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IMPACT OF ANALYTICAL ERROR IN AN ESTIMATION OF LIVER ENZYMES

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ABSTRACT

Backgrounds: Laboratory professionals should produce accurate, sensitive and specific information using new age technologies to guide clinical decision making. It is the role of laboratory professionals to inform physicians about which tests have the highest effectiveness in given clinical conditions. **Objective:** The objective of this study was to determine the analytical errors of liver enzymes, and also the AST, ALT and ALP levels are a valuable aid primarily in the diagnosis of liver disease. **Methodology**: cross sectioned study was conducted during the period of the November to April 2013, to measure the accuracy and precision of laboratories by estimation of AST, ALT and ALP in normal and pathological control sera in 10 clinical laboratories in Khartoum state, Sudan. The percentage were used to assess the laboratories quality management requirement of each selected laboratories. **Results:** The study showed that10% of total laboratories give excellent level for normal and pathological control materials of AST, ALT and ALP while 60% of total laboratory gives poor level for normal and 50% for pathological for AST, 70% of total laboratory gives poor level for normal and 60% for pathological for ALT and 90% of total laboratory gives poor level for normal and70%for pathological for ALP. **Conclusions:** In spite of all these laboratory have Implementation of quality control procedures, Documentation and interpretation of control material results, and the instrument used to estimate liver enzymes is automated machine and calibration was done daily by senior staff, there is a variation between AST, ALT and ALP analytical results among the normal and pathological level due to technical problems such as inappropriate sample handling, failure to calibrate pipettes. Based on this result we conclude that the absence of total quality management especially the adopted quality requirement for clinical chemistry laboratories lead to gap of implementation and weak laboratory performance.

KEYWORDS: Quality management, analytical Error, liver enzymes.

INTRODUCTION

Clinical laboratories provide information and services that contribute to maximizing the effective delivery of care in today's complex healthcare system by assuring that the correct test is performed on the right person, at the right time, producing accurate test results that enable providers to make the right diagnostic and therapeutic decisions using the right level of health care resources.[1] The primary purposes of every clinical laboratory are testing patient samples and reporting accurate results to clinicians.[1] Therefore, the laboratory designs a quality control (QC) system to accomplish this desired purpose.[1] The international organization for standardization (ISO) defines quality as "the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs" and the Webster's dictionary defines quality as degree of excellence and the verb "to control" as to exercise control over.[1,2] So, that QC system applied in clinical laboratory to increase the degree of excellence that required proving the laboratory's ability to operate within a certain grade and to provide worth to the clinician.[1] In most European countries, concepts of quality management in medical laboratories have been based on general standards for test laboratories (EN 45001, ISO 25) or specific adapted standards.[3] However, quality control is a part of good manufacturing practice (GMP) which focused on testing of the environment and facilities, as well as the testing of the materials, components and product in accordance with the standard.[1] Quality control is a key component of total quality management (TQM) to ensure high quality performance.[1,4] Laboratory diagnostics, a pivotal part of clinical decision making. The laboratory errors occurred in every testing step but most frequently in pre analytical process. Patient misidentification errors are potentially associated with the worst clinical outcome

due to the potential for misdiagnosis and inappropriate therapy. While it is misleadingly assumed that identification errors occur at a low frequency in clinical laboratories, misidentification of general laboratory specimens is around 1% and can produce serious harm to patients, when not promptly detected.[5] The AST, ALT and ALP levels are a valuable aid primarily in the diagnosis of liver disease. The objective of this study was to determine the analytical errors of liver enzymes.

MATERIALS AND METHODS

Study population

Cross- sectioned design was used. This study was conducted in central hospital state, clinical chemistry laboratories department during the period from November 2012-April 2013. Ready prepared control sera were sent to the selected laboratories and then were analyzed by the laboratory method. Also questionnaire was used to collect the information about the instrument calibration and reagent validation.

