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Original Contribution

A point-of-care chemistry test for reduction of turnaround and clinical decision time☆,☆☆,★

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Abstract

Purpose: Our study compared clinical decision time between patients managed with a point-of-care chemistry test (POCT) and patients managed with the traditional central laboratory test (CLT).

Basic Procedure: This was a randomized controlled multicenter trial in the emergency departments (EDs) of 5 academic teaching hospitals. We randomly assigned patients to POCT or CLT stratified by the Emergency Severity Index. A POCT chemistry analyzer (Piccolo; Abaxis, Inc, Union City, Calif), which is able to test liver panel, renal panel, pancreas enzymes, lipid panel, electrolytes, and blood gases, was set up in each ED. Primary and secondary end point was turnaround time and door-to-clinical-decision time.

Main Findings: The total 2323 patients were randomly assigned to the POCT group (n = 1167) or to the CLT group (n = 1156). All of the basic characteristics were similar in the 2 groups. The turnaround time (median, interquartile range [IQR]) of the POCT group was shorter than that of the CLT group (14, 12-19 versus 55, 45-69 minutes; $P < .0001$). The median (IQR) door-to-clinical-decision time was also shorter in the POCT compared with the CLT group (46, 33-61 versus 86, 68-107 minutes; $P < .0001$). The proportion of patients who had new decisions within 60 minutes was 72.8% for the POCT group and 12.5% for the CLT group ($P < .0001$).

Conclusions: A POCT chemistry analyzer in the ED shortens the test turnaround and ED clinical decision times compared with CLT.

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1. Introduction

The length of stay (LOS) in the ED is a surrogate index of overcrowding despite many factors that can influence the LOS. The laboratory turnaround time (TAT) and the time from drawing blood samples to reporting results to physicians are regarded as some of the most important determinants of the LOS [1-3]. During the last decade, advances in bioengineering have shortened the TAT of the complete blood count to less than 30 minutes. On the other hand, the blood chemistry, one of the most frequent emergency laboratory studies, still takes more than 30 minutes in more than 90% of cases [3].

Previous studies point-of-care testing (POCT) and the use of a satellite laboratories near to the ED have been shown to reduce TAT [3-13]. However, most of these studies only focused on certain diseases and associated laboratory results, such as urine human chorionic gonadotropin for pregnancy and serum troponin for acute myocardial infarction. Thus, it is hard to generalize these results to other ED patients [4,5,8,14].

A routine emergency blood chemistry includes a liver panel, renal panel, pancreatic enzyme, and electrolytes. Blood gases and lipid panel may be added for some specific patients. The TAT of blood chemistry is often regarded as the rate-determinant process [3]. Therefore, POCT for comprehensive chemistry analyzer may improve the clinical decision time, resulting in improving throughput process in the ED. In this study, we compared the effect of the POCT and the central laboratory test (CLT) on the speed of specimen turnaround and clinical decisions for patients who need blood chemistry testing.

2. Methods

2.1. Study design

This study was a randomized controlled multicenter trial, which was conducted at the EDs of 5 tertiary teaching hospitals. This study was reviewed and approved by the institutional review board of the study coordinating hospital, and we received written consent from all participants.

2.2. Setting

This study was performed in 5 EDs. Three were urban EDs with 30 000 to 45 000 annual visits, and 2 were suburban EDs with 15 000 to 25 000 annual visits. Each hospital has its own central laboratory that can test the same emergency chemistry tests, including liver panel (alkaline phosphatase, protein, albumin, total bilirubin, direct bilirubin, glutamic-oxaloacetic transaminase, and glutamic-pyruvic transaminase), renal panel (blood urea nitrogen, creatinine, calcium, and phosphorus), pancreas enzymes (amylase, lipase), electrolytes (sodium, potassium, chloride, total CO_2), lipid panel (total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol), and blood gases (pH, pO_2, pCO_2, and bicarbonate).

