Accuracy and Precision of the *i-STAT* Portable Clinical Analyzer : An Analytical Point of View

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Abstract

The introduction of a new point-of-care testing (POCT) instrument into the market affects medical practice and laboratory services. The i-STAT is designed to improve the speed in the decision making of the medical profession. However, reliability of results would ensure the quality of laboratoy data. We, therefore, made an evaluation of the performance of i-STAT using a disposable cartridge EG7 + .which is capable of measuring pH, pO_2, pCO_2 (blood gas), Sodium, Potassium (Electrolytes), Ionized calcium and Hematocrit with only 10 µl of lithium heparinized blood in 2 minutes. The results were compared with those obtained from routine methods. The results were found to be accurate, precise and correlated with acceptable methods used routinely in the laboratory.

Key word : i-STAT, Point-Of-Care Testing, Blood Gas, Electrolytes, Ionized Calcium

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The trend of laboratory service is to focus on the improvement of patient care especially in areas of simplification of test processes and shortened turn-around-time[1,2]. In recent years, Portable Clinical Analyzers (PCA) for use in point of care testing are constantly being introduced in the market. They are especially designed for use not only by medical technologists but also by non-laboratory personnel in the emergency rooms, surgical and intensive care units.

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The i-STAT is one such portable clinical analyzer which has been developed and utilizes advanced biosensor technology. It is a portable hand-held-clinical analyzer that can analyze electrolytes and blood gas.

The i-STAT systems provide various types of cartridges for use in clinical diagnosis. This has made it possible to conduct a variety of diagnostic tests on site especially for therapeutic interventions such as during major surgery where an intensive monitoring procedure is required[3-5]. For hospitals with decentralized clinical laboratory services, instantaneous laboratory analysis results may be required "on the spot" for quick decision in the management of patient care especially in the monitoring of blood gas, electrolytes and hematocrit[6]. A common concern from within and beyond the laboratory is to ensure quality results whether performed by professional technologists or health personnel. With such a background in mind, we therefore aimed to study and compare results of blood gas, electrolytes and hematocrit obtained from the i-STAT PCA compared with results obtained from established laboratory methodologies. Their precision and accuracy were accessed accordingly.

MATERIAL AND METHOD

Samples

Blood samples were collected with lithium heparin. All samples were carefully preserved in an ice bath during transport to the laboratory and were promptly analyzed.

Equipment and Methodology

The i-STAT, a hand-held PCA uses a single-use disposable cartridge. Cartridge EG7+ for blood gas and electrolytes was used. Ten microliters of whole blood was placed in the cartridge and the results were obtained within 2 minutes.

The specimen that was transported to the laborotary was immediately processed. The samples were remixed and analyzed without delay using the i-STAT PCA and NOVA Stat Profile 5 (NOVA Biomedical, Waltham, MA). All analyses were done within 10 minutes after the samples arrived in the laboratory.

The results were calculated, analyzed and compared according to NCCLS protocol[7].

Calibration

The PCA cartridge's biosensors were calibrated according to the manual provided, i.e. the calibrants available were used to calibrate the analyzer each time the analyzer was turned on.

Precision studies

Imprecision study was done by analyzing each sample and grouped as low and high levels. The results were then calculated for mean, standard deviation and per cent CV.

Accuracy studies

Forty-two whole blood samples were used in comparing the performance of i-STAT and NOVA Stat Profile 5.

Linearity studies

To assess the linearity of the tests using the i-STAT PCA, three levels of the aqueous standards solution containing all constituents except for hematocrit were used in the study.

RESULTS

Imprecision and linearity study

In this study, the imprecision of the i-STAT system was determined by a trained medical technologist. Within-run imprecision (CV) obtained from our study ranged from 0.06-3.5 per cent (Table 1). As for sodium and potassium, the overall CVs were less than 2 per cent.

Three levels of aqueous standard were used in accessing the linearity of the i-STAT performance. Linear regression analysis was used. Fig. 1 shows the plot of the data obtained for the six chemistry components studied. No outlier in the data set was found in the entire range tested.