Data collection and analysis

The analytical data was collected in special format and other data was collected by using questionnaire. Descriptive statistics was used to find out the degree of accuracy and precision. The results and questionnaire were collected from the all participating laboratories and then were analyzed using Microsoft offices excel 2007 to calculate the SDI and CV. The SDI was used to determine an overall average. It expresses the differencebetween the test results and the overall average in terms of the number of standard deviations from the overall mean calculated by the following formula:

$$SDI = \frac{\text{laboratory mean - target value}}{\text{SD of manufacture}}$$

The target SDI is 0.0, which indicates there is not any difference between the laboratory mean and the consensus group mean. A SDI ±1 indicates a possible problem with the test.[21, 22]

Also the CV was calculated to measure the performance of a laboratory over a range of laboratories. CVs of 5% or less generally give us a feeling of good performance, the CV formula is:

$$CV\% = (SD/X)100$$

For accuracy used Z score, for precision used CV

Ethical consideration

Permission of this study was obtained from the local authorities in the area of the study. The objectives of the study were explained to all laboratories participating in this study. An informed consent was obtained from all participants in the study.

RESULTS

Figure (1) Shows the accuracy of laboratories in an estimation of normal and pathological AST

The accuracy of AST analytical results(normal and pathological levels) as 10% of total laboratories give excellent level for normal control materials while 0% result give satisfied result for normal control materials result and 40% scored the satisfied level for pathological control materials, while 30% of total laboratory gives acceptable level for normal control materials 0% result for pathological. while 60% of total laboratory gives poor level for normal and 50% for pathological.

Figure (2) Shows the accuracy of laboratories in an estimation of normal and pathological ALT

The accuracy of ALT analytical results(normal and pathological levels) as 10% of total laboratories give excellent level for normal control materials while 30% of them give excellent results for pathological control materials, while 20% of them five satisfied result in normal control materials and 10% in pathological control materials, while 0% of total laboratory gives acceptable level for normal control materials and 10% of them give acceptable for pathological control materials, 70% of total laboratory gives poor level for normal and 60% for pathological.

Figure (3) Shows the accuracy of laboratories in an estimation of normal and pathological ALP

The accuracy of ALP analytical results(normal and pathological levels) as 10% of total laboratories give excellent level for normal control materials while 0% of them give excellent results for pathological control materials, and 0% give satisfied result for normal control materials and 30% scored the satisfied level for pathological control materials, 0% of acceptable level for normaland pathological control materials result, 90% of total laboratory gives poor level for normal and 70% for pathological.

Figure (4) Show the CV for normal and pathological control materials AST(20%)

Figure (5) Show the CV for normal and pathological control materials ALT(40%)

Figure (6) Show the CV for normal and pathological control materials of ALP(40%,30%)

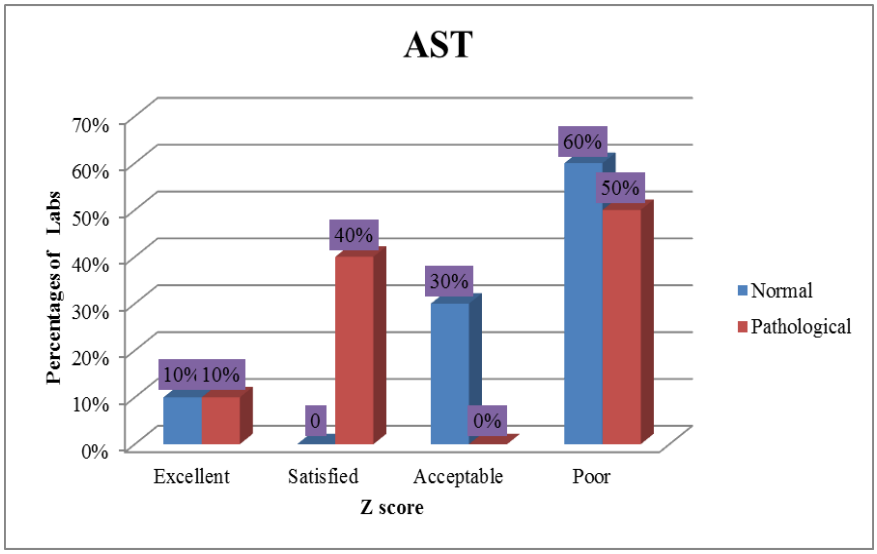

Figure (1): Shows the accuracy of laboratories in an estimation of normal and pathological AST.