Most chemistry laboratory tests in all EDs in this study can be covered with national insurance system. Therefore, attending physicians can order chemistry laboratory test without fear for the price if there is any blood chemistry to be needed. There is little difference among 5 EDs for disposition and admission process in regard with chemistry laboratory test. Most emergency physicians usually order the chemistry laboratory test if needed. After getting results from laboratory department, they make a decision for disposition and admission process. If the patient should be admitted for specialty and definite care, the duty emergency physician calls the specialty department duty doctor for consulting inpatient care. Specialty department doctors usually ask the routine laboratory test results for most cases for inpatient care and take the patient to their ward.

This study used 2 Piccolo xpress devices (Piccolo; Abaxis, Inc, Union City, Calif) and Piccolo Comprehensive Metabolic Reagent Discs for chemistry testing with 14 items (protein, albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin, total CO_2) [15]. The Piccolo xpress is a compact, portable clinical chemistry system designed for point-of-care patient testing. The precision study shows that the Piccolo analyzer performs well within acceptance ranges of the monitor controls and correlates extremely well with CLTs [16].

The participant EDs have the usual care provider that consists of emergency medical technicians and registered nurses. They are responsible for initial patient evaluation, blood sampling, and some kinds of treatment. For this study, they received training of operation POCT. The training consists of a half hour didactic session followed by a hands-on session. Quality control was performed as manufacture's guideline by company staffs.

2.3. Selection of participants

Patients older than 15 years clinically required to have chemistry laboratory tests were defined as eligible patients. If the eligible patients agreed to participate in this study, they were enrolled and randomized. A convenience sample method was selected to enroll patients due to study coordinators' duty.

2.4. Study protocol

Patients were registered at ED and then triaged according to Emergency Severity Index (ESI) version-4 protocol by usual care providers. The eligible patients were randomized on the basis of a stratified randomization table by ESI, which had 2 groups: the POCT group and the CLT group. Every

randomization was done after patients agreed with study consents. After randomization, the patients were routinely cared at the discretion of their attending physician. The attending physician, patients, and nurses were blinded to the allocation results.

In the CLT group, when the attending physician ordered chemistry testing, the usual care provider drew blood and delivered the sample to the central laboratory room, as is the usual practice. When the results were inputted in the order communication system, the providers reported the results to the ED physicians as soon as possible. The patients in the POCT group were also drew blood by the usual care providers. The providers delivered the samples to the POCT device and immediately analyzed them. When POCT completed the tests, the providers reported the results to the ED physicians as soon as possible. The printed papers on results reported by usual care provider were different between 2 groups. The CLT group used formal report form of order communication system, whereas POCT group used a small piece of result sheet designed for the small POCT device. Blindness to attending physicians for study arms was incomplete. When the emergency attending physicians received result sheet from routine care providers for laboratory test, they might know that the result papers printed were very different. However, they could not know study protocol and study aims.

No additional human resources were used in either study arm except study coordinators who are responsible for randomized allocation, interviewing the physicians. The ED attending physicians made clinical decisions after interpretation of the results and carried on treating the patients. Study coordinators filled out case report form, which included a patient identification number, ESI level, time of registration (door time), sampling time, reporting time, clinical decision making time, contents of clinical decision making (disposition, treatment, further laboratory and/or imaging study, consultation to specialty department), and final outcome in the ED (discharge or admission). Time of clinical decision and their contents were recorded by interviewing the attending physicians.

2.5. Sample size

We hypothesized the reduced time would be at least 40 minutes based on pilot trials (n = 40). When we calculated sample size on the basis of 80% power and α error .05, the estimated sample size was approximately 1300 patients in each arm after considering stratification by the ESI scores.

