

Aggressive Use of Diagnostic Services is Counterproductive

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Abstract

Background: Medical fraternity requisitions diagnostic tests for multiple reasons. More often than not, the tests lead to more tests either to exclude or to confirm doubts raised by the test results. These tests have an inherent morbidity, discomfort and cost. Growing expenditure on diagnostic tests without matching improvement in the health status warrants an internal audit of the laboratory utilization.

Methods: A retrospective utility audit was done for certain routinely advised laboratory tests at a hospital. Blood urea estimation in annual / periodic medical examination (AME/ PME), bleeding and clotting time in pre-anaesthetic check-up and aspartate aminotransferase (AST) and antibodies to hepatitis C virus (anti-HCV) in diagnostic work-up of acute onset jaundice were included in the audit.

Results: During the study period, 793 individuals underwent AME / PME and urea estimation did not provide any additional information in these cases which was not inferred by serum creatinine. Similarly, in diagnostic workup of acute onset jaundice, 6049 aspartate aminotransferase (AST) estimations in 1024 patients did not contribute anything more than what was inferred by alanine aminotransferase (ALT). Prevalence of anti HCV antibodies in acute onset jaundice in serving soldiers (11 out of 1225; 0.89%) though more than that in the blood donors from the same population (17 out of 4105; 0.41%) was less than anticipated false positives (18 out of 1225; 1.5%) as per the claimed specificity (98.5%) of the test kit. None of the 2766 bleeding and clotting time tests detected a bleeding or coagulation disorder.

Conclusion: The study reveals significant overuse of the laboratory that may not be good for the patient and the organization in terms of direct and indirect costs due to false positive results. This laboratory overload adversely affects the quality and availability of laboratory results. Therefore, a test should only be advised, if positive or negative result would dictate a change in patient management.

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Key Words: Laboratory overuse; Aspartate aminotransferase; Anti HCV; Bleeding time; Clotting time; Blood urea

Introduction

Laboratory services are as essential to the health and vitality of medical profession as the medical profession is to the health and vitality of society. No doubt, laboratory services account for a big chunk in the ever-fattening bill of medical care paid by the patient. Expenditure on diagnostic tests is growing without matching improvement in the health status suggesting that investigations are being overused [1].

Medical fraternity requisitions laboratory tests for screening risk factors in the population, differential diagnosis and staging of various diseases. Tests are also required for evaluation of severity, monitoring the course, estimating prognosis, detecting recurrence, selecting drug and adjusting therapy as part of management. Physicians sometimes order diagnostic tests to reduce the risk of malpractice liability without realizing that aggressive testing reduces the overall quality of patient care [2].

However, there is a price to be paid beyond the bleeding of the patient and his purse. Tests do have inherent morbidity (mortality?) and discomfort. More often than not, the tests lead to more tests either to exclude or to confirm doubts raised by the test results. Anxiety and cost involved in detecting inconsequential abnormalities and false positives is one more reason for us to redefine laboratory utilization.

The aim of the study was to audit the relevance and utility of specific laboratory tests in screening and diagnosis of disease. The screening tests audited were blood urea with serum creatinine estimation in annual and periodic medical examination and bleeding and clotting time in pre-anaesthetic check-up. Diagnostic tests audited were aspartate aminotransferase (AST), alanine aminotransferase (ALT) and anti hepatitis C virus (anti-HCV) antibodies in differential diagnosis and monitoring of acute onset jaundice.

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Material and Methods

We analysed indications and utility of the following routine laboratory investigations done in a large hospital.

- Blood urea and serum creatinine estimations being done as part of annual / periodic medical examination of personnel as per the existing orders. Blood urea was estimated by glutamate dehydrogenase-urease method (Erba Diagnostics Mannheim, Transasia) and serum creatinine by alkaline picrate method.
- Bleeding and clotting time being done for pre anaesthetic screening of bleeding and coagulation disorders. Bleeding time was done by Dukes method and clotting time by Dale and Laidlaw's capillary tube method.
- ALT, AST and anti-HCV testing in acute onset jaundice for hepatic damage assessment. ALT and AST estimations were done by UV- Kinetic (IFCC) method (Autopack, Bayer Diagnostics). Anti-HCV was detected by enzyme-linked immunosorbent assay (ELISA) kit (Zhongshan HCV, Zhongshan Biotech Co, China).

