LETTER TO THE EDITOR

# Reference Intervals of Certain Liver Specific Biochemical Analytes in Indian Population

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**Dear Editor**

Most of the laboratories, all over the world consider that Reference Intervals (RI) in vogue are either inaccurate or in-appropriate for the population they serve and needs updation. The IFCC has also stressed upon that every laboratory must have their own set of reference limits. The recent Clinical and Laboratory Standards Institute (CLSI)/ International Federation of Clinical Chemistry (IFCC) document is an excellent aid for design and implementation of such studies [1]. Most of the laboratories in India follow RI available in literature which is based on Western population. These RI can be questioned because of differences arising due to variations in diet, life style and environmental conditions and ethnicity related variations. There is hardly any documentation regarding RI of liver specific biochemical parameters in North Indian population. In view of this, we examined RI of liver specific biochemical analytes in North Indian population using IFCC/CLSI guidelines [1].

The present study was conducted on 2,021 apparently healthy individuals of North Indian origin ranging in age 20–60 years selected randomly using defined criteria, out of which 494 were excluded using appropriate exclusion criteria defined by IFCC and NCCLS [1]. Finally 1,527 individuals were included in present study.

After an overnight fasting, venous blood was drawn from antecubital vein using aseptic technique. Samples were analysed for liver specific biochemical parameters using standard methods on fully autoanalyzer Olympus AU–400 after proper standardization with the help of calibrators and quality of tests was ensured by using internal and external quality controls. Data were analyzed for middle 95 percentile (2.5th–97.5th percentile), median and 95% confidence interval using SPSS software package version 10.0 [4].

The results of our study are depicted in the Table 1 as shown below.

The upper and lower limit of RI (Reported vs. Observed) for Bilirubin (0–1.2 vs. 0.30–1.30), SGOT (0–40 vs. 13–52.80), SGPT (0–50 vs. 10–68), ALP (110–310 vs. 107–361.80) showed wide variation as compared to reported standard RI while GGT (0–50 vs. 5.00–50.60) which is related to biliary disease and marker for alcoholism remained within the reported standard RI. For both enzymatic and non enzymatic biochemical parameters upper cutoff value was greater in males (SGOT 14–55, SGPT 11–70.35, GGT 6.76–51.09, Bilirubin 0.40–1.34) as compared to females (SGOT 13–50.43, SGPT 9–63.43, GGT 3.92–48.70, Bilirubin 0.30–1.20) (Table 1). Our findings are though consistent with studies conducted in south Indian population by Sultana et al. and Ashavaid et al. to the extent that upper cut off for most of the parameters was higher than the reported RI. However cut off for SGOT, SGPT and GGT in present study was lower as compared to values reported by Sultana et al. [2] and Ashavaid et al. [3]. The variations in findings may be attributed to differences in size and habitat (rural/urban) of reference population, dietary habits, life style and climatic conditions.

With respect to age a progressive narrowing of reference interval of bilirubin was observed, this may be attributed to

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**Table 1** Reference interval of liver specific biochemical analytes in Indian population

| Parameters | Percentile | Total bilirubin | Direct bilirubin | SGOT | SGPT | ALP | GGT | Protein | Albumin |
|---|---|---|---|---|---|---|---|---|---|
| Reported values | 2.5 | 0.00 | 0.00 | 0.00 | 0.00 | 110.00 | 0.00 | 6.00 | 3.50 |
| | 97.5 | 1.2 | 0.40 | 40.00 | 40.00 | 310.00 | 50.00 | 8.00 | 5.00 |
| All subjects | 2.5 | 0.30 | 0.10 | 13.00 | 10.00 | 107.00 | 3.50 | 6.00 | 3.50 |
| | 97.5 | 1.30 | 0.50 | 52.80 | 68.00 | 361.80 | 5.00 | 8.00 | 4.90 |
| Male | 2.5 | 0.40 | 0.10 | 14.00 | 11.00 | 116.30 | 6.76 | 6.37 | 3.60 |
| | 97.5 | 1.34 | 0.50 | 55.00 | 70.35 | 388.00 | 51.09 | 8.30 | 4.80 |
| Female | 2.5 | 0.30 | 0.10 | 13.00 | 9.00 | 100.58 | 3.92 | 6.50 | 3.40 |
| | 97.5 | 1.20 | 0.50 | 50.43 | 63.43 | 323.00 | 48.70 | 8.30 | 4.60 |
| Age <20 years | 2.5 | 0.40 | 0.10 | 15.00 | 12.00 | 118.00 | 2.30 | 6.50 | 3.80 |
| | 97.5 | 1.50 | 0.50 | 50.00 | 56.00 | 622.00 | 48.43 | 8.20 | 4.70 |
| Age 20–40 years | 2.5 | 0.30 | 0.10 | 13.00 | 9.50 | 103.58 | 6.00 | 6.40 | 3.5 |
| | 97.5 | 1.30 | 0.50 | 52.00 | 71.00 | 328.00 | 52.00 | 8.30 | 4.70 |
| Age 41–60 years | 2.5 | 0.35 | 0.10 | 13.00 | 10.20 | 114.20 | 5.00 | 6.40 | 3.50 |
| | 97.5 | 1.20 | 0.50 | 54.80 | 65.00 | 318.00 | 54.00 | 8.30 | 4.70 |

Table depicts comparison of 95% reference interval of liver function test parameters in Indians

decreased efficiency of liver functioning with advancing age. For liver specific enzymes, a mild to moderate increase in cutoff values of lower and upper limits of RI was noticed with progression of age except for ALP which showed reverse trend. These findings are consistent to findings observed by other workers [2, 3]. The increase in reference interval of SGPT was more pronounced in age group 20–40 years as compared to age groups 41–60 years. This may be because of irregularity in daily activities and life style in younger age group (Table 1).

In view of this it may be surmised that every laboratory should develop their own RI for various biochemical analytes for improving patient care.

## References

1. IFCC&CLSI C28-P3: Guideline for defining, establishing, and verifying reference intervals in the clinical laboratory; proposed guideline—third edition.
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3. Ashavaid TF, Todur SP, Dherai AJ. Establishment of Reference Intervals in Indian Population. Ind J Clin Biochem. 2005;20(2):110–8.
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