ORIGINAL RESEARCH

Investigation of pre-analytical errors in the determination of procalcitonin and interleukin-6 in patients with COVID-19

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ABSTRACT

Background: In laboratory medicine, the preanalytical phase is crucial. It includes the time that passes between the sample being ready for analysis and the clinician giving the order for the test. Every one of the three stages of the testing process has errors that need to be found and fixed. **Materials and Procedures:** The investigation was carried out at the Department of Biochemistry, Index Medical College, Indore, Madhya Pradesh, India. The study incorporated all of the preanalytical errors that were made when estimating IL-6 and procalcitonin. Using Beckman immuno assay kits, the Beckman Coulter Access 2 was used to estimate PCT and IL-6. Findings and **Result:** Nine preanalytical mistakes were found in our investigation while estimating IL-6 and procalcitonin. Early serum separation from the clotted sample is necessary to prevent cell-released cytokines from leaking into the serum and potentially producing false-positive results. **Conclusion:** Pre-analytical errors affect overall error and, in turn, the precision of the diagnosis. Repetition of training for lab technicians and ward staff nurses can lower the percentage of preanalytical mistakes.

Key words: Procalcitonin, IL6

INTRODUCTION

One essential aspect of laboratory medicine is the preanalytical stage. It encompasses the interval between the clinician's test order and the sample's preparation for analysis.It is necessary to identify and fix errors that occur at each of the three testing process stages[1].

In the COVID-19 pandemic, procalcitonin (PCT) was demonstrated to be an effective technique for identifying patients at low risk for bacterial co-infection and unfavourable outcome. In COVID-19, PCT may serve as a disease severity indicator and be one of the two factors used to assess sickness severity[2].

The 2019 coronavirus disease is mostly controlled by the inflammatory response, and interleukin 6 (IL-6) has been identified as one indication of the inflammatory cytokine storm [3].

In order to formulate quality goals and measures to achieve these goals, which would vary from laboratory to laboratory, it would be extremely helpful to monitor the type and magnitude of preanalytical errors that occur in individual laboratories as well as the knowledge regarding their burden on TQM. This will help to improve the overall quality and reliability in the laboratory diagnostic process[4].

This has sparked interest in our laboratory, which aims to investigate and assess the kinds, frequency, and severity of errors in the preanalytical testing process in our tertiary health care clinical biochemistry laboratory, as well as their overall influence on our laboratory's quality management system. Additionally, we have attempted to develop specific correction actions that would get rid of any potential preanalytical errors in the future.

MATERIALS AND METHODS

Study samples from Covid-19 patients (both ICU and wards) were estimated for IL-6 and Procalcitonin at the Department of Biochemistry, Index Medical College Indore. The study was conducted over a period of three months (December 2022 to February 2023) and preanalytical variables were reported at the end of the study. All preanalytical variables for the samples encountered in the estimation of Procalcitonin and IL6 were included in the study, while all other preanalytical errors on other samples for routine biochemistry parameters were excluded.

Clinical department employees execute phlebotomies on inpatients, while laboratory staff members gather blood samples from outpatients in a central collection centre on-site. The paramedical staff from the wards and the laboratory support staff from the OPD, respectively, bring the samples to the laboratory.

Using Beckman immunoassay kits, IL-6 and procalcitonin were measured in the chemiluminiscence immunoassay analyzer (Beckman).

RESULT AND DISCUSSION

NO. OF TOTAL SAMPLES

Marker	No. of total samples (100)
Pro calcitonin	25
Interleukin 6	75

LEVEL OF RISK IN PROCALCITONIN ANALYSIS

Procalcitonin	No. of samples
Normal range	13
Low risk	3
Moderate risk	5
Severe risk	4

NO. OF PREANALYTICAL ERRORS

Preanalytical errors	Numbers
Incomplete requisition form	2
Homolysed/Lipemic sample	1
Collection of samples in inappropriate container	2
Quantity of sample not sufficient	3
Delay in transportation	1
Delay in processing	0
Wrong entry of lab no.	0

The preanalytical phase of the testing process accounts for a large portion of all laboratory procedures that are prone to error due to the increasing rate of human intervention [5]. The total testing process in a clinical laboratory is divided mainly into 3 phases:

1) Preanalytical.
2) Analytical.
3) Post analytical errors in any of the steps can invalidate the quality of analysis diminishing the quality goals of the laboratory.

It has been documented that approximately 70% of laboratory errors are due to preanalytical testing process. This has a significant impact on the Total Quality management process (TQM) of the laboratory. Quality assurance system, an integral part of the feedback loop of TQM system of a laboratory, is found to be significantly affected by errors which occur during the preanalytical phase [6].

Nine percent (9%) of the total samples received at our laboratory were found to be related to pre-analytical errors in the study.

In our investigation, we discovered that about 1% of the samples that were sent for analysis were lipemic and hemolyzed, which are known to have varying effects on assays. Our results agreed with the research done by Jones and colleagues [7].

The laboratory must create training curricula for all staff members participating in phlebotomy and ensure that sample collectors are correctly taught to maintain collection standards in order to prevent getting hemolyzed samples [8].

Another common preanalytical error included the incomplete requisition form and the quantity of sample not being sufficient.

These mistakes have an impact on the laboratory's reporting system, making it more difficult to determine the accurate reference values for the desired analyte, prevent needless test repetitions, and promptly notify the treating physician [9, 10].

In order to prevent collecting insufficient quantities and to take into consideration repeating the test if necessary, the laboratory should record and examine the requirements on a regular basis on the sample volume needed for various tests, including the dead volume required in the analyzer and serum blank[11].

CONCLUSION

Effective communication, proper training for personnel involved in sample collection, labelling, and transportation, and teamwork amongst all members of the healthcare team should be the first steps in preventing these preanalytical errors.

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