2.6. Outcome measures

The primary outcome was door-to-clinical-decision (D2D) time, which was defined as the time from registration to making clinical decisions after receiving the test results—an important interval of the ED throughput process. Emergency department LOS will be critically influenced by the D2D time. Although the LOS is a more practical value, we selected the D2D time as a primary outcome because the LOS is influenced by many factors in the ED. The secondary outcome was the TAT, which was defined as the time from drawing samples to reporting results. Another secondary outcome was the percentage of tests with a TAT and D2D time of less than or equal to the targeted 30 and 60 minutes, respectively. Subgroup analysis according to the types of clinical decisions (disposition, treatment, additional laboratory tests, radiologic tests, and consultation of specialty departments) was also planned a priori.

2.7. Primary data analysis

We analyzed D2D and TAT between 2 arms. If the POCT test failed due to any reason, the patient was conversed to CLT group and excluded from final analysis. When data were incomplete, we excluded them for final analysis (nonintention-to-treat analysis). We calculated conversion rate of POCT group.

Continuous variables (D2D time and TAT) were described as medians and interquartile ranges (IQRs) and compared using the Mann-Whitney-Wilcoxon test. Other categorical variables were compared with χ^2 tests.

3. Results

The total number of included patients was 1258 in the POCT group and 1192 in the CLT group. Of these, incomplete data were found for 21 (1.7%) in the POCT group and 36 (3.0%) in the CLT group. The number of test failures was 70 (5.6%) in the POCT group, which was due to operating errors by providers, most of which occurred during the first 2 weeks of the study. The most common cause of error was an insufficient amount of blood for test (approximately 70%), which was corrected during the study period. We excluded these incomplete data cases and the test failure cases from the analysis (Fig. 1).

The baseline characteristics of the participants were similar between the 2 groups. Although there were more females in the POCT group compared with the CLT group, there was no difference (52.7% versus 48.9%, P = .07). Emergency Severity Index level 5 was none because all enrolled patients needed at least 1 resource (Table 1). Table 2 shows the main outcomes. The number of new decisions made after receiving the laboratory reports was 791 (67.8%) in the POCT group and 787 (68.1%) in the CLT group. The distribution of clinical decisions was 52.8% for disposition, 38.5% for treatment, 11.4% for additional laboratory tests, 29.0% for additional new radiologic tests, and 24.9% for the consultation of specialty departments in the POCT group. The CLT group showed a similar distribution of decision types. The median D2D time group of at least 1 of new clinical decisions made was 46 minutes in the POCT group

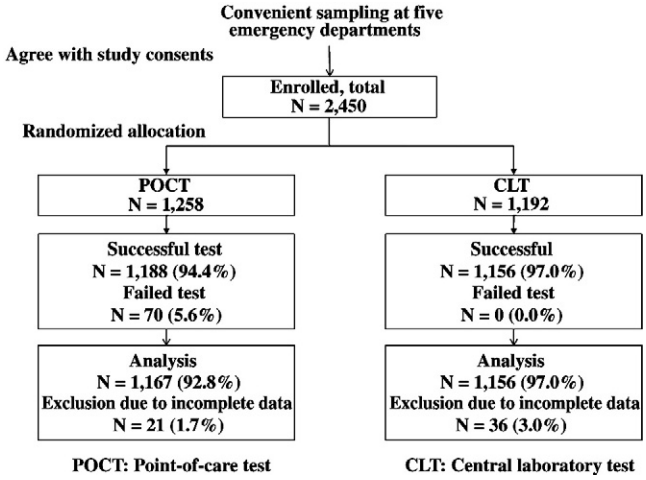

Fig. 1 Randomized allocation of the participants into the POCT and the CLT groups.

and 85 minutes in the CLT group ($P < .0001$). Subgroup analysis according to type of clinical decisions showed consistent results with shorter D2D times in the POCT group.

The TAT (median, IQR) of the POCT group was shorter than that of the CLT group (14.0, 12.0-19.0 versus 55.0, 45.0-69.0; $P < .0001$). Subgroup analysis according to type of clinical decisions also showed that the TATs of subgroups were shorter in the POCT group.

