An Evaluation of the Point-of-Care Analyzer, i-Smart 30, for Measurement of Electrolytes

Subhash C. Arya · Nirmala Agarwal ·
Beena Michael

Received: 3 June 2013 / Accepted: 11 November 2013 / Published online: 26 November 2013
© Association of Clinical Biochemists of India 2013

Abstract Analytical functioning of a point-of-care analyzer, i-Smart 30 (i-sens: Seoul, South Korea), for electrolyte quantification was investigated at Sant Parmanand Hospital, a tertiary-care hospital in Delhi, India. Samples that were received for electrolyte assay were assayed, double-blinded for their Na and K level using the arterial blood gas analyzer, the ABL 555 (Radiometer, Copenhagen) and the i-Smart 30 electrolyte analyzer. There was satisfactory correlation between the results obtained with the two analyzers with an encouraging bias, standard deviation and the 95 % limits of agreement between the data generated for Na and K levels. The performance of the i-Smart 30 would be satisfactory during the point-of-care measurements of Na and K levels in emergency rooms and clinical laboratories with inadequate infrastructure only if its day-to-day performance was monitored to ensure reliability of the generated reports.

Keywords Electrolytes · Point-of-care assays · Field studies · Emergency investigations · Laboratory infrastructure

Introduction

The estimation of electrolyte levels is an important laboratory investigation and is recommended both in hospitalized and ambulatory cases. The results guide clinicians in offering judicious therapeutic recipes. Electrolyte estimations involve several laboratory actions that are carried out in a semi-automatic or fully-automated analyzer. The

analyzers require several reagents, electrodes and valves. Their calibrations with reference preparations are carried out periodically by the manufacturer and laboratory personnel. In many regions around the world, the laboratory infrastructure is weak and there are not many laboratories capable of generating accurate estimations of electrolyte levels [1]. At the same time, there is little appreciation of the role of clinical laboratories in medical practice or public health interventions [2].

At the Sant Parmanand Hospital, a multi-disciplinary, tertiary care hospital in Delhi, India, we carried out analytical experiments on i-Smart 30 Electrolyte analyzer (i-sens: Seoul, South Korea. In order to find out the accuracy of the results obtained from this analyzer for quantification of Na and K levels we compared them with the results obtained from a blood gas analyzer (ABL 555; Radiometer, Copenhagen) already in use for arterial blood gas measurements and electrolyte assays. These comparisons were approved by the hospital authorities.

Methods

Blood samples were collected during December 2012 at the hospital which caters to a large population in and around Delhi. These were drawn after due consent by venipuncture in ordinary vials from ambulatory and hospitalized patients for quantification of electrolytes, including renal function tests. The sample selection for i-Smart 30 electrolyte analyzer was through a randomized, double-blinded process. That guaranteed uniformity in selection of samples from three categories of patients and eliminated any individual bias. The random numbers were generated online using Random Sequence Generator at <http://www.random.org/sequences/>. The identities of the patient or the laboratory

S. C. Arya (✉) · N. Agarwal · B. Michael
Sant Parmanand Hospital, 18 Alipore Road, Delhi 110054, India
e-mail: Subhashbhappaji@gmail.com

Table 1 Passing and Bablok regression: Na levels with ABL 555 and i-Smart

	Variable X	Variable Y
Lowest value	114.0000	107.0000
Highest value	155.0000	161.0000
Arithmetic mean	138.7077	139.6154
Median	138.0000	139.0000
Standard deviation	6.5806	8.2589
Standard error of the mean	0.8162	1.0244
Regression equation		
$y = -31.941176 + 1.235294 x$		
Systematic differences		
Intercept A	-31.9412	
95 % CI	-45.3333 to -16.5000	
Proportional differences		
Slope B	1.2353	
95 % CI	1.1250 to 1.3333	
Random differences		
Residual standard deviation (RSD)	1.5422	
± 1.96 RSD interval	-3.0228 to 3.0228	
Linear model validity		
Cusum test for linearity	No significant deviation from linearity ($P = 0.80$)	

Variable X ABL 555, variable Y i-Smart, sample size 65

reference number details were not disclosed to the technologists working with the ABL 555 and i-Smart 30 Electrolyte analyzers. These results were available within 1–2 h of venipuncture.

The results were analyzed using the SPSS 11.5 (SPSS Inc. Chicago, USA), the GraphPad Prism and the MedCalc software to carry out the Bland–Altman analysis and to calculate the Passing–Bablok regression.

Results

Among the 65 samples, eight were drawn from outpatients and 57 from inpatients. Of the samples assayed for Na, the levels of 20 samples were outside the normal range of 135–145 mEq/L, being lower in nine and higher in 11 cases (Table 1). Likewise, there were 22 samples outside the normal K range of 3.5–5.0 mEq/L—14 below and 8 above (Table 2). There was a satisfactory correlation between the results obtained with the two analyzers with no significant deviation from linearity (Tables 1 and 2). The Bland–Altman bias for Na was 0.9, standard deviation 2.7 and the 95 % limits of agreement ranged from -0.4479 to 6.295 (Fig. 1). With K, the Bland–Altman bias was 0.067,

Table 2 Passing and Bablok regression K levels with i-Smart and ABL 555

	Variable X	Variable Y
Lowest value	2.6000	2.7000
Highest value	8.1000	7.9000
Arithmetic mean	4.2215	4.2892
Median	4.2000	4.3000
Standard deviation	0.9390	0.8894
Standard error of the mean	0.1165	0.1103
Regression equation		
$y = 0.289474 + 0.947368 x$		
Systematic differences		
Intercept A	0.2895	
95 % CI	0.10000 to 0.4083	
Proportional differences		
Slope B	0.9474	
95 % CI	0.9167 to 1.0000	
Random differences		
Residual standard deviation (RSD)	0.1604	
± 1.96 RSD interval	-0.3143 to 0.3143	
Linear model validity		
Cusum test for linearity	No significant deviation from linearity ($P = 0.09$)	

Variable X i_Smart, variable Y ABL_555, sample size 65

standard deviation 0.23 and the 95 % limits of agreement had ranged from -0.52 to 0.38 (Fig. 2).