Method comparision

Fig. 2 (A-G) shows the analytical performance of the i-STAT system compared to the results obtained from NOVA Stat Profile 5. The regression analysis reveals good correlations with correlation coefficient $r > 0.95$ for all the tests examined.

DISCUSSION

The ongoing development for rapid and reliable analysis of blood constituents has paved the way for point-of-care testing. Instantaneous results that can be obtained on the spot for the treatment of critically sick patients may be valuable in saving lives. Here in this study we have shown that the small but efficient PCA gave results comparable (Fig. 2 A-G) to the results obtained from analyzers

Table 1. The precision study for blood gas, electrolytes and hematocrit by i-STAT PCA. The data shows mean, standard deviation and per cent CV of the chemical contstituents analyzed.

Tests	Units	Level 1			Level 2		
		Mean (SD)		C.V. (%)	Mean (SD)		C.V. (%)
pH	Unit	7.134	(0.006)	0.08	7.514	(0.005	0.06
pO_2	mmHg	81.33	(2.081)	2.55	191.4	(4.098)	2.14
pCO_2	mmHg	25.3	(0.283)	1.12	48.4	(0.624)	1.28
Sodium	mmol/L	107	(1.224)	1.14	141.2	(0.836)	0.59
Potassium	mmol/L	3.9	(0.06)	1.50	7.5	(0.07)	0.93
Ionized calcium	mmol/L	0.99	(0.014)	1.41	1.207	(0.005)	0.41
Hematocrit	%PCV	31.2	(1.095)	3.5	37.2	(1.303)	3.5

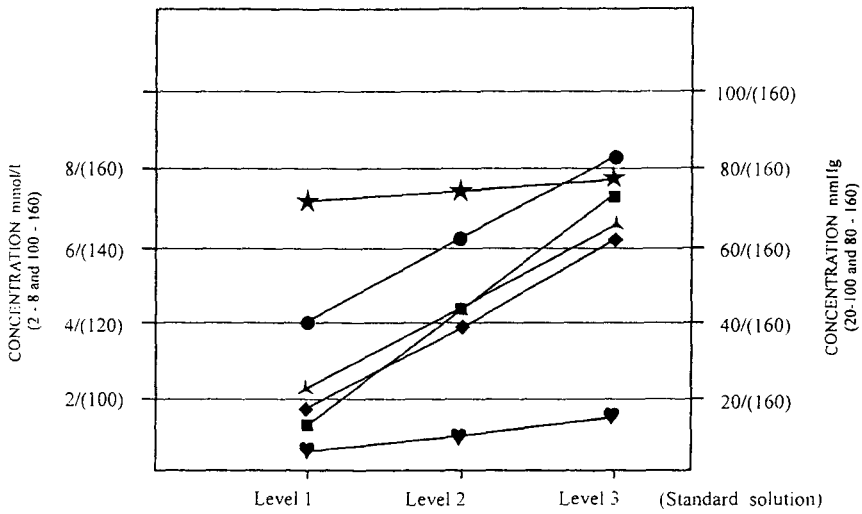

Fig. 1. Linearity of i-STAT system for pH, pO2, pCo2, potassium, sodium and ionised calcium.
● sodium (mmol/L) ◆ pCO_2 (mmHg) ⅄ potassium (mmol/L)
■ pO_2 (mmHg) ♥ ionised calcium (mmol/L) ★ pH