We categorized LOS into 5 groups: less than 1 hour, 2 hours, 3 hours, 6 hours, and more than 6 hours. Table 3 shows an analysis of TAT and D2D times stratified by LOS. For example, among patients with LOS less than 3 hours, the POCT patients had shorter times (TAT 13, 12.0-17.0, D2D time 40.0, 30.0-55.0) than the CLT patients (TAT 53.0, 43.0-65.0 and D2D time 79,0, 64.0-95.0).

The percentage of studies with TAT and D2D time of less than or equal to 30 and 60 minutes was higher in the POCT group (94.3% and 72.8%) than in the CLT group (4.2% and 12.5%) (Table 4).

Table 1 Baseline characteristics of study participants

Factors	Total	POCT		CLT		*P*
Total, n (%)	2323	1167	50.2	1156	49.8	
Sex, n (%)						
Male	1143	552	47.3	591	51.1	.07
Female	1180	615	52.7	565	48.9	
Age (y), mean ± SD		54.43	18.2	54.25	18.3	.71
Glasgow Coma Scale, mean ± SD		14.68	1.7	14.81	1.5	.48
ESI						
Level 1	113	55	4.7	58	5.0	.98
Level 2	398	202	17.3	196	17.0	
Level 3	1598	802	68.7	796	68.9	
Level 4	214	108	9.3	106	9.2	
Level 5	0	0	0.0	0	0.0	
Week, n (%)						
Weekend	878	438	37.5	440	38.1	.79
Weekday	1445	729	62.5	716	61.9	
Shift, n (%)						
Day (8 AM-6 PM)	1514	757	64.9	757	65.5	.75
Night (6 PM-8 AM of next day)	809	410	35.1	399	34.5	
Disposition, n (%)						
Admission	993	511	43.8	482	41.0	.31
Discharge or transfer	1330	656	56.2	674	58.3	
Hospital, n (%)						
Hospital 1	551	288	24.7	263	22.8	.88
Hospital 2	590	292	25.0	298	25.8	
Hospital 3	312	156	13.4	156	13.5	
Hospital 4	400	198	17.0	202	17.5	
Hospital 5	470	233	20.0	237	20.5	

4. Limitations

This study has several limitations. First, this study did not deal with or examine clinical outcomes when the POCT was introduced to the participating EDs. Further study should evaluate the effects on clinical outcome. Second, our study was limited to patients 15 years and older. Thus our results may not generalize to pediatric patients. Third, this study was incompletely blinded to attending physicians even though they did not know the study protocol and aims, which could affect on the attending physicians' real practice. Fourth, final analysis excluded POCT failure group. Including these patients in the POCT group would have increased their TAT and disposition time due to retest. Lastly, although this POCT test usually needs very little time (=12 minutes for 1 sample), emergency provider should do additional work to conduct the testing without a commission. Therefore, the cost for POCT may be more expensive comparing with that of CLTs.

5. Discussion

The aim of this study was to compare the times for laboratory turnaround and clinical decision making when we introduced a comprehensive POCT device for blood chemistries for adult ED patients.

There are several time-consuming steps in the ED laboratory process including door (ED registration)-to-order, order-to-draw, draw-to-receipt, receipt-to-report, report-to-decision [2]. Also, each time intervals are determined by factors such as the type of personnel who collects a specimen, extent of computerization, mode of transportation, and others [2].

Some studies defined TAT as receipt-to-report time interval, but we defined TAT as time interval from draw-to-report time including delivery time, which means time interval from draw to receipt. To be similar, the D2D time was defined as time interval from ED registration-to-decision