Discussion

The above comparison was made after randomization of samples, as done earlier by us for two hematology analyzers [3], for a double-blind assay for the estimation of Na and K levels. The data generated on the i-Smart 30 matched very well with ABL 555 which was used as the reference analyzer. We used ABL 555 for reference since it has been in our use for more than five years and electrolyte results generated thereby are being assessed externally in the Randox International Quality Assessment (RIQAS) [4]. Facilities for carrying out such assays using ion-selective electrodes or flame photometer are not available in the hospital. The bias and its standard deviation including the 95 % limits of agreement between the data generated with ABL-555 and i-30 Smart have been heartening (Figs. 1, 2).

Our laboratory personnel involved in comparative investigations with these analyzers are well conversant with internal quality control and external quality assessment for electrolytes. The technologists are also acquainted with the use of ABL 555, including its cleaning solution, a

Fig. 1 Bland–Altman plot Na levels

Na: Bland-Altman: Bias and agreement

Bias	0.9077
SD of bias	2.748
95% Limits of Agreement	
From	-4.479
To	6.295

K Bland-Altman : Bias and agreement
 Bias = 0.06769; standrad deviation 0.23
 95% limits of agreement = from -.5196 to 0.382

Fig. 2 Bland–Altman plot K levels

salt bridge solution, calibration solution 1, calibration solution 2, protein removal solution, hypochlorite solution, rinse solution, the gas cylinder of 10 % CO₂ and thermal paper [5].

We did not face any problem in the operation of the electrolyte analyzer i-Smart 30 which is a sensor- and cartridge-based analyzer. With 60 µL of blood sample, the results are available within 60 s. With an attached handle and built-in rechargeable batteries, it is possible to move it to different point-of-care testing sites. Furthermore, its consumable parts such as reagents, electrodes, valves, tubing, sampler and especially the waste bag are enclosed within a cartridge [6].

The initial cost of purchase and the running cost per sample tested with ABL 55 are 2–3 times higher than i-Smart 30. While it is possible to monitor in any laboratory both the arterial blood gas levels and to measure electrolyte levels with ABL 555, only electrolytes can be measured with i-Smart 30. Also, it would not be possible to use ABL 555 outside a laboratory e.g. emergency room, physician's surgery or in the field. During usage of i-Smart 30, users are protected from any secondary infection since samples are cleaned automatically and the cartridge can be removed after use or expiration date. Its maintenance is easy and there is no need to replace reagents or consumables [6]. It would be suitable for carrying out screening activities on large scale by charitable organizations or for the care of patients in remote areas during natural disasters.

Our experience has convinced us that there should be no room for skepticism among those laboratory personnel and clinicians about the accuracy of results obtained with i-Smart 30. That can be achieved by exercising an internal quality control on the results generated even in laboratories located in remote locations. Aliquots from samples from patients with lower, normal and higher electrolyte values could be picked up. By testing such aliquots repeatedly, it would be possible to work out the mean and standard deviation [7]. If the results of this basic investigation are consistently satisfactory, it can be presumed that the quality of the results generated by the electrolyte analyzer i-Smart 30 is up to the mark.

Conclusion

An assessment of the Na and K levels can be carried out using the i-Smart 30 (i-sens: Seoul, South Korea) in laboratories, the emergency-room setting, the physician's clinic and in field locations though it would be essential to exercise an internal quality control over the results generated.

Conflict of Interest An i-Smart 30 analyzer was lent to our hospital for assessing the efficacy of its results. The analyzer has since been returned to the supplier.

References

1. Mundy CJ, Bates I, Nkhoma W, Floyd K, Kadeweile G, Ngwira M, et al. The operation, quality and costs of a district hospital laboratory service in Malawi. *Trans R Soc Trop Med Hyg.* 2003;97(4):403–8.
2. Nkengasong JN, Nsubuga P, Nwanyanwu O, Gershy-Damet GM, Roscigno G, Bulterys M, et al. Laboratory systems and services are critical in global health: time to end the neglect? *Am J Clin Pathol.* 2010;134(3):368–73.
3. Arya SC, Agarwal N. Evaluation of automated blood count analyzers for utility in resource poor laboratories. *Clin Chim Acta.* 2009;401(1–2):187.
4. Arya SC, Agarwal N, Agarwal S, Michael B. External quality assessment of clinical biochemical assays in a medium non-academic, non-research hospital laboratory. *Saudi Med J.* 2011; 32(1):87–8.
5. Radiometer 5, 50, 500, 510, 520, 555, EML, 100,105. <http://www.diamonddiagnostics.com/english/consumables.htm>. Accessed 2 Feb 2013.
6. i-Smart 30. <http://www.i-sens.com/html/electrolyte-analyzer.php>. Accessed 2 Feb 2013.
7. WHO. Quality assurance in clinical chemistry: internal quality control. In: Kumari S, Sharma KB, editors. Health laboratory services in support of primary health care in south east-Asia region. WHO regional office publication. South-East Asia Series. 2nd ed. no. 24. Geneva: WHO; 1999. p. 123–1234.