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RESEARCH ARTICLE

Clinical laboratory technician skill is one of a disease deciding factor on border line risk patients

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ABSTRACT

In this study clinical diagnostic error (pipetting error) was disclosed. These diagnostic errors cause serious problems on borderline risk patients. In this article glucose, cholesterol and urea content of the clinical serum was estimated and analysed the pipetting error. The under developed and the developing countries still use manual method of analysis/semi-autoanalyzer for the determination of glucose, urea, cholesterol and other biochemical components. So these manual errors make them to undergo treatment.

KEYWORDS: Diagnostic error, pipetting error, laboratory technicians, errorious treatment.

1. INTRODUCTION

Diagnosis errors are frequent and important, but represent an underemphasized and understudied area of patient-safety [1-3]. There is increasing evidence that the magnitude of failed, missed or delayed diagnosis is significant. According to a meta-analysis funded by the Agency for Healthcare Research and Quality, Gordon Schiff of the Dept of Medicine, Cook County Hospital in Chicago reported that most medical error studies find that 10–30% of errors are errors in diagnosis [4]. Medical laboratory plays a central role in the delivery of these services as over 70% of clinical decisions are taken based on laboratory reports [5]. The laboratory and hospital need to design systems that reduce the possibility of errors and to rapidly identify and resolve the errors that do occur. Because the pre- and post-analytical processes extend into the clinical operations of the hospital, the laboratory can play an important role in promoting patient safety by assisting clinicians with test ordering, communicating test results appropriately and aiding in the interpretation of results [6].

Two major types of errors may occur in a laboratory: Random errors that arise due to inadequate control on pre-analytical variables, patient identity, sample labelling, sample collection, handling and transport, measuring devices etc. Systemic errors that occur due to inadequate control on analytical variables; e.g. due to error in calibration, impure calibration material, unstable/ deteriorated calibrators, unstable reagent blanks etc. There has been a steady improvement in the quality of tests due to improved technology. Laboratory automation has also taken on a new level of importance in improving quality. Automation in clinical laboratory is a process by which analytical instruments perform many tests with the least involvement of an analyst. In fully automated machines, analysis was carried out with any number of selected tests on each sample. In Semi-auto analyzers, the samples and reagents are mixed and read manually. In

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developing and under developed countries, all laboratories were not equipped with semi-autoanalyzer/auto analyzer. In these countries, most of the small laboratories depend on manual experiments using spectrophotometer/colorimeter, subsequently lab technician's technical skill play a vital role on disease diagnosis. It is too common to investigate the glucose, cholesterol and urea content of the patients in these laboratories. So, the present study was undertaken to disclose the possible diagnostic error (pipetting error) by clinical laboratory technicians.

2. MATERIALS AND METHODS:

2.1. Samples:

The clinical serum samples were obtained from Joyce Laboratory, Kanyakumari, India. About 1.0 ml of blood was collected from the individuals and centrifuged at 5000 rpm for 10 min and the serum was separated. This was stored as aliquots at -20 °C for further use. Fresh serum was always used for glucose determination.

2.2. Determination of glucose, cholesterol and urea:

The clinical diagnostic kits (glucose, cholesterol and urea) were obtained from Aspen Laboratories, New Delhi, India. Experiments were performed as per manufacturer's instructions. All experiments were conducted in triplicates and the average values were recorded. In the present study various standard volume (8-12 µl) and serum volume (8-12 µl) were used for the determination of glucose, cholesterol and urea content of the clinical specimen.

2.3. Clinical significance of glucose, cholesterol and urea:

Measurement of glucose concentration in serum or plasma is mainly used in diagnosis and monitoring Diabetes mellitus. Other applications are the detection of neonatal hyperglycemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrates metabolism in various diseases [7]. Diabetes is rapidly emerging as a major health-care problem in India, especially in urban areas where the prevalence of Type 2 diabetes has been reported as 12% of the adult population [8]. Determination of cholesterol in serum is strongly associated with coronary heart diseases [7]. Urea is the nitrogen-containing end product of protein catabolism. Status associated with elevated levels of urea in blood is referred to as hyperuremia or azotemia. In renal diseases urea concentrations are elevated when glomerular filtration rate is markedly reduced and when the protein intake is higher than 200 g/day [7].