Table 2 D2D time by types of subgroup by clinical decision

Subgroups by clinical decision	Total		POCT				CLT				*P*
	n	%	n	%	Median	IQR	n	%	Median	IQR	
Total	2323	100	1167	100	46.0	33.0-61.0	1156	100	86.0	68.0-107.0	<.0001
Any clinical decision	1578	67.9	791	67.8	46.0	33.0-62.0	787	68.1	85.0	70.0-106.0	<.0001
Disposition	1225	52.7	616	52.8	47.0	34.0-64.5	609	52.7	87.0	70.0-107.0	<.0001
Admission	354	15.2	198	17.0	42.0	29.0-64.0	156	13.5	83.5	68.0-106.0	<.0001
Discharge	316	13.6	128	11.0	47.0	35.0-64.5	188	16.3	86.5	70.5-111.0	<.0001
Observation	1,653	71.2	841	72.1	51.0	38.0-65.0	812	70.2	87.0	72.0-107.0	<.0001
Treatment	875	37.7	449	38.5	45.0	32.0-61.0	426	36.9	86.0	69.0-104.0	<.0001
Intravenous fluid	497	21.4	274	23.5	48.0	36.0-65.0	223	19.3	89.0	73.0-106.0	<.0001
Electrolyte correction	165	7.1	84	7.2	40.5	30.0-54.5	81	7.0	84.0	74.0-103.0	<.0001
Medication	453	19.5	225	19.3	46.0	34.0-64.0	228	19.7	84.0	68.0-105.0	<.0001
Nursing	383	16.5	197	16.9	44.0	31.0-63.0	186	16.1	86.5	68.0-106.0	<.0001
Additional laboratory studies	281	12.1	133	11.4	42.0	30.0-58.0	148	12.8	84.0	68.0-106.0	<.0001
Additional imaging studies	648	27.9	338	29.0	49.5	36.0-64.0	310	26.8	85.5	69.0-106.0	<.0001
X-ray	284	12.2	152	13.0	51.0	38.0-63.5	132	11.4	86.5	68.5-105.5	<.0001
Ultrasonography	37	1.6	19	1.6	49.0	28.0-71.0	18	1.6	82.0	67.0-107.0	<.0001
CT	380	16.4	188	16.1	49.0	35.0-63.0	192	16.6	87.5	72.0-106.0	<.0001
MRI	80	3.4	49	4.2	52.0	33.0-68.0	31	2.7	97.0	68.0-115.0	<.0001
Consult to specialty department	583	25.1	290	24.9	42.0	30.0-58.0	293	25.4	83.0	67.0-104.0	<.0001

making, which included all the steps that we could consider. Due to the comprehensive definition, we could estimate TAT and D2DT more realistically.

In a previous study, Kendall et al [11] reported that TAT and clinical decision making time were reduced by approximately 75 minutes after introducing POCT for sodium, potassium, chloride, urea, glucose, and blood gas analysis. Grodzinsky et al [17] reported that POCT for glucose, erythrocyte sedimentation rate, and C-reactive protein could reduce TAT in a primary care clinic. These studies measured the reduction times for each specific chemistry item. However, we tested the overall effect of POCT using a comprehensive panel of common chemistry tests. Our results demonstrated in how many patients' decision times were affected and the amount of time saved when these decisions were found in the POCT group. Every subgroup according to type of clinical decisions showed consistent results about TAT and D2D time.

We did not consider the LOS at the ED as an outcome variable. The LOS can be affected by many confounders such as fluctuations in the daily number of, as well as the occupancy rates of, the inpatient wards [18]. Several studies failed to demonstrate an effect of the POCT on LOS, likely due to these confounders, or the very limited items tested at the chemistry laboratory [5,6]. However, some studies of POCT or satellite laboratory testing for troponin found that these could reduce ED LOS [3,4,8,12]. Medical costs can also be reduced by the POCT [14,19]. Storrow et al [20] showed that reducing TAT could reduce both the ambulance diversion rate (from 63% to 32%) and LOS (from 2.8 to 2.2 hours).

We designed this study as a multicenter randomized controlled trial to generalize the findings to other similar settings. Previous studies have used the before-and-after design, which can be influenced by factors like changes in human resources, processes, and patients flow in the ED between the 2 study periods. We stratified the patients according to severity, which can affect clinical decisions to different degrees. This distinguishes this study from previous studies in terms of generalization of the findings.