Fig.2a

Y=0.689+1.092X, r=0.978

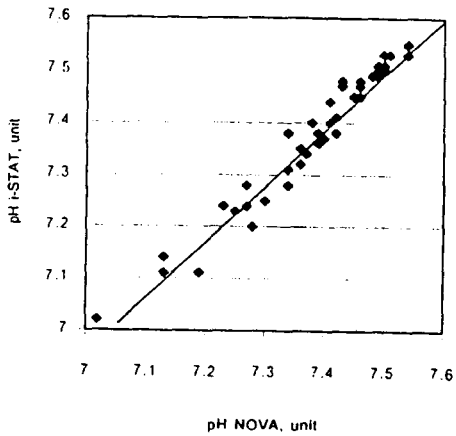

Fig.2b

Y=0.756+0.973X, r=0.994

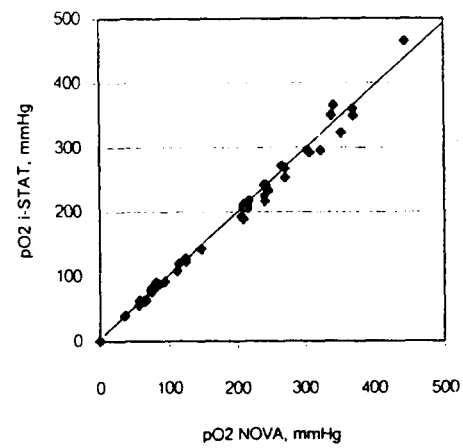

Fig.2c

Y= -0.689+1.092X, r=0.978

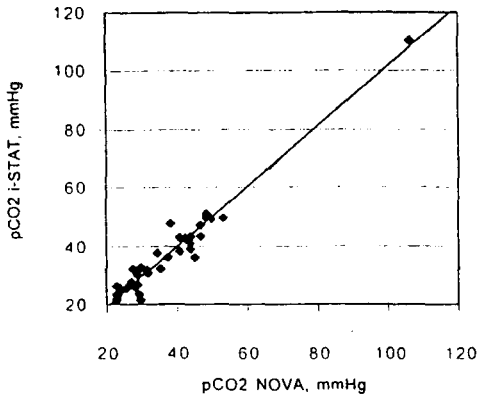

Fig.2d

Y=4.155+0.962X, r=0.964

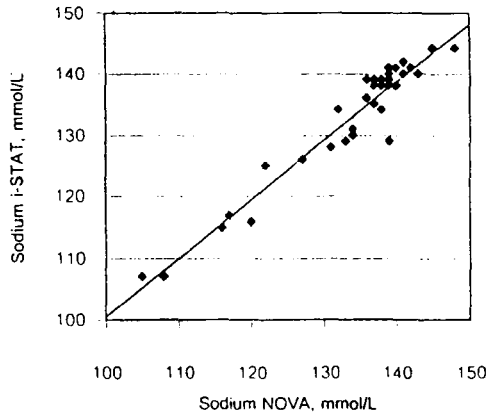

Fig.2e

Y= -0.179+1.036X, r=0.996

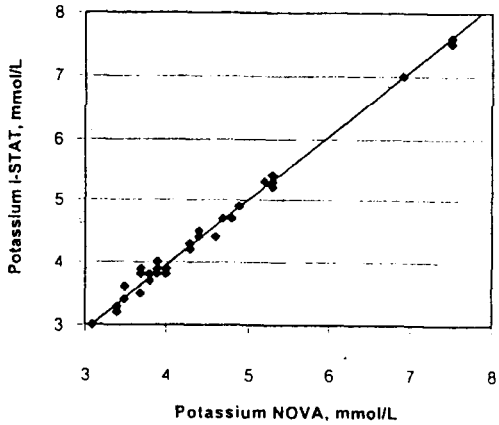

Fig.2f

Y= -0.143+1.145X, r=0.984

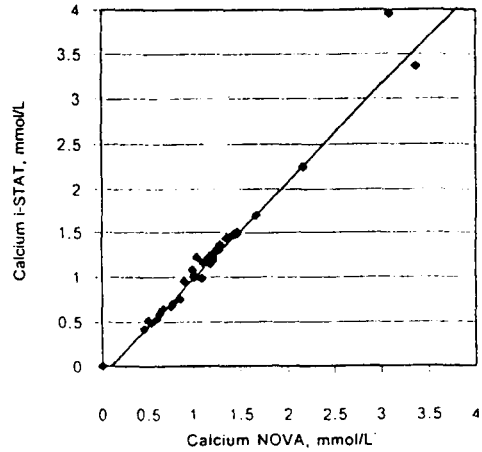

Fig.2g

Y=0.579+0.925X, r=0.970

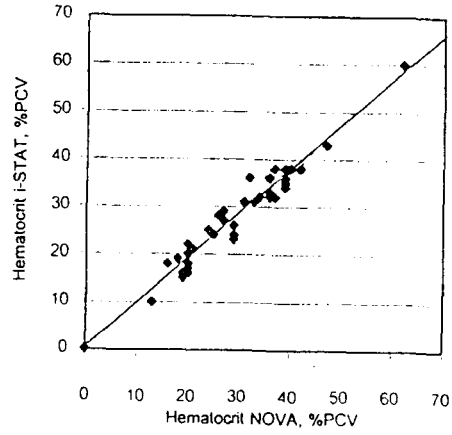

Fig. 2 (A-G). Comparison of results obtained from i-STAT and NOVA Stat Profile 5.

