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PERFORMANCE EVALUATION OF THE BS-120 AND BS-200E CHEMISTRY ANALYZER

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ABSTRACT

The prevalence of chronic diseases is growing due to aging population and westernized lifestyle habits in South Korea. Primary care enables continuous management of chronic diseases and even prevention of chronic diseases in healthy individuals, for which diagnostic tests play an important role. Primary care facilities generally use small pieces of equipment that can only handle a few tests, such as the Mindray BS-120 and BS-200E used in the present experiment, to manage chronic diseases and promote people's health. This study was conducted upon an understanding that performance assessments for small-size equipment have not been adequately performed. In this study, precision and cross-contamination rates were investigated based on the Clinical and Laboratory Standards Institute (CLSI) guidelines EP5-A3 and EP10-A3. Test categories were those included by the National Health Insurance Service (NHIS) in primary health diagnosis. In the precision assessment, the total coefficients of variation (total %CV) for BS-120 and BS-200E were within 10.0%. Cross-contamination rate was within 1.0% for all items on BS-120 except for HDL-cholesterol, LDL-cholesterol, and triglyceride and for all items on BS-200E except for ALT, HDL-cholesterol, creatinine, and glucose. Therefore, it is difficult to conclude that these two types of equipment have excellent performance, but improvements should be made to increase the reliability of the test results.

KEYWORDS: Chronic disease, CLSI, Performance assessment, Preventive medicine, Primary care.

INTRODUCTION

Recently, the prevalence of chronic diseases has increased due to rapid progress of aging and western lifestyle, resulting in increasing burden on individuals and society.[1-2] Therefore, the role of primary care is also emphasized. People with chronic illnesses can be managed on a primary basis, without getting worse or receiving unnecessary medical services.[3] The general public can detect or prevent the disease early through primary care. Therefore, the necessity of diagnostic tests is emphasized in order to detect chronic diseases early and to monitor the treatment effects of diseases, and accordingly, the number of laboratories performing diagnostic tests is increasing.[4] Diagnostic tests provide a key basis for evidence-based medicine, including screening, prophylactic and management of chronic diseases, and monitoring prognosis.[4] In recent years, about 70% of medical decisions such as diagnosis and treatment are dependent on diagnostic tests.[4] However, the performance evaluation of the large diagnostic test equipment used in the tertiary medical institution has been done a lot, but the performance evaluation of the small diagnostic test equipment used in the primary medical institution was not much.

Health and care services that give a rapid diagnosis, advice and help in improving lifestyle, good treatment, good rehabilitation and continuous follow-up during stable phases can slow the development of disease and improve the quality of life and functional ability of the individual.[5] At the same time, the incidence of complications, hospital admissions and premature death will be reduced.

The term *primary care* is thought to date back to about 1920, when the Dawson Report was released in the United Kingdom.[6] That report, an official "white paper," mentioned "primary health care centres," intended to become the hub of regionalized services in that country. Despite the greater recognition of the importance of primary care to health services systems,[7] professionals have recently called for increasing even further the supply of specialist physicians in the United States.[8] Primary care refers to the medical services that the patient receives after first accessing a specialist physician, and provides the necessary medical services appropriately, but there is a coordination function that suppresses overuse for unneeded medical services.[9] The primary medical facility is a place where we can provide quick and convenient medical care and treatment when

we need it, and it is more important for the elderly patients with chronic illness because of the "convenient access".

In this study, we used nine test items such as AST, ALT, gamma-lipid, total cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol, serum creatinine, (Clinical and Laboratory Standards Institute) guideline to evaluate the performance of Mindray BS-120 and BS-200E. The Mindray BS-120 and BS-200E are installed in hospitals and clinics nationwide, and can be used even in coincidental medical institutions with a small number of tests. Among the papers related to performance evaluation of biochemical equipment, there were many papers on equipment that can perform a large number of tests at one time, but papers related to equipment that performs a small number of tests are few. Therefore, the accuracy and cross contamination rate of BS-120 and BS-200E were evaluated to evaluate the performance of both equipment.

MATERIALS AND METHODS

Reagents and instruments

The reagents used to measure AST, ALT, gamma-lipid, total cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol, creatinine, and glucose were manufactured by Shenzhen Mindray Bio-medical Electronics Co., LTD. The equipment used for the measurement was Mindray BS-120 and BS-200E (Fig. 1). The BS-120 can perform 100 tests per hour and the BS-200E can perform 200 tests per hour. Both can maintain the refrigerated temperature and use Halogen-tungsten lamp. The number of reagents that can be loaded into the instrument at one time is 28 in BS-120 and 40 in BS-200E. The number of samples is 8 in BS-120 and 40 in BS-200E. The range of wavelengths to be measured is 340-670 nm for BS-120 and 340-800 nm for BS-200E (Table 1).

Fig. 1. BS-120 (left) and BS-200E (right) of Mindray.

Table. 1: The Characteristics of BS-120 and BS-200E.