3. RESULTS AND DISCUSSION:

For serum glucose determination 1.0 mL blood was drawn and analysed it's serum glucose content. The serum glucose value was 110 mg/dL. For every microliter of serum glucose the variance made was 11±0.012 mg/dL. The serum glucose content was 150.7 mg/dL, if the sample and standard volume were 11 and 8 µl, respectively. The reference range of glucose was 70-115 mg/dL [7]. But the glucose content exceeded 120 mg/dL in 9 positions in the Table 1. In clinical biochemical kits, the recommended sample/standard volume (Enzymatic method) was 10 µl in most of the cases, here, 10 ± 2 µl error is possible. So in the present study these error limits (10 ± 2 µl) were considered. Based on the results presented in the Table 1, false hyperglycemic condition was created in the clinical specimen.

Sample Volume (µl)	Standard volume (µl)				
	8	9	10	11	12
8	106	97.9	86.2	79	70.8
9	**121.2**	111.5	98.1	90.48	80.6
10	**135.9**	**125**	110	101.5	90.4
11	**150.7**	**138.5**	**122**	112.5	100
12	**160**	**147**	**129**	119	106

Table.1 Glucose content of the serum in comparison with different sample/standard volume
 # The significant errors are indicated by bold letters

Sample Volume (µl)	Standard volume (µl)				
	8	9	10	11	12
8	180	159	140	125	122
9	**215**	191	167	150	146
10	**236**	**209**	183	164	160
11	**259**	**229**	**201**	180	175
12	**278**	**246**	**215**	194	188

Table. 2 Cholesterol content of the serum with various volumes of sample and standard
 # The significant errors are indicated by bold letters

Sample Volume (µl)	Standard volume (µl)				
	8	9	10	11	12
8	34	30	27	23	22
9	40	35.1	31.61	27.9	26.7
10	**44**	40	35	31	30
11	**50**	**43**	39	34	33
12	36	**47**	**42**	37	36

Table. 3. Urea content of the serum with various volumes of sample and standard
 # The significant errors are indicated by bold letters

The cholesterol content of the experimental serum was 186 mg/dL. But every microlitre variance of sample showed 18 ± 0.009 mg/dL difference. The calculated value the cholesterol content was 278.49 mg/dL with the sample volume 12 µl and the standard volume 8 µl. On the other hand the cholesterol content was 122 mg/dL if the sample volume is 8 µl and standard volume is 12 µl. The reference range for cholesterol is less than 200 mg/dL and 200-240 mg/dL indicated borderline high risk [9]. The tabulated cholesterol content exceeded 200 mg/dL in 8 places in the Table. 2. This kind of result may force doctors to initiate treatment.

The urea content of the experimental serum was 35 mg/dL. Every micro litre pipetting error showed 4.5±0.0076 mg/dL increase/decrease value of urea. According to the tabulated value the urea content was 49.4 mg/dL if the sample volume was 11 µl and the standard volume was 8 µl. On the other hand the tabulated urea content was 44.5 mg/dL if the sample volume was 10 µl and standard volume was 8 µl. The reference range of the blood urea was 19-44 mg/dL [7]. The tabulated urea content exceeded 40 mg/dL in 7 places in Table. 3. To conclude, laboratory technician skill (pipetting skill) is one of a disease deciding factor. The under developed and the developing countries still use manual method of analysis/semi-autoanalyzer for the determination of glucose, urea, cholesterol and biochemical components. To avoid these kinds of false positive/negative results, need to repeat the experiments in triplicates with the clinical specimen and with the standard also.

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