Table 3 TAT and D2D time by LOS at the ED between POCT and CLT

LOS at ED, h	Total cases				TAT					D2D time				
	POCT		CLT		POCT		CLT		*P*	POCT		CLT		*P*
	n	%	n	%	Median	IQR	Median	IQR		Median	IQR	Median	IQR	
<1	20	1.7	7	0.6	13.0	11.0-16.5	47.0	32.0-64.0	.0007	36.0	26.5-42.0	58.0	39.0-77.0	.02
<2	176	15.1	129	11.2	13.0	12.0-17.0	49.0	42.0-60.0	<.0001	38.0	28.5-51.5	70.0	60.0-85.0	<.0001
<3	394	33.8	376	32.5	13.0	12.0-17.0	53.0	43.0-65.0	<.0001	40.0	30.0-55.0	79.0	64.0-95.0	<.0001
<6	776	66.5	777	67.2	13.0	12.0-18.0	55.0	45.0-70.0	<.0001	44.0	32.0-59.0	84.0	67.0-104.0	<.0001
≥6	391	33.5	379	32.8	15.0	12.0-20.0	55.0	45.0-68.0	<.0001	49.0	38.0-67.0	92.0	72.0-113.0	<.0001

Table 4 Proportion of patients within specific time window of TAT and D2D time

Time window (min)		POCT		CLT		*P*
		n	%	n	%	
TAT	<30	1100	94.3	49	4.2	<.0001
	<60	1147	98.3	679	58.7	<.0001
D2D time	<60	850	72.8	144	12.5	<.0001
	<120	1141	97.8	971	84.0	<.0001

We found that clinical decision making was possible within 60 minutes for 72.8% of emergency patients enrolled, which means that the ED process would be shortened. Thus, it is reasonable to assume that introducing POCT to the ED can facilitate the ED process, especially throughput.

We could find the shorter LOS in subgroup of the most severe group (ESI level 1) and admission group. This partial finding suggested that LOS of more severe patients can be reduced when we used the POCT chemistry compared with CLT chemistry. For total patients, however, we could not find any difference of LOS, which means that there would be each different mechanism for severity-based effect of chemistry laboratory test.

Although the POCT has shown the shortening of TAT and time to clinical decision for emergency patients, the main downsides to POCT should be considered as the following: time-consuming process spend by busy ED staff performing the tests, the cost difference between POCT and centralized laboratory analysis, and difficulty in quality control and maintenance. Some decisions are worth the extra money and personnel time to have the rapid POCT result—for example, glucose level in an altered patient, hematocrit in the hypotensive patient with the gastrointestinal bleeding, and creatinine in the patient ready for computed tomography (CT) scanning with intravenous contrast. We also should consider that most clinical decisions made in the ED do not hinge on the sodium level, but rather on a clinical picture based on a thorough history and physical examination. The advantage of POCT should be carefully investigated and compared for those complex reasons.

The number for additional imaging after the report of chemistry laboratory examination was 648 (27.9%) including simple x-ray (284, 12.2%), ultrasonography (37, 1.6%), CT (380, 16.4%), and magnetic resonance imaging (MRI) (80, 3.4%), respectively. Most of CT scan and MRI should be done after confirming the safe creatinine level when the patient with high risk of contrast-induced nephropathy needs to be checked in this study setting. Those were responsible for 71% of the additional imaging studies. Additional x-rays after the report of chemistry laboratory are usually ordered when there is any abnormality of liver battery or electrolyte due to routine check for the chest X-ray or abdomen supine and erect view. These findings also suggest that the POCT can be beneficial for the additional radiologic examination.

6. Conclusions

Comprehensive POCT for chemistry laboratory tests reduced the laboratory TAT and the time for clinical decision making in adult ED patients. Further investigation is needed to directly examine the effect of POCT on ED crowding and outcome.

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