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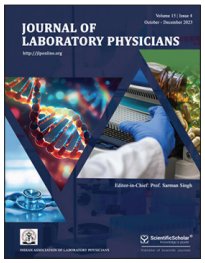

Short Communication

Can splitting the blood sample for photometric chemical assay and immunoassay reduce turnaround time for chemical assay?

Navya Gupta[1], Sumana Kundu[1], Kajal Nandi[1], Anuupama Suchiita[1], Bidhan Chandra Koner[1]

[1]Department of Biochemistry, Maulana Azad Medical College, New Delhi, India.

***Corresponding author:**
Navya Gupta,
Department of Biochemistry,
Maulana Azad Medical College,
New Delhi, India.

guptadrnavya@gmail.com

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ABSTRACT

The analytical phase of sample processing contributes to total turnaround time (TAT) in a clinical biochemistry laboratory. Integrated systems combine photometry-based chemical assays with enhanced chemiluminescence-based immunoassays on one platform. This study aimed to decrease TAT by introducing samples separately (for photometry-based chemical tests and chemiluminescence-based immunoassays) in the analyzer. On 3 consecutive days, 40 samples each were run on the integrated biochemistry analyzer by taking (a) a single sample for all tests and processing using the automation track, (b) separate samples each for photometry-based chemical tests and chemiluminescence-based immunoassays using the track, and (c) separate samples for each run without the use of automation track. The time taken in the analytical phase was recorded for all. Data were presented as mean and standard deviation. For comparison, a one-way analysis of variance (ANOVA) followed by Tukey's Honest Significant Difference (HSD) *post hoc* test was used. $P < 0.05$ was considered significant. The average time in the analytical phase for photometry-based chemical tests was observed to be lesser than that of chemiluminescence-based immunoassays. A significant difference in the mean time in the analytical phase was observed when samples were processed separately for photometry-based chemical tests and chemiluminescence-based immunoassays with or without using track (one-way ANOVA, $F = 3.07$, $P < 0.05$, followed by Tukey's HSD *post hoc* test). There is a need to develop a laboratory information system that can segregate the reports of photometry-based chemical and chemiluminescence-based immunoassay tests even when performed from a single sample, and, till such a development occurs, separate samples for each should be introduced in such a system for patients admitted, particularly to intensive care units.

Keywords: Analytical phase, Immunochemiluminescence, Photometry, Turnaround time

INTRODUCTION

The "quality" of a laboratory is defined as its ability to satisfy the consumers' expectations, focusing on the precision and accuracy of reports in the laboratory.[1] For decision-making, timeliness is an important indicator of quality to a clinician, which may be overlooked by clinical biochemists for technical or analytical intricacies.[2] Turnaround time (TAT), total or therapeutic, can be described as the time from "vein to brain" or "brain to brain," i.e., from test requisition to therapeutic decision-making.[3] The testing process can be divided into three phases, namely pre-analytical (from requisition of test/receipt of sample to its preparation), analytical (actual testing), and post-analytical (verification/printing/dispatch/interpretation of results), upon which TAT depends.[4,5] It is important to balance the "faster is better" approach with the accuracy and precision of reports, and various strategies can help shorten the steps in the TAT cycle.[6,7]

There are integrated systems that incorporate photometry-based chemical assays with enhanced chemiluminescence-based immunoassays on the same platform. When many such systems are attached to an efficient track system and controlled by the Laboratory Information System (LIS), it eliminates the need to split samples for photometry-based chemical assays and chemiluminescence-based immunoassays. This capability of independently processing a high sample volume/load helps in the efficient utilization of space and aims to improve TAT by quicker patient reporting.[8,9]

Despite the high throughput of such a track system controlled by LIS, the change in TAT was not as expected for the samples that need both photometry-based chemical assays and chemiluminescence-based immunoassays. It was felt that the use of a track system, per se, may be the cause of the increased time of the analytical phase, or else when both photometry-based chemical assays and immunoassays are done from a single sample, it results in an increase in time required at the analytical phase leading to increase in TAT. To check this hypothesis, this study was designed to assess whether,

a) By introducing samples separately (for photometry-based chemical tests and chemiluminescence-based immunoassays) in the analyzer, we can decrease TAT
b) By avoiding the use of the track and using the standalone system, the TAT can be improved.

MATERIALS AND METHODS

The study was an experimental study conducted in the Biochemistry laboratory of a tertiary care hospital in Delhi, India. Patient consent/ethical clearance was not obtained as no patient data/information was used for the study.