Symptomatic individuals and those with previous history of kidney disease were excluded while analysing blood urea and serum creatinine. Individuals with a known history of bleeding disorder or intake of non steroidal anti inflammatory drugs (NSAIDS) were excluded in the analysis of bleeding time and clotting time while old cases of hepatitis C were excluded from the analysis of anti-HCV testing.

Results

Blood urea and serum creatinine estimations were done in 793 individuals as part of annual/periodic medical exam. None of these individuals had serum creatinine in abnormal range (>1.5 mg/dl). Abnormal blood urea levels (>40 mg/dl) were found in 20 individuals. In these 20, a repeat estimation in basal conditions after ensuring hydration revealed normal values for urea as well as creatinine. Bleeding time and clotting time was normal in all the 2766 cases.

All patients with jaundice having bilirubin of more than 1.0 mg/dl and who underwent ALT and AST estimation were analysed. During the course of disease, 6049 paired ALT and AST estimations were done in these 1024 patients. The test results were ALT >100 & AST >100 IU in 1732 instances, ALT >100 & AST <100 IU in 762 instances, and ALT <100 & AST <100 IU in 3555 instances. No patient ever had ALT <100 & AST >100 IU. Therefore it can be inferred that AST estimation gave no additional information over ALT in acute onset jaundice.

Out of 1225 patients, 11 were positive for anti-HCV (0.89%), while the prevalence in blood donors from the same hospital was 17 out of 4105 (0.41%). Specificity of the ELISA kit in hospitalised patients as claimed by the manufacturers (Zhongshan HCV, Zhongshan Biotech Co, China) is 98.5%, suggesting a possible false positivity of 1.5% (100-specificity = false positivity). Thus observed prevalence of anti-HCV antibodies in jaundice patients, though more than that in the blood donors, is far less than anticipated false positives (18 / 1225) as per the claimed specificity of the test.

Discussion

As per the existing orders, healthy individuals in the armed forces are screened for kidney diseases by estimating blood urea and serum creatinine periodically.

Large number of variables affect blood urea estimation namely protein intake, state of hydration etc. Urea is predominantly handled by kidneys via re-absorption and filtration. Creatinine is formed at a relatively constant rate by muscle and its excretion is not routinely affected by diet. Estimation of serum creatinine has established methodology, reproducibility, accuracy and a defined reference range for the given population. Blood urea and serum creatinine estimations have independent indications in people with kidney disease. However, creatinine is a better indicator of overall functioning of kidneys in asymptomatic individuals. In this study blood urea estimation did not provide any additional information that was not inferred by serum creatinine in any individual. Therefore, routine testing of blood urea in periodic medical examination may be dispensed with, resulting in reduced cost and workload.

With normal platelet counts, the bleeding time should fall within the laboratory's established reference interval. The usefulness of bleeding time is less accurate in the frequently encountered haemostatic screening of asymptomatic patients. The predictive utility of relationship between platelet count and bleeding time also has been questioned [3]. A prospective study in 40 patients with negative history and no recent intake of non steroidal anti inflammatory drugs (NSAIDS) after coronary artery bypass surgery, found no predictive relationship between preoperative bleeding time test and either peri or post-operative bleeding [4]. This questions the utility of bleeding time estimation in asymptomatic patients with no history of bleeding tendency [5]. A normal bleeding time does not imply normal haemostasis and the results of the test do not correlate with bleeding at other sites [6].

In hepatitis the cardinal finding is rise of serum AST and ALT, where both become more than 200 IU/L. The AST/ALT ratio is close to one. AST and ALT catalyze reversibly the reductive transfer of amino group of either aspartate or alanine to alpha ketoglutarate to yield glutamate plus the corresponding keto acid of the starting amino acid. AST is ubiquitous in the body tissues including heart and muscle, where as ALT is found primarily in the liver. While 80% of AST is located in the mitochondria, ALT is non-mitochondrial. ALT is increased more than AST in patients of acute or chronic viral hepatitis and ALT activity is more specific in detecting liver disease in non-alcoholic patients. AST/

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