Establishment of reference interval for selected clinical chemistry parameters in apparently health adult in sekela and burie woredas, Ethiopia

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Abstract

Background: Clinical laboratory reference ranges are vital events for clinical diagnosis, prognosis, treatment, and monitoring of any health complications. So locally established reference range is required to correctly interpret clinical laboratory results. So this study aimed to determine reference interval for selected biochemical tests for apparently healthy participants in Sekela and Burie Woredas, North West Ethiopia.

Methods: A community-based cross-sectional study was conducted among apparently healthy individuals in Sekela and Burie Woredas, Ethiopia from December 2019 to June 30, 2020 on a total of 360 healthy participants. The analysis was done with the Biosystem 25; a fully automated clinical chemistry analyzer. The data was analzed using SPSS software. By use of Clinical Laboratory and Standards Institute (CLSI) guidelines, we determined reference ranges, at 95% reference intervals, following specific exclusion criteria.

Result: This study observed statistically significant differences between males and females in serum total cholesterol, serum triglyceride, LDL, urea and creatinine Reference intervals. The established reference intervals for females and males, respectively, were: LDL (mg/dl) 70.0-161.3 vs. 90.0-197.4, serum total cholesterol (mg/dl) 95.0-152.4 vs. 105.0-200, serum triglyceride (mg/dl) 75.4-152.0 vs. 100.4-176.7 mg/dl, blood urea nitrogen (mg/dl) 11-29.4 vs. 9.9-28, and serum creatinine (mg/dl) 0.54-1.1 vs. 0.61-1.2. The combined RIs for high density lipoprotein were 42-84.3 mg/dl, FBS 68-115 mg/dl.

Conclusion: The result the current study indicated that significant difference was among sex, with other studies done in Africa and Europe and with the company derived reference interval values for selected clinical chemistry parameters. Due to this fact, use of age and sex specific locally established reference intervals for clinical chemistry parameters is recommended.

Quality control:

To ensure accuracy; each activity including taking clinical information, blood sample collection, transportation, and storage were based on Good Laboratory Practices (GLP) using Standard Operating Procedures (SOPs). Also, the accuracy and precision of the test results, all pre-analytical, analytical, and post analytical precautions were carefully controlled. Besides, to maintain internal quality control, the equipment had been calibrated monthly by the type-Auto calibrator. Also, two levels (normal and pathological) of Internal Quality Control (IQC) samples were run along with the serum sample. The control sample results were to be interpreted using the Westgard multirule algorithm. The sample was analyzed after well understood the leaflet for each analyte by the principal investigator and senior laboratory technologists.

About 10 ml of the blood sample was collected from each study participant using an SST tube in the morning from 7:30 AM to 10:00 AM. The collected blood samples were centrifuged at 2500 rpm (revolution per minute) for 5 minutes at the site laboratory department to separate serum from the whole blood. Then the separated blood sample was analyzed for the selected clinical chemistry tests by using bio system 25 A (Bio system, Spain), a fully automated clinical chemistry analyzer. The selected parameters were analyzed by using preferable methods of analysis for all selected analytes.

Biography

It have more than 15 years of experience in medical and Pharma (incl. targeted therapy or immunotherapy) as well as other fields.