Sample

The experiment was conducted on initial 40 blood samples received for liver function tests (i.e., serum levels of albumin, protein, total and direct bilirubin, and enzymes aspartate transaminase, alanine transaminase, alkaline phosphatase), kidney function tests (i.e., serum urea, creatinine), thyroid function tests (i.e., serum-free triiodothyronine, free thyroxine, thyroid-stimulating hormone levels), Vitamin B12 assay and 25(OH) vitaminD3 assay, from blood collection center for the outpatient department patients, collected between 8 am and 9.30 am. On consecutive 3 days, the 40 samples each were loaded into the system without any interruption from 10 am for the above-mentioned tests by different methods as described below. The total number of photometry-based chemical tests (9/sample) and chemiluminescence-based immunoassays (5/sample) remained constant every day.

System used

Vitros 5600® integrated system (Ortho Clinical Diagnostics, Johnson and Johnson, USA) was used to process the samples. The system integrates dry chemistry (MicroSlide), special chemistry, and immunoturbidimetry with photometric detection (MicroTip), immunoassays with enhanced chemiluminescence (MicroWell), and photometric measurement of sample quality indices (interferences) (MicroSensor). This system is attached to an efficient track system and controlled by the LIS software.

Intervention

On day 1, 40 samples "(a)" were analyzed for the above-mentioned parameters by taking a single sample for all parameters (photometry-based chemical tests as well as chemiluminescence-based immunoassays) and loading on the analyzer using the track. On day 2, select 40 samples "(b)" were analyzed by taking separate samples for photometry-based chemical/chemiluminescence-based immunoassays and loaded using the track. And on day 3, standalone separate samples (40 each) for photometry-based chemical/chemiluminescence-based immunoassays "(c)" were processed on the analyzer, bypassing the track.

Outcome variable

The time required in the analytical phase (a contributor to TAT) for each sample was measured as the outcome variable. The analytical phase of sample processing began after the generation of a barcode for the samples, with sample insertion in the track, from where they were picked up for analysis. Once complete, the results were available on the interface, and the time taken was recorded.

Confounder-control method

The same technicians were used to avoid differences in ability among the technicians. On all 3 days, the test samples were run with routine samples that had mainly serum glucose, urea, and creatinine to be analyzed.

Method of measuring time of analytical phase

The time taken from the generation of barcodes for the samples till the generation of results on the analyzer was taken as the analytical phase in the study. For scenario (a), the time when the results were available was recorded (twice) from the analyzer, once each for the photometry-based chemical tests and chemiluminescence-based immunoassay results. Two different barcodes were generated for each of the separate samples in scenarios (b) and (c), following which the samples were processed on the analyzer.

Statistical analysis

Data were presented as mean and standard deviation (SD). For comparison, a one-way analysis of variance followed by Tukey's Honest Significant Difference *post hoc* test was used. $P < 0.05$ was considered significant.

RESULTS

The mean time and SD in the analytical phase for all three scenarios are presented in Table 1.

All three scenarios are as follows: Mean time in the analytical phase in (a) single sample for all tests using the track, (b) separate samples for photometry-based chemical tests and chemiluminescence-based immunoassay using the track, and (c) standalone samples for each without using track (n = 40 in each group).

DISCUSSION

The timeliness of laboratory services to patients and clinicians is an important determinant of laboratory quality, together with accuracy and precision.[3] TAT has come up to become a cornerstone of laboratory efficiency in recent times, and it is the prerogative of laboratory managers to ensure timeliness. Despite making significant technical, transport, and information-technology advancements in recent years, TAT continues to be a cause of consumer dissatisfaction with laboratory services. Laboratory staff are kept on their toes, trying to balance these factors. [10,11]

As shown in Table 1, the average time in the analytical phase for the photometry-based chemical tests was observed to be lesser than that of chemiluminescence-based immunoassays, irrespective of the type of intervention made. This was despite the number of immunochemiluminescence-based tests (5/sample) being lesser than photometry-based chemical tests (9/sample). This could be attributed to the longer incubation period with antibodies in immunochemiluminescence methods, as has been documented by other studies performed both by the manufacturer of the equipment and users.[8,9] Owing to this, chemiluminescence-based immunoassay tests become one of the deciding factors for TAT.