	BS120	BS200E
Throughput (Tests/Hour)	100	200
Keeping cold storage	yes	yes
Reagent tray	28	40
Sample tray	8	40
Wavelength (nm)	340-670	340-800
Light source	Halogen-tungsten lamp	Halogen-tungsten lamp

National sample

Commercially available low and high concentration control substances (Clinchem multi control level 1, level 2) were used. The low concentration and the high concentration control substance used in this experiment are the same lot.

Inspection items

Aspartate aminotransferase (ALT), alanine aminotransferase (ALT) and gamma-glutamyltransferase were tested for hepatic function tests according to the items of the first medical examination provided by the National Health Insurance Corporation. Total cholesterol, triglycerides, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol were measured in lipid tests. Creatinine and Glucose were measured for the renal function test (Table 2).

Table 2: Analytical methods available and measurable ranges for the Mindray's devices.

Parameter	Unit	Test method	Range
Aspartate aminotransferase(AST)	U/L	IFCC (without pyridoxal phosphate activation)	4-800
Alanine aminotransferase(ALT)	U/L	IFCC (without pyridoxal phosphate activation)	4-1000
Gamma-Glutamyltransferase(γ-GT)	U/L	Szasz/IFCC stand	4-650
Total cholesterol	mg/dL	CHOD-POD	3.85-769
High-Density lipoprotein cholesterol	mg/dL	Direct	1.9-230
Low-Density lipoprotein cholesterol	mg/dL	Direct	1.9-992
Triglycerides	mg/dL	GPO-POD	8.8-1106
Creatinine	mg/dL	Modified Jaffe	0.1-27.4
Glucose	mg/dL	GOD-POD	5.4-630

Precision

We assessed low-concentration and high-concentration control materials commercialized for 20 days according to the CLSI EP5-A3 guidelines. Twenty days, twice a day, twice a day, twice a day, twice a day, more than two hours apart. In order to evaluate the accuracy, within run% CV, between run% CV, between day % CV and total % CV were calculated. The coefficient of variation is a value that is expressed as a percentage by dividing the standard deviation by the average. The coefficient of variation can be used to compare the mean value or the scatter of different groups of units.[10]

Cross-contamination rate

We used low-concentration and high-concentration control materials commercialized in accordance with CLSI EP10-A3 guidelines (Krouwer et al., 2014). Concentration of cross-contamination between samples was calculated by the following formula.

$$\text{Carry-over (\%)} = \{L1 - (L3 + L4)/2\}/\{(H2 + H3)/2 - (L3 + L4)/2\} \times 100$$

Statistical analysis

Using Microsoft Excel 2016 (Microsoft Cooperation, Santa Rosa, Calif.), within run % CV, between run % CV, between day % CV, the coefficients (total % CV) and cross-contamination (% carry-over) were calculated.

RESULTS

Precision

According to the CLSI EP5-A3 guidelines, low and high concentration control substances were measured for 20 days. Mean, Standard Deviation (SD), coefficient of variation within run (within run % CV, coefficient of variation between run (between run % CV), coefficient of variation between day (between day % CV), and total coefficient of variation (total % CV) were calculated. The total coefficient of variation (total% CV) of BS-120 was 5.2% for low-concentration AST and 5.9% for low-concentration triglyceride. The remaining items were within 5.0% (Table 3). The total coefficient of variation (total% CV) of BS-200E was 5.9% in low concentration AST, 7.4% in low concentration γ-GT, 9.1% and 8.7% in low concentration and high concentration HDL-cholesterol, respectively and in low and high concentration LDL-cholesterol 9.7% and 8.3% respectively. The remaining items were below 5.0%.

Table. 3: Precision using 2 levels of control materials with BS-120.

Parameter	Level	Mean	SD	CV (%)			
				Within-run	Between-run	Between-day	Total
AST	1	51.76	2.69	0.6	1.4	4.8	5.2
	2	144.34	5.71	0.5	0.7	3.8	4.0
ALT	1	55.89	1.84	0.8	1.3	2.7	3.3
	2	126.28	5.80	0.5	0.9	4.4	4.6
γ-GT	1	55.09	0.82	0.4	0.9	0.7	1.5
	2	242.00	4.39	0.3	0.5	1.7	1.8
Total cholesterol	1	98.23	2.38	0.8	1.8	0.7	2.4
	2	173.63	4.48	0.6	1.3	1.9	2.6
HDL-cholesterol	1	32.98	0.96	0.8	1.7	1.1	2.9
	2	61.28	1.53	0.4	0.9	2.2	2.5
LDL-cholesterol	1	55.89	0.98	0.7	1.1	0.6	1.8
	2	95.64	1.54	0.5	0.9	0.9	1.6
Triglycerides	1	109.38	6.40	1.1	1.5	1.6	5.9
	2	208.48	8.67	1.1	1.5	0.4	4.2
Creatinine	1	1.03	0.05	1.0	2.2	2.3	4.4
	2	3.92	0.11	0.5	1.3	2.1	2.9
Glucose	1	106.54	1.94	0.7	1.0	1.0	1.8
	2	233.33	4.11	0.4	0.8	1.4	1.8

Table. 5: Precision using 2 levels of control materials with BS-200E.