used routinely in our laboratories. This is especially true in the use of i-STAT where blood gas and electrolytes together with hematocrit can be obtained within a few minutes with reliability. This would then enable medical health personnel to make quality and quick decisions for the benefit of the patients concerned.

SUMMARY

The performance of the i-STAT system was reliable as shown in the study of precision and method comparisons. The i-STAT system is simple to operate and used a small volume of blood which makes it a valuable diagnostic tool particularly in point of care testing (POCT). There was an agreement in the results obtained from i-STAT and NOVA Stat proflie-5. No statistical outliers were seen in data set at the level of $p = 0.05$ and over the range being tested Moreover, additional data storage and optional central station was available which enabled a cummulative management of patient data for proper documentation and thereby safeguarding quality performance which is central to laboratory management.

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ประเมินผลความถูกต้องและความแม่นยำของเครื่องวิเคราะห์ i-STAT point-of-care testing

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เครื่องมือ point-of-care testing นิยมนำมาใช้ในโรงพยาบาลมากขึ้นเพราะปัจจุบันการตรวจทางห้องปฏิบัติการจะนำมาช่วยสนับสนุนการรักษาและติดตามภาวะความรุนแรงของโรค รวมถึงการบริการที่ต้องการความรวดเร็ว แม่นยำและเครื่องมือมีขนาดเล็กเคลื่อนย้ายได้สะดวก

i-STATเป็นเครื่องมือที่ใช้เทคโนโลยีสูงสำหรับห้องปฏิบัติการเพื่อติดตามอาการผู้ป่วยโดยเฉพาะในภาวะวิกฤติหรือในระหว่างผ่าตัด ดังนั้นจึงทำการศึกษาผลของการวิเคราะห์ blood gas (pH, pO_2, pCO_2) sodium, potassium (electrolytes) ionized calcium และ hematocrit จากเลือดที่ใช้แฮฟพารินเป็นสารกันเลือดแข็ง เปรียบเทียบกับผลที่วิเคราะห์ได้จากเครื่องที่ใช้งานประจำวันคือ NOVA Stat Profile 5 พบว่า ผลการวิเคราะห์มีค่าความสัมพันธ์ของสองวิธีที่ค่า r อยู่ระหว่าง 0.964 ถึง 0.996 และการดูความแม่นยำ (Coefficient Variation) ของการวิเคราะห์ทั้งหมด พบว่าอยู่ระหว่าง 0.006% ถึง 3.5% นอกจากนี้เรื่องประสิทธิภาพของความเป็นเส้นตรง (linearity) ของเครื่องในการวิเคราะห์พบว่า สามารถครอบคลุมผลการรายงานตั้งแต่ค่าต่ำสุดถึงค่าสูงสุดของการเปลี่ยนแปลงพยาธิสภาพของร่างกายได้

ดังนั้นจะเห็นได้ว่าเครื่อง i-STAT เหมาะที่จะนำมาใช้ในงานการวิเคราะห์เพื่อการรายงานผลที่รวดเร็ว กรณีสั่งตรวจแบบ "STAT" โดยเฉพาะเรื่องของ blood gas, electrolytes และ ionized calcium ซึ่งจะต้องรายงานเร่งด่วนโดยใช้เลือดเพียง 10 ไมโครลิตร และรายงานผลใน 2 นาที

คำสำคัญ : i-STAT, ตรวจข้างเตียงผู้ป่วย, อีเล็กโตรไลท์, ก๊าซในเลือด, ไอออนไนซ์แคลเซียม

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