As shown in Table 1, when a single sample was run for photometry-based chemical and chemiluminescence-based immunoassays using the track controlled by LIS, the mean time for photometry-based chemical tests was 100 min (SD = 58.9) and that for chemiluminescence-based immunoassay parameters was 211 min (SD = 106.5). However, as LIS generates a single report when the system completes all the tests, the mean time for analysis of both photometry-based chemical tests and chemiluminescence-based immunoassays turns out to be 211 min, although the system completes the photometry-based chemical assays on average 100 min. In the second scenario "(b)," when separate samples for photometry-based chemical and chemiluminescence-based immunoassays were run using the track system controlled by LIS, the average assay time for photometry-based chemical assays was 136 min (SD 80.9) which was less than that 211 min when a common sample was used for both photometry-based chemical and chemiluminescence-based immunoassays. Although processing samples in different vials for different tests is more time and resource-consuming, the TAT for reporting photometry-based chemical tests can be significantly decreased. A number of factors came into play with the use of the automation track, like the number of samples (increased further as separate samples were taken for photometry-based chemical tests and chemiluminescence-based immunoassays), crowding the track. Furthermore, any failure or breakdown of equipment, as often occurs in laboratory settings, can lead to a further increase in TAT. In view of this, we infer that by splitting the samples for photometry-based chemical tests and chemiluminescence-based immunoassays or by acquiring two different samples for each, we may be able to reduce the TAT for photometry-based chemical assays and report them earlier. This is crucial because photometry-based chemical test reports are more often used in clinical decision-making in emergencies and wanted by the treating physician as early as possible, whereas chemiluminescence-based immunoassays are not often needed urgently (except in some rare situations like a hypothyroid coma). Hence, we recommend the splitting of the samples for photometry-based chemical and chemiluminescence-based immunoassays or acquiring two different samples for each from the source, particularly for patients admitted to intensive care and high dependency units (ICU/HDU). Alternatively, LIS may be improved in such a way that the system will generate

Table 1: Mean time (±SD) in the analytical phase for all samples.

	Mean time±SD in the analytical phase for photometry-based chemical tests (in minutes)	Mean time±SD in analytical phase for chemiluminescence-based immunoassay (in minutes)
Single sample for all the tests using track	100±58.9	211±106.5
Separate samples for photometry-based chemical tests and chemiluminescence-based immunoassay using track	136±80.9*	283±99.3*
Standalone separate samples for photometry-based chemical tests and chemiluminescence-based immunoassay (without using the track)	61±43.8*#	145±71.4*#

*P<0.001 in comparison to mean time in analytical phase when single sample was processed for photometry-based chemical tests and chemiluminescence-based immunoassays using track; and #P<0.001 in comparison to mean time in analytical phase when separate samples were processed for photometry-based chemical tests and chemiluminescence-based immunoassays using track by one-way analysis of variance (F=3.07, P<0.05) followed by Tukey's Honest Significant Difference *post hoc* test, SD: Standard deviation

separate reports for photometry-based chemical tests (that can be taken/dispatched as soon as these tests are complete) and chemiluminescence-based immunological tests.

In the third scenario "(c)," when separate samples for photometry-based chemical and chemiluminescence-based immunoassays were used analyzed in a standalone equipment (capable of performing all assays), bypassing the automation track and LIS, the mean time required during analysis phase was 61 min (SD = 43.8) for photometry-based chemical tests and 145 min (SD = 71.4) for chemiluminescence-based immunoassay parameters, that was far less than that in the first and second situations. This observation refutes the very fundamental essence of the automation track and LIS in reducing TAT in laboratory set up. However, despite this observation, we do not recommend using a LIS-regulated track-based system attaching multiple auto analyzers on track, as it reduces the manpower and space requirement and performs many other functions, reducing the final TAT. In this study, those things were not factored in. Another limitation of the study includes the fact that the samples sent into the track following our study samples may have affected the order of processing of some of the study samples due to the organization of the track. Furthermore, such a specific type of study design tailored for one laboratory may not be directly applicable to many.

CONCLUSIONS

Hence, we conclude that there is a need to develop an LIS that can segregate the reports of photometry-based chemical and chemiluminescence-based immunoassay tests even when performed from a single sample, and, till such a development occurs, separate samples for photometry-based chemical tests and chemiluminescence-based immunoassays should be introduced in such a system for patients admitted, particularly to ICU and HDU.

Author's contribution

Navya Gupta - Literature search, data analysis, statistical analysis, manuscript preparation and editing.
Sumana Kundu- data acquisition, manuscript review.
Kajal Nandi- definition of intellectual content, manuscript review
Anuupama Suchiita- manuscript review.
Dr BC Koner- concept, design, manuscript review.

Ethical approval

Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent is not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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