Parameter	Level	Mean	SD	CV(%)			
				Within-run	Between-run	Between-day	Total
AST	1	50.20	2.94	1.2	1.3	5.3	5.9
	2	143.71	3.53	0.5	0.9	2.0	2.5
ALT	1	57.24	2.65	1.1	0.5	3.9	4.6
	2	129.20	5.03	0.7	0.4	3.7	3.9
γ-GT	1	56.43	4.16	1.8	2.1	2.3	7.4
	2	247.44	4.31	0.5	1.0	1.0	1.7
Total cholesterol	1	99.89	2.53	1.2	1.1	0.9	2.5
	2	180.35	3.98	1.0	1.5	0.9	2.2
HDL-cholesterol	1	33.51	3.04	1.5	0.9	8.5	9.1
	2	64.02	5.59	1.2	1.6	8.2	8.7
LDL-cholesterol	1	59.78	5.79	0.9	0.6	9.5	9.7
	2	105.45	8.75	0.7	1.3	8.1	8.3
Triglycerides	1	107.84	2.12	0.9	0.5	1.0	2.0
	2	208.61	3.47	0.7	0.9	0.5	1.7
Creatinine	1	0.97	0.05	1.7	1.6	2.2	5.0
	2	3.65	0.17	1.3	2.1	1.5	4.7
Glucose	1	99.39	2.03	0.9	0.7	1.2	2.0
	2	232.04	3.98	0.6	1.2	0.5	1.7

Cross-contamination rate

According to the CLSI EP10-A3 guidelines, high-concentration and low-concentration control substances were measured four times in each case. In BS-120, HDL-cholesterol and LDL-cholesterol were 4.0% and 2.8%, respectively, and all items were below 1.0% (Table 4).

Table. 4: Carry over (%) of BS-120.

Parameter	Carry over (%)
AST	0.0
ALT	0.8
Gamma-GT	0.3
Total cholesterol	0.5
HDL-cholesterol	4.0
LDL-cholesterol	2.8
Triglycerides	1.0
Creatinine	0.0
Glucose	0.8

Table. 7. Carry over (%) of BS-200E

Parameter	Carry over (%)
AST	0.5
ALT	3.0
Gamma-GT	0.0
Total cholesterol	0.0
HDL-cholesterol	4.4
LDL-cholesterol	0.3
Triglycerides	0.5
Creatinine	1.9
Glucose	1.9

DISCUSSION

Recently, population aging of Korea is rapidly progressing and the prevalence of chronic diseases is increasing due to western lifestyle.[1] Also, as society becomes an aging society in the future, social costs due to this will also increase.[11] Therefore, chronic diseases are not a dimension of health care services but are a complex problem that includes the whole social part.[12] These chronic diseases can reduce the incidence of illness and unnecessary hospital use through primary care, and primary care plays an important role in continuous management.[1] However, there is a lack of awareness of primary care in Korea and the lack of a common strategy for prevention and management of primary care and chronic diseases.[1] Advantages of primary care include easy access, affordable health care services, appropriate care to prevent disease progression and symptoms of chronic illnesses, or prevention of illness in advance, resulting in costly health care services. Primary health care with these characteristics is essential to improve the quality of life by providing a comprehensive approach to the most cost-effective medical expenditure and the majority of chronic illnesses with accompanying diseases.[12]

Based on the guidelines of the Clinical and Laboratory Standards Institute (CLSI) EP5-A3 and EP10-A3, the National Health Insurance Corporation's primary screening items AST, ALT, Gamma GPT, total cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol, Serum creatinine, and blood glucose need inspection. The performance of BS-120 was verified for these items. The total coefficient of variation (total% CV) was 5.2% for low - concentration AST and 5.9% for low - concentration triglyceride. The cross-contamination rate was 4.0% for HDL-cholesterol and 2.8% for LDL-cholesterol in BS-120, and all items except for these items were below 1.0%. In BS-200E, the ALT was 3.0%, HDL-cholesterol was 4.4%, creatinine was 1.9%, glucose was 1.9%, and other items were within 1.0%. However, the criterion for evaluating the cross contamination rate is within 1.0%. The allowable

criterion for estimating the cross contamination rate is 1.0% or less. The reason for this result is probably due to the probe cleaning function of BS-120.We think it is most appropriate to select equipment that meets the requirements of each laboratory rather than BS-120 or BS-200E. As the result of this experiment, there is an item exceeding the allowable limit value in the precision and cross contamination rate, so it is essential that the quality control and periodic performance evaluation of the equipment should be performed.

CONCLUSION

Total coefficients of variation (total %CV) for BS-120 and BS-200E were within 10.0%. It is most appropriate to select equipment that meets the requirements of each laboratory rather than BS-120 or BS-200E.

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