Theme 6: Laboratory diagnosis and Pharmaceuticals OP32

Comparative analysis of total cholesterol POCT device and standard enzymatic method for total cholesterol measurement among healthy adults at Faculty of Allied Health Sciences, University of Jaffna

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Introduction and Objectives: Total cholesterol (TC) is a screening marker for dyslipidemia related disease conditions. Regular monitoring of cholesterol was recommended for the early detection and initiating of treatment for hyperlipidemia. Lately, Point of care testing (POCT) devices with dry chemistry-based test strips became popular for the *in-vitro* measurement of cholesterol, due to its simplicity, portability, and rapid display of reliable results. When choosing a cholesterol POCT device, its accuracy is considered relative to clinical laboratory measurements. This study aimed to compare the commercially available cholesterol POCT device and reference enzymatic method (EZ) using a spectrophotometer for the measurement of TC.

Methods: A total of 66 venous and capillary blood samples were collected from healthy, voluntary participants from the Faculty of Allied Health Sciences, University of Jaffna, through a random sampling method. TC levels were measured on capillary blood using POCT device strips based on enzymatic hydrolysis methodology. Serum TC was determined using a spectrophotometer on the same day using the enzymatic method. The agreement between both methods was statistically evaluated using paired sample t-test and Pearson correlation.

Results: The mean (±SD) of TC by POCT device and EZ were 165.41±26.352 mg/dl and 164.89 ± 25.702 mg/dl, respectively. The mean difference was 0.515 (p=0.324), and it was not statistically significant (p>0.05). There was a strong positive correlation between both methods, and it was statistically significant (r=0.987, p<0.001). The analytical imprecision (2.5%), bias (0.351%) and total error (8.77%) were within the acceptable limits of the National cholesterol education program guidelines (NCEP). The overall total misclassification rate was 9.09%, and the misclassification rate was generally higher for lower value categories.

Conclusion: TC measured by the POCT device and EZ method showed a smaller mean difference, and results support the commutability of both methods. The EZ method manifested a strong positive correlation and a strong agreement with the POCT device, and it meets the limits of analytical acceptability by the NCEP. It indicates the possibility to use the POCT device as an alternative for the EZ method and benefit in large scale population-based screening studies, self-monitoring, fieldwork, and resource-limited settings.

Keywords: Total cholesterol, Point of care testing device, Enzymatic method.