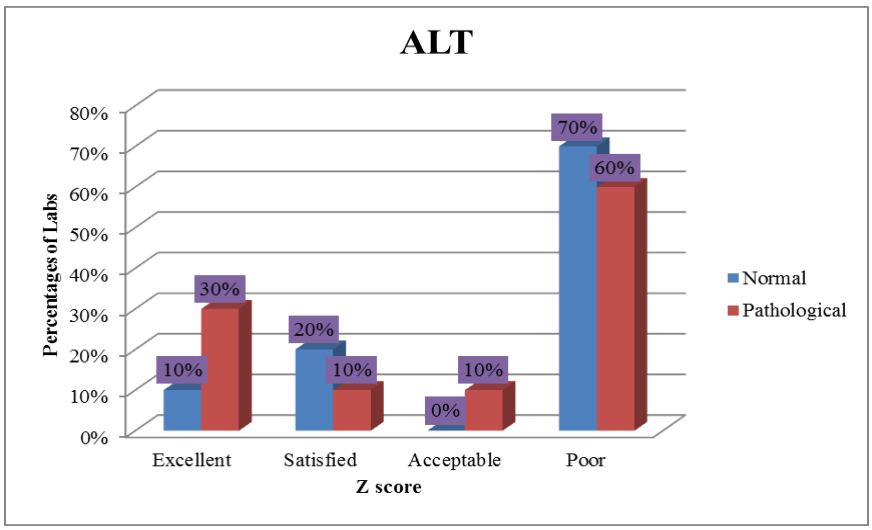

Figure (2): Shows the accuracy of laboratories in an estimation of normal and pathological ALT.

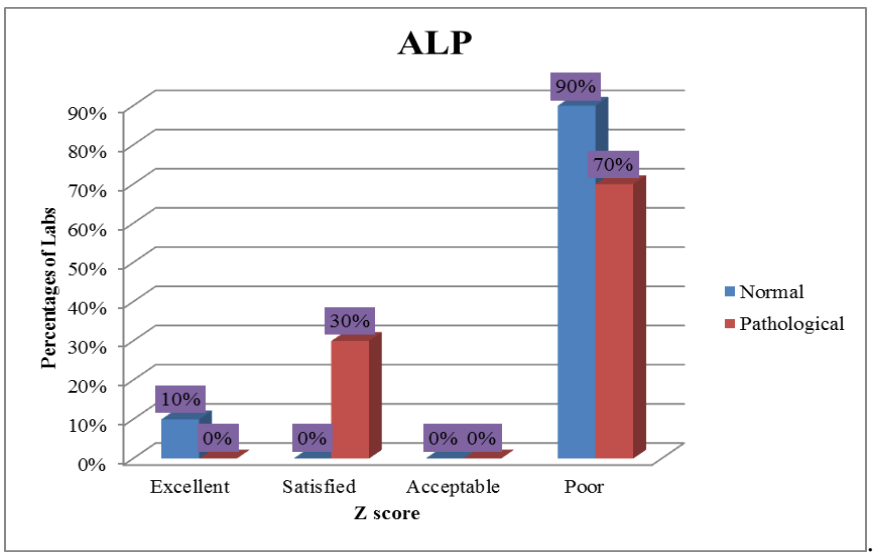

Figure (3): Shows the accuracy of laboratories in an estimation of normal and pathological ALP.

