

Interference of serum indices in the analyzer function

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Abstract:

Background: Analyzer has the capability to detect hemolysis, icterus, and lipemia in samples and produces semi quantitative unit less index values for hemoglobin, bilirubin, or intralipid (so-called serum indices), but these serum index functions are not intended for diagnostic purposes. With increasing amounts of the specific interfering compounds, increasing index values are generated, which are linearly correlated with the amount of interfering. Aim of our study is to find the influence of serum indices on the functioning of the analyzer.

Methodology: Blood glucose estimation was done for twenty samples. Serum indices analysis was done for the same set of samples along with glucose in the next run. Time taken for analysis was noted.

Results: The time taken for the estimation of glucose by automated chemistry analyzer is 9.27 minutes. When analyzed with serum indices, time required is 9.45 min.

Conclusion: We have proved that there is an increase in the turnaround time when serum indices was analyzed along with glucose. However increase of 1.94% is acceptable when compared to interfering compounds influencing patients' reports.

Key words: analyzer function ,serum indices, turnaround time

Running title : serum indices and turnaround time

I. Introduction

Authors have reported on improvements in process performance to reduce analytical errors, assay interference by endogenous or exogenous substances is an underrated problem with potential detrimental effects for the patient (1–3). Four major endogenous compounds that often interfere with most laboratory results are hemoglobin, bilirubin, lipids, and paraproteins (3–5).

Each of these interfering substances is a potential source of biological and analytical biases which ultimately compromises the reliability of testing and makes the systematic identification of unsuitable specimens virtually unavoidable for preventing that unreliable or misleading test results. Recognition by a colour or turbidity of the specimen is proved to be unreliable. It is very difficult to predict the effect of these components on report because each sample has to be visualized immediately after centrifugation. So automated determination of potential interference of hemolysis, hyperbilirubinemia and turbidity came in to picture. Serum indices (SI) is a tool which makes laboratory professionals aware of interferences, helps to increase the quality of the sample ,minimize aberrant test results.

There is widespread perception that systematic measurement of SI may decrease throughput and contextually increase TAT, implementation of SI is a debate. No manufacturer data are available regarding this matter.

To the best of our knowledge , there are a few number of studies which have analyzed the interference of SI in analyzer functions. Aim of our study is to compare the performance of the analyzer with and without SI analysis. We compared the time interval required for the estimation of glucose with and without SI.

II. Methodology

Twenty samples were selected randomly from the specimens that came to our laboratory for blood glucose estimation. 2 ml of blood sample was taken in grey colored vacutainer, centrifuged at 3000rpm for 15 minutes. Blood glucose estimation was done independently as well as along with SI analysis. Time taken to complete the assay in both the cases was noted. The analysis was carried out in Transasia XL-640.

Since we have not obtained sample for our study purpose and preexisting samples were used, ethics committee approval was not needed. But we sought permission of head of the department and head of the institution.

The instrument works on the principle of light photometry combined with the best mechanics for sampling. The sample under test is sampled in to cuvette, which is read at defined time intervals to find out optical densities. The entire operation is divided in to the following sequences:

- i. Getting ready for operation
- ii. cuvette rinsing
- iii. reagent 1 addition
- iv. sample addition
- v. stirrer 1 mixing
- vi. reading and reporting
- vii. reagent 2 addition (optional)
- viii. stirrer 2 mixing
- ix. reading and reporting
- x. cleaning

Estimation of blood glucose involves steps i-vi.

III. Results

We have noted an increase in the analytical phase by 0.18 min. The time taken for the estimation of glucose by automated chemistry analyzer is 9.27 minutes. When analyzed with serum indices, time required is 9.45 min. There is an increase in turnaround time by 1.94 percent as represented in the table.

Table:Duration of analytical phase			
Only glucose(in min)	Glucose and serum indices (in min)	Increase in turnaround time(min)	Increase in turnaround time(%)
9.27	9.45	0.18	1.94

IV. Discussion

We have found that SI estimation prolongs analytical phase ,we can say that total turnaround time is prolonged.

A unique study by G Lippi *et al*, studied influence of serum indices on turnaround time in five different analyzers, Beckman Coulter, Roche, Abbott ,Siemens and Ortho Vitros. Among these first three showed prolonged turnaround time whereas others showed shortened turnaround time (6).

Since no much data is available on the interference of serum indices on analyzer function, manufacturer has to provide the information about his instrument. Advantages of serum indices to assess interference of hemoglobin, bilirubin and lipemia on patient results over prolonged turnaround time have to be analyzed. When compare these two aspects ,a delay of 0.18 minutes is acceptable .As serum indices reduce the cost incurred in repeating the erroneous samples and it contributes to the patient management by eliminating false positive and negative reports it is advantageous from patient point of view.

Manual inspection can be performed on every sample before analysis (pre-analytical) or inspecting specimens that produce suspect results (post-analytical) (7).This is very time consuming and produces inconsistent results. When serum indices are produced by the instrument , consistent evaluations are made and remove potential human errors. It saves operators time.

Even though it slightly increases analytical time , but largely decreases pre and post analytical time and thereby reduces turnaround time. With less operator time involved in examining suspicious samples not only TAT is reduced , the costs involved in operting out of limit results due to interferences are reduced. The SI results reported simultaneously with the test result enables the operator to acknowledge presence of interfering substance are cause of abnormal result or removes the need to ask for new sample, thus reducing costs.

Verner in 2005 reported on improvements in patient results with respect to endogenous interferences after introducing automated detective reporting system (8).Test specific serum index decision thresholds were used to

- detect interference
- alert operator
- add appropriate comments
- reject a report where necessary

SI measurement is multi wavelength scanning of samples which can be performed as an add on test and almost simultaneously with routine measurements (9,10).Despite all manufacturers claim that SI has no influence on analyzer performance,there is no published data on impact of SI on it.

Our results confirm that SI interferes with analyzer performance through prolonging analytical phase TAT. Limitations of our study is that we have not studied pre analytical and post analytical phases or total turnaround time.

V. Conclusion

We have proved that there is an increase in the turnaround time when serum indices was analyzed along with glucose. However this minimal increase is acceptable when compared to interfering compounds influencing patients' reports. As serum indices reduce erroneous reports and minimize cost, estimation of SI can be done routinely along with all the tests. More studies need to be done to assess the interference of serum indices on analyzer function as the data available is minimal.

Acknowledgements

We thank Dr Poornima RT, HOD Biochemistry for the support.

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