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Original Article

A Comparative Study on Instrumental Precision of Refrigerated and Non-Refrigerated Auto-Analyzers in Order to Improve Quality Assurance in Biochemistry Laboratory

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ABSTRACT

Background and Objective: **Quality control is one of the most important components in order to improve quality assurance in laboratories during analytical steps. For this purpose, coefficient of variation plays an important role. Due to the fast improvement in technology, application of inferential statistics for the comparisons of laboratory techniques, including instrument and chemicals and fast replacement of them would be technically essential.**

Materials and Methods: **In this research study, we tried to determine the precision of one auto-analyzer with refrigerator and the other one without such facility for the analysis of glucose, triglyceride and cholesterol in 30 successive days and compared the coefficient of variations that are an important factor for analytical precision.**

Results: **Comparing the means of aimed groups by paired t-test with P=0.05 in measurement of glucose, triglyceride and cholesterol showed that there was no significant difference between the two instruments. In determination of glucose, triglyceride and cholesterol by auto-analyzer with refrigerator, CV% of these analytes was 1.3%, 1.4%, and 0.9% respectively. By the auto-analyzer without refrigerator, the CV% of those analytes was 1.5%, 2.5% and 1.11% respectively.**

Conclusion: **There is reasonably higher precision for auto-analyzer with refrigerator than the other one.**

Key words: Refrigeration, Quality assurance, Instrument, Glucose, Triglyceride, Cholesterol

Introduction

The aim of the clinical laboratory is the acceptance or rejection of medical diagnosis, follow up, determination of prognosis, progression of disease, screening, and assisting the physicians. Quality control and achievement of these aims is related to the accuracy and precision in the laboratories (1), and then the triple activities in the laboratories should be assured in the pre-analytical, analytical and post-analytical steps. Quality control in the analytical step is very important in quality assurance and in this stage evaluation of instrumental analytical precision is very significant (2). Due to the fast improvement in technology, application of inferential statistics for the comparison of laboratory techniques including

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instrumentation and chemicals and fast replacement of them would be very essential. Currently, different types and models of auto-analyzers are being used in clinical laboratories, some of which have refrigerator and some without refrigerator.

In this research study, we tried to determine the precision of two more popular auto-analyser systems which are similar in all instrumentation and mechanical equipment except in refrigerator for the analysis of glucose, triglyceride and cholesterol and then to compare the results.

Materials and Methods

In this study, the lyophilized qualified controls of Randox Company in level II (with red caps) were used. At first, vial of lyophilized control material mixed up with 5 ml of distilled water for 30 minutes without shaking. The dried lyophilized substances were dissolved completely and a homogenous solution was created. Then, 1 ml of prepared qualified controls was aliquoted in 30 cups of each auto-analyzers, refrigerated (Lyasis) and non-refrigerated (Technicon RA-1000). The cups were covered with parafilm to prevent evaporation and over-concentration of the samples. The cups were freezed in -20^{0}C. Freezer temperature was daily controlled. Next, glucose, triglyceride and cholesterol levels were determined for 30 days by the enzymatic methods with refrigerated and non-refrigerated auto-analyzers. Kits and calibrators for measuring these analytes provided from Pars-Azmoon Co (Iran). After gathering 30 control results in related analytes by the two aimed analyzer after the omission of outlier counting (3), the mean and standard deviation was calculated.

Results

For assessment of precision in each group and analyte, standard deviation and coefficient of variation was calculated (Table 1). Comparing the means by paired t-test with p=0.05 showed that there is no significant difference between the two auto-analyzers (Table 1). Coefficient of variation for glucose, triglyceride and cholesterol with non-refrigerated auto-analyzer were 1.5%, 2.5%, and 1.11% and with refrigerated auto-analyzer were 1.3%, 1.4%, and 0.9% respectively.

Discussion

Method and instrumental selection and evaluation are two cardinal steps in establishing and ensuring high quality laboratory services. Before a new or improved method or instrument is introduced into a laboratory, it must be selected with care and its performance must be rigorously and impartially evaluated under laboratory condition.

Due to the fast improvement in technology, applic-ation of inferential statistics for comparison of laboratory techniques including in-strumentations such as refrigerator and chemical and fast replacement of them would be essential.

There are several studies on comparison of laboratory instruments and auto-Analyzers (4-9).

The studying of instrumental precision in determination of different analytes is one of the principal investigations of quality control in analytical steps and is shown by coefficient of variation (CV%). According to Westguard and Barnett suggested method, coefficient of variation should not be more than one forth of fixed limits goals of CLIA (10) and according to CLIA recommendation for the precision, the maximum standard deviation for glucose, triglyceride and cholesterol is 3.15 mg/dl, 10 mg/dl and 5 mg/dl respectively (11). In this study, no standard deviation was more than the permitted levels and the two aimed auto-analyzers showed the proper precision (Table1). Based on national cholesterol education program guidelines (NCEP) for determining lipids including cholesterol and triglyceride and lipoproteins, the coefficient of variation (CV %) should be less than 3% to 5% respectively (12). Also, the CV% of none of the groups exceeded more than NCEP guidelines. Analyzing the means by paired t-test with p=0.05 for evaluation of glucose, triglyceride, and cholesterol by enzymatic methods showed that there was no significant differences by refrigerated and non-refrigerated auto-analyzers.

Conclusion

By refrigerated auto-analyzers, coefficient of variations (CV%) for glucose, triglyceride and cholesterol were 1.3%, 1.4%, and 0.9% respectively and by non-refrigerated auto-analyzer, the CV% of those analytes was 1.5%, 2.5% and 1.11% respectively. Thus, there is more precision for refrigerated auto-analyzer than non-refrigerated one.

Table 1. Comparison of standard deviation, coefficient of variation, and P-value in determination of glucose, triglyceride and cholesterol by auto-analyzers of Technicon RA-1000 and Lyasis

Analytes	Non-refrigerated analyzer			Refrigerated analyzer			P -value
	mean (mg/dl)	S.D(mg/dl)	CV%	mean (mg/dl)	S.D (mg/dl)	CV%	
Glucose	87.8	1.30	1.50	88.2	1.2	1.3	1.18*
Triglyceride	90.4	2.30	2.50	91.0	1.3	1.4	1.47*
Cholesterol	163.0	1.81	1.11	162.8	1.5	0.9	0.42*

* There is no significant difference

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