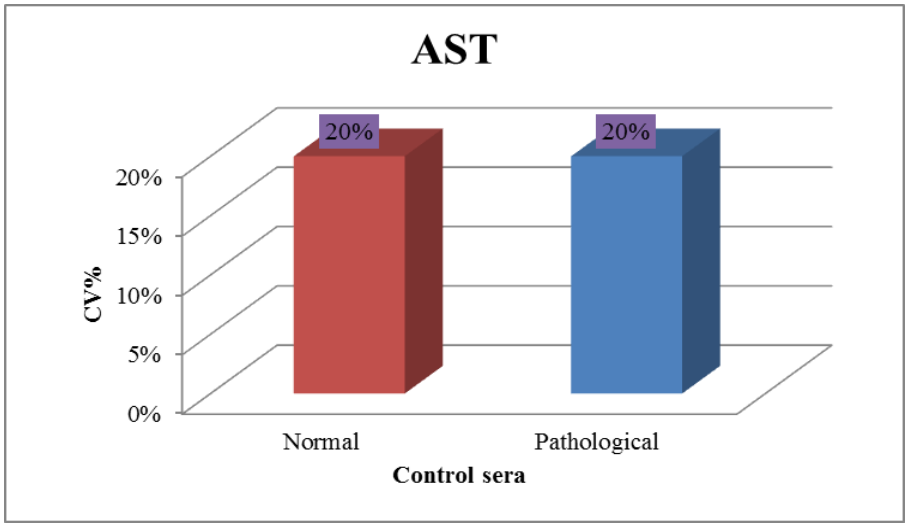

Figure (4): Shows the CV of normal and pathological AST.

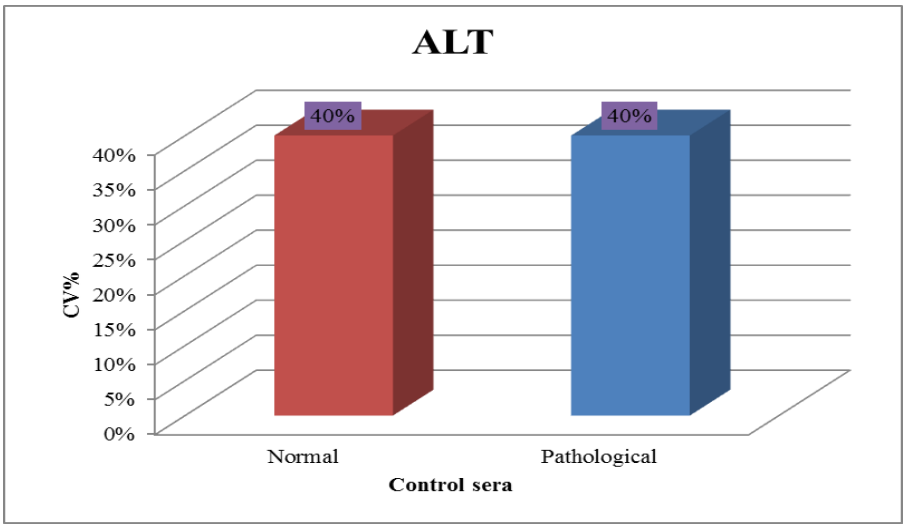

Figure (5): Shows the CV of normal and pathological ALT.

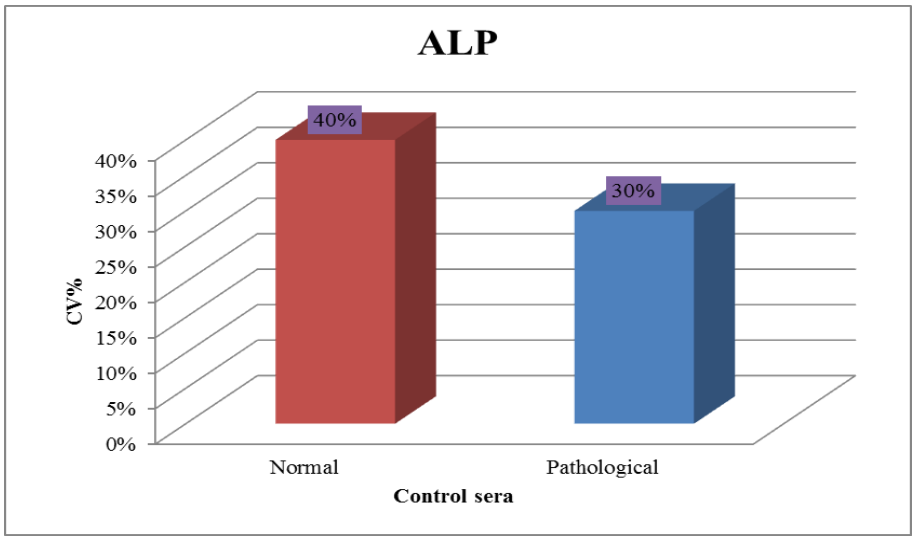

Figure (6): Shows the CV of normal and pathological ALP.

