Table 1.

Table 1. Summary of the serum concentrations of sodium, potassium and chlorides determined by both analyzers.

Values	Concentrations of sodium (mmol/l1)		Concentrations of potassium (mmol/l)		Concentrations of chlorides (mmol/l)	
	i-Smart 30 PRO	ILyte	i-Smart 30 PRO	ILyte	i-Smart 30 PRO	ILyte
Lowest value	111.000	112.000	1.800	1.700	77.000	75.000
Highest value	161.000	160.000	7.400	7.100	133.000	129.000
Mean ± SD[2]	140.714 ± 7.357	139.690 ± 6.613	3.857 ± 0.788	3.598 ± 0.759	103.020 ± 7.373	101.571 ± 7.114
Standard error of the mean	8.864	8.8	0.243	0.227	6.49	6.398
Median	142.000	141.000	3.8.000	3.500	104.000	102.000
p-value	$4.00x10^{-18}$		$2.06x10^{-37}$		$1.81x10^{-23}$	

Note: [1] millimole per liter, [2] Standard deviation.

The Passing-Bablok regression parameters are summarized in Table 2. There was a significant deviation from linearity for sodium. However, there was no significant deviation from linearity for potassium and chlorides.

Table 2. Summary of Passing-Bablok regression parameters.

Parameters	Concentrations of sodium (mmol/l)	Concentrations of potassium (mmol/l)	Concentrations of chlorides (mmol/l)
Regression equation	y = 0.9306x + 8.850	y = x – 0.300	y = x – 2.000
Systematic difference			
Intercept A	8.85	-0.3	-2
95 %CI	- 1.000 à 15.588	- 0.300 à - 0.300	- 2.000 à -2.000
Proportional difference			
Slope B	0.9306	1	1
95 %CI[3]	0.882 à 1.000	1.000 à 1.000	1.000 à 1.000
Random difference			
Residual Standard Deviation	1.965	0.247	3.21

95 %CI	- 3.851 à 3.851	- 0.485 à 0.485	-6.291 à 6.291
Validity of linear model			
Cusum test for linearity	Significant deviation from linearity	No significant deviation from linearity	No significant deviation from linearity
	(p = 0.024)	(p = 0.278)	(p = 0.948)

[3]Confidence Interval.

The Bland-Altman analysis is summarized in Table 3. The concentrations of sodium and chloride are more biased than those of potassium.

Table 3. Summary of Bland-Altman analysis.

Parameters	Sodium (mmol/l)	Potassium (mmol/l)	Chlorides (mmol/l)
Bias	1.024	0.259	1.448
95 %CI	0.756 à 1.291	0.228 à 0.290	1.050 à 1.847
SD of bias	2.155	0.248	3.21
95% limits of agreement	- 3.200 à 5.248	- 0.226 à 0.744	- 4.843 à 7.740

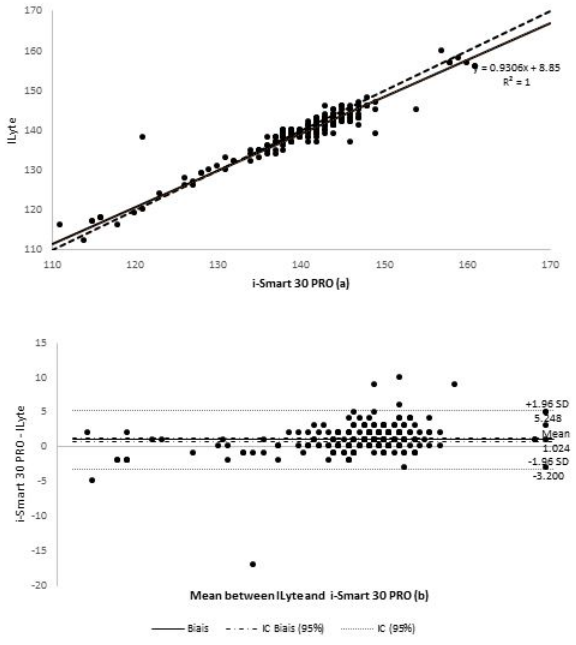

Figure 1. Passing-Bablok regression (a) and Bland-Altman plot (b) of sodium.

(a) The linear regression line of sodium (black line) is almost superimposed to the equality line (dashed line of equation y=x, making an inclination angle of 45° with the abscissa axis) for concentrations below 140 mmol/l. Above 140 mmol/l, there is a distance between the two lines in Figure 1.

(b) The 95% limits of agreement (-3.200 to 5.248 mmol/l) are broad and contain 97.62 % (246/252) of the serum sodium concentrations couples.

