Original Research Paper

Biochemistry

STUDY OF PREANALYTICAL VARIABLES IN THE ESTIMATION OF PROCALCITONIN AND INTERLEUKIN-6 AMONG COVID 19 PATIENTS

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ABSTRACT **Introduction: Aims and Objectives:** 1. To estimate IL-6 and Procalcitonin in covid 19 samples. 2. To study and detect the percent of preanalytical errors in the estimation of IL-6 and Procalcitonin. 3. To formulate corrective measures to reduce such errors. **Materials and methods:** The study was conducted at Central laboratory Biochemistry, ACSR Government medical college, Nellore. All the Preanalytical errros encountered during the estimation of IL-6 and Procalcitonin were included in the study. The estimation of IL-6 and PCT were done on Beckman coulter Access 2 using Beckman immuno assay kits. **Results and Discussion:** In our study we have identified 172 preanalytical errors during the estimation of IL-6 and Procalcitonin. Serum should be separated from the clotted sample as early as possible or else the cytokines released from cells leak into serum and may lead to false positive results. **Conclusion:** Pre analytical errors influence total error and thereby the diagnostic accuracy. The percentage of preanalytical errors can be reduced by conducting repeated trainings to lab technicians and to ward staff nurses.

KEYWORDS : IL-6 (Interleukin 6) and PCT (Procalcitonin)

INTRODUCTION

The inflammatory response plays a critical role in coronavirus disease 2019 and Interleukin 6 (IL-6) was identified as a marker of inflammatory cytokine storm.[1]

Procalcitonin (PCT) was shown to be a valuable tool in the COVID-19 pandemic to identify patients at low risk for bacterial co infection and adverse outcome. PCT may be an indicator of disease severity in COVID-19 and may contribute to determining the severity of illness.[2]

The preanalytical phase is an important component of laboratory medicine. It includes the time from the order of test by the clinician until the sample is ready for analysis. Identifying and correcting the mistakes arising at various levels of the testing process needs to be addressed.[3]

Monitoring the type of preanalytical error and the knowledge regarding its burden on the TQM will help in improving the overall quality and reliability in the laboratory diagnostic process.[4]

Quality is the core issue for all laboratories and this requires total quality management in the laboratory process in the preanalytical, analytical and post analytical phases.3,4

It is, therefore, important that interpretation of laboratory data should be done with caution at all three stages.

The study was designed to estimate PCT and IL6 and to study the preanalytical errors.

AIMS and OBJECTIVES

1. To estimate IL-6 and Procalcitonin in covid 19 samples.
2. To study and detect the percent of preanalytical errors in the estimation of IL-6 and Procalcitonin.
3. To formulate corrective measures to reduce such errors.

MATERIALS AND METHODS

The study was conducted at Biochemistry central laboratory ACSR Government medical college. Samples from Covid-19 patients (Both ICU and wards) were estimated for IL-6 and Procalcitonin.

Study was conducted for a period of two months (september to october 2020) and preanalytical variables identified were reported at the end of the study. Institutional ethical committee approval was obtained. All the Preanalytical variables for the samples encountered in estimation of Procalcitonin and IL6 were included in the study. All the other preanalytical errors on other samples for routine biochemistry parameters were excluded.

IL-6 and procalcitonin were estimated in chemiluminiscence immuno assay analyser (Beckman) using Beckman immunoassay kits.

SOP for estimation of these parameters was prepared and circulated in the wards.

RESULTS:

Table no.1 Total number of IL6 and Procalcitonin samples

Total Samples N=100	Il6 samples=80 PCT samples =30
Only IL6	68
Both IL6 & PCT	12
Only PCT	18

Table no.2 Level of Sepsis risk values in Procalcitonin estimation

PCT Normal range <0.1ng/ml	Total samples 30
Normal range	16
Low risk of severe sepsis < 0.5	4
Moderate risk > 0.5 and < 2.0	5
High risk of septic shock > 2.0	5

Table no 3. No of IL6 samples normal and abnormal ranges

IL6 Samples total no(N: 80)	Normal range < 6.4 pg/ml
Within normal range	17 Samples
> 1000pg/ml	5 Samples

Table no 4. Number and percentage of Preanalytical errors

Name of Preanalytical error	Number	Percentage %
Wrong Patient identification	5	5.5
Wrong sample tube	21	23.1
Non reporting time of collection	64	70.4
Delay in transport of samples	27	29.7
Delay in serum separation	3	3.3

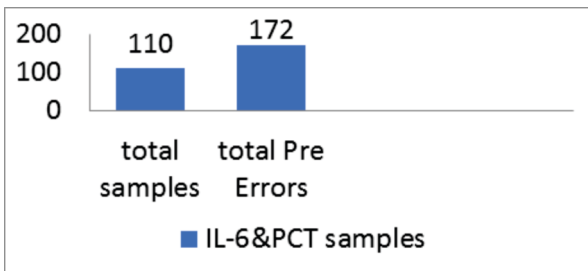|		
Insufficient sample	11	12.1
Jaundice	4	4.1
Lipemia	7	7.7
Request form without diagnosis	31	34.1

Figure. No 1: Total no of samples and total no. of Preanalytical errors

DISCUSSION:

Pre-analytical errors influence the total error and thereby affect the diagnostic accuracy.[5] Table no 1 indicates the number of Individual IL6 and PCT requested and also the samples that required both IL6 and PCT estimation. Out of 30 samples estimated for procalcitonin, 16 samples were normal, 4 samples indicated low risk of severe sepsis, 5 samples were suggestive of moderate risk and 5 other samples were indicative of high risk of severe sepsis.

In our study we have noticed 172 preanalytical errors as seen in Figure no 1. Table no. 4 indicates various preanalytical errors noted. This study demonstrates that PCT may be an indicator of disease severity and may contribute to determining the severity of patients with COVID-19. Some of the preanalytical errors can be corrected if a sample rejection register is maintained and acted accordingly during the time of receipt of sample in the lab. Some of the Preanalytical errors like wrong patient identification, wrong tube, request form without mention of time of collection or the diagnosis may be rejected and entered in the sample rejection register so that the sample and request form is sent back for corrective action.

Sample types, centrifugal timing, storage temperature, and time of collection of samples may affect the IL.6 levels. A standard blood sample handling procedure should be performed to ensure the accuracy and stability of IL.6 values.[6] There is a dynamic balance between the degradation and production of cytokines in vitro. The half.life of cytokines is relatively short and various stimuli lead to the continuous secretion of cytokines by the blood cells.[7] Table no. 3 indicates the total number of IL-6 samples along with their normal and abnormal ranges. Serum should be separated from the clotted sample as early as possible or else the cytokines released from cells leak into serum and may lead to false positive results.

Our study was in accordance with study conducted by Aysenur Atay etal [8] They concluded that the preanalytical errors were attributable to inappropriate test requests, improperly labelled samples and insufficient sample specimens. Further studies should be performed after corrective and preventive actions to detect a possible decrease in rejecting samples.

Hence time of collection, delay in transport of sample and serum separation are the utmost important preanalytical variables to be taken care of along with other errors in the estimation of IL-6. Repeated Training programs to technicians and ward staff nurses can help in reduction of these errors.

CONCLUSION:

Assessing the quality of laboratory services using Quality indicator is important to ensure systematic and consistent data collection by addressing all stages of analysis in a laboratory.

Effective improvement to reduce the preanalytical errors should be made by adopting standard operating procedures in the initial steps of laboratory testing.

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