DISCUSSION

For normal control sera of liver enzymes, 10% of labs give excellent result(z score less than 0.5) due to they have implementation of quality control procedures, documentation and interpretation of control material result and the instrument used to measure Liver enzymes

is an automated machine, and calibration is doing daily by the senior staff. Only 20% of labs give satisfied result(z score more than0.5) during estimation of ALT and 0% during estimation AST and ALP, 30% of labs give acceptable result(z score more than1) during estimation AST and 0% during estimation ALT and ALP, 60% give poor result(z score more than 1.5) during estimation AST and 70% during estimation ALT and 90% during estimation ALP suspected random error. For pathological control sera 10% of labs give excellent result during estimation of AST, 30% during estimation of ALT and no excellent result for ALP this may occur due to improper calibration, reagent of ALP may be not valid and also may have a technical error. 40% of labs give satisfied result during estimation AST, 10% during estimation ALT and 30% during estimation ALP. only 10% of labs give acceptable result during estimation AST and no excellent result for ALT and ALP. 50% of labs gives poor result during estimation AST, 60% during estimation ALT and 70% during estimation ALP suspected random error. In spite of all these labs have Implementation of quality control procedures, Documentation and interpretation of control material results, and the instrument used to estimate liver enzymes is automated machine and calibration is doing daily by senior staff. There is a variation between AST, ALT and ALP analytical results among the normal and pathological level due to technical problems such as inappropriate sample handling, failure to calibrate pipettes. So agree with Zoe c (2007)[6] in seven laboratories using pooled patient samples (AST.ALT,ALP) and they revealed that variations in reference intervals significantly impact the clinical interpretation of laboratory results.[7]. Study conducted by Brooks, Zoe c (2007)[6] in seven laboratories using pooled patient samples(AST.ALT,ALP) and they revealed that variations in reference intervals significantly impact the clinical interpretation of laboratory results.[7] On aother study In 2002, the Institute for Reference Materials and Measurements (IRMM) surveyed approximately 900 global laboratories in an International Measurement Evaluation Program for two commonly measured enzymes in human serum [AST, ALT and ALP]. Results for AST and ALT showed biases of -60% to +30% and results for ALP showed a deviation from the enzyme certified value ranging from -50% to >250%! This large variation of results among laboratories may easily lead to a loss of information for clinicians.[8] On other study[9] a study involving 70 European laboratories assessed enzyme assays from six major manufacturers for traceability to IFCC RMSs through a commutable serum-based material targeted with ALT, AST, ALP. Results from commercial methods were assessed by a system using a maximum allowable error derived from the desirable analytical performance that is based on the biological variation model. Of these enzyme measurements, AST and ALT results were very good., only two company systems would fully comply. Finally, ALP measurements had still major drawbacks, suggesting need of major improvement. This was mainly the result of using methods with different analytical specificity for these enzymes.[8].

From the this study, it is recommended that, Improving the performance of laboratories is a continuous process, through a continuous program of education and training to the laboratory staff to be able to achieve the national and international levels. Inter laboratory standardization may be achievable by calibration to a standard assigned by a reference laboratory and distributed to all laboratories to control this variation. Application of a problem-solving process to investigate causes of this variation and provide guidance for laboratory staff in identifying contributing causes of error and appropriate corrective action. Comparing this unsatisfactory performance with the international level, emphasizes the need for more training of laboratory staff in this inquality control methodsto improve Quality Assurance practices in their laboratories. Participation in EQA program for continuous improvement process and to share experiences withother laboratories in their region.

CONCLUSION

From the results of current study, it is concluded that: A substantial degree of inter laboratory variation for selected biochemical measurements exists in laboratories of hospitals in Khartoum state. There is a variation extent between laboratories in testing process of the selected biochemical analyst; this may lead to difficulties in interpretation when an investigation is done by different laboratories in the same patient over time. There is an absence of QC program application within the periodically laboratory activities lead to unsatisfactory laboratories performance to produce accurate test results. There is a lack of awareness about the importance and benefits of QC program application among the laboratory staff to be applied within the daily laboratory activities. The capability of each laboratory to produce accurate test results is weak and incompatible when compare with the international levels.

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