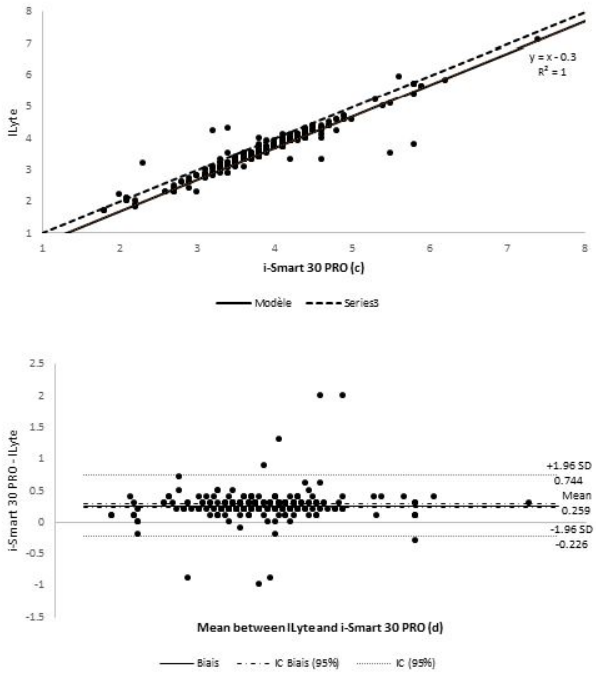

Figure 2. Passing-Bablok regression (c) and Bland-Altman plot (d) of potassium.

The linear regression line of potassium (black line) is parallel to the equality line (dashed line of equation y=x, making an angle of inclination of 45° with the abscissa axis). The distance between these two lines (-0.3) corresponds to the systematic error between both analyzers shown in Figure 2.

The 95% limits of agreement (- 0.226 to 0.744 mmol/l) are narrow and contain 96.83% (246/252) of the serum potassium concentration couples.

The linear regression line of chlorides (black line) is parallel to the equality line (dashed line of equation y=x, making an angle of inclination of 45° with the abscissa axis). The distance between these two lines (-2) corresponds to the systematic error between both analyzers shown in Figure 3.

The 95% limits of agreement (-4.843 to 7.740 mmol/l) are also broad and contain 98.02% (247/252) of the serum chloride concentrations couples.

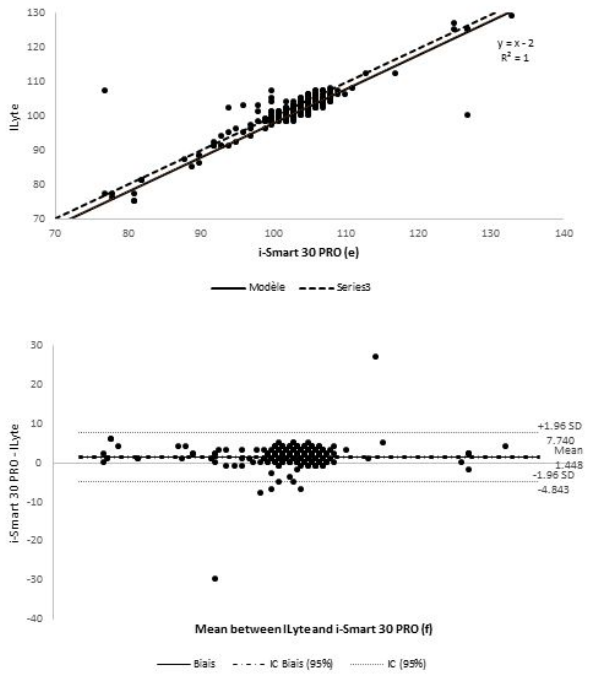

Figure 3. Passing-Bablok regression (e) and Bland-Altman plot (f) of chlorides.

DISCUSSION

When an analyzer under assessment gives the same results as the gold standard, it can be used with confidence. Even if there are differences, biochemists expect that there are not significant. In this study, we used validated procedures to assess the agreement of a certified equipment following the specifications in the user's manual (Rosero et al., 2009). The analyzers assessed are based on the same analytic principle: potentiometry (Kim et al., 2015). The Laboratory of Clinical Biochemistry and Toxicology has been using the ILyte analyzer for many years. In addition, that analyzer had already been used in previous studies that is why we used it as the gold standard (Meliani et al., 2011).

We used two hundred and fifty-two samples to obtain valid and credible results. In the study by Arya et al. (Arya et al., 2014), they used sixty-five samples. Calibrations and internal quality controls allowed us to check the correct operation of both analyzers. To reduce biases, technicians had been trained to well use the new i-Smart 30 PRO analyzer before starting the testings.

The sodium concentrations obtained with the i-Smart 30 PRO analyzer were systematically overestimated by 8.850 mmol/l. On the other hand, those of potassium and chlorides were underestimated respectively by -0.300 and - 2.000 mmol/l. The results we obtained were still biased despite the measures taken. These biases express the systematic and random errors related to the use of any laboratory device. The random error expresses the variation among the results obtained by different operators. However, the systematic error is specific to the analyzers and is not avoidable.

Despite the biases and the significant differences between the means of serum concentrations ($p<0.05$ for all the electrolytes), more than 95% of the concentrations couples are within the 95% limits of agreement. However, these differences have no major incidence on patients' health care. The use of different calibrators, incorporated into the reagent cartridges of each analyzer, could explain the differences. In addition, the delay in performing the second testing could affect the results obtained by the second laboratory technician.

The perform of the testings by the technicians one after another might allow to have more consistent results but would not guarantee the results confidentiality. That point is so important since not taking it into account would certainly contribute to unreliable results of our study.

CONCLUSION

The i-Smart 30 PRO electrolyte analyzer can be used alternatively with the ILyte electrolyte analyzer in the laboratories where both are available. However, further studies are needed to assess its analytical quality on other matrices such as urine and cerebrospinal fluid.

CONFLICT OF INTEREST

The authors declare that they have no competing interests regarding the publication of this paper. Also, there is no conflict with the manufacturers of the electrolytes analyzers tested.

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