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Selected Biochemical Values of Suitable Blood Donors at Kenyatta National Hospital

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Abstract

Background: Clinical values derived from groups of apparently normal individuals are used for the determination of reference ranges. Only individuals with good health are recruited as blood donors and so can form a suitable cohort for the development of reference intervals. Reference intervals are necessary in interpreting and making critical decisions in diagnostic and research purposes. In this cross-section study, male and female selected biochemical values were determined on blood donors attended to at Kenyatta national Hospital donor unit. *Objective*: To determine gender-based means, medians, 2.5th and 97.5th interquartile ranges of: aspartate transaminase, alanine aminotransaminase, gamma-glutamyl transaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, and creatinine. *Methods*: A total of 202 blood donors aged between 18 and 60 years were recruited for the study. Of these 108 (53.5%) were females and the rest males. Social demographic data of the participants was captured in structured questionnaire form. Blood samples for the analytes were collected from the participants into red capped vacutainer for serum extraction. Serum samples were stored at ≤−18˚C till testing. Analysis was done using standard laboratory methods. Obtained data was entered into SPSS version 21 where statistical analysis was done. Bootstrap methods were used to calculate means, medians and confidence intervals. The fit of distribution of the obtained data was determined using Shapiro-Wilk test with $P > 0.05$ indicating Gaussian distribution. Means, medians and 2.5th and 97.5th interquartiles were determined. Gender-based differences were compared using Wilcoxon rank-sum test; P value of less than 0.05 was considered significant. *Results*: Recruited males were majorly either in business or in formal employment (35.1%) and had tertially education (51.1%); while females were in business (45%) and had tertially education (43.5%). Males demonstrated significantly higher median values than females in: aspartate transaminase (AST), alanine aminotransaminase (ALT), alkaline phosphatase (ALP), total bilirubin (T.Bil), direct bilirubin (D.Bil), albumin (ALB) and creatinine (CRT). Conversely, females dem-

onstrated significantly higher values in total protein (TP). *Conclusion:* There exist gender-based disparities in biochemical reference intervals that need to be considered in the interpretation and making of accurate decisions in clinical practice and in research.

Subject Areas

Immunology

Keywords

Biochemical Values, Blood Donors, Kenyatta National Hospital

1. Introduction

Factors such as race, geographical locations, sex, altitude, climate, diet, and environment influence reference ranges of biochemical values [1] [2] [3]. These ranges are used in making critical decisions on laboratory results for both diagnosis and determination of therapeutic outcomes. Levels of biochemical values may be indicators of functional disorders of various body systems and organs. For example, liver function state can be assessed by measuring serum levels of: alanine aminotransaminase (ALT), aspartate transaminase (AST), gamma-glutamyl transaminase (GGT), alkaline phosphatase (ALP), total bilirubin (T.Bil), direct bilirubin (D.Bil), total protein (TP) and albumin (ALB) among others. Conversely, kidney function can be assessed by determining serum levels of creatinine (CRT) and urea [4]. Results of these assays should be compared with the reference ranges of the respective parameters in order to ascertain whether the functions of these organs are deranged or not. Incidentally, these ranges are not universally the same. For example, people of African descent have been shown to have higher ranges in ALT, AST, ALP, TP, ALB, and CRT than the Caucasians [5]. There are significantly higher median values in ALT, GGT, TP, ALB in males below 60 years than those above 60 years, but significantly lower values in T.Bil, D.Bill. Females below 60 years have demonstrated lower AST, ALT, GGT, ALP and TP median values but higher ALB, T.Bil and D.Bil than those above 60 years [6]. Significantly higher median values in males than in females have been demonstrated in: AST, ALT, ALP, GGT, T.Bil, D.Bil, Urea and CRT [7]. There is seasonal variation in biochemical values in which significant decreases in AST, ALT and T.Bil, median values between dry- and rainy-seasons among Guneans aged between 6 and 45 years have been demonstrated. In the same study, gender-based disparities were demonstrated in different age groups with males demonstrating significantly higher AST, ALT and CRT median values [8]. With the background of such variations, the recommendation for national and regional based biochemical reference intervals is justified [9]. Further to this pursuit, the current study aims at determining reference intervals for routinely evaluated biochemical values that can be used for diagnosis and research in the set-

tings of the study.

2. Materials and Methods

2.1. Ethical Statement

The Ethics and Research Committees of Kenyatta National Hospital-University of Nairobi (KNH-UoN) approved the study protocol.

2.2. Study Design, Setting and Population

This was a cross section study carried out on blood donors attended to at Kenyatta national Hospital, Kenya between 2018 and 2019. A total of 202 adults aged between 18 and 60 years were consecutively recruited into the study. Female participants comprised of 108 (53.5%) and the rests were males. The social demographic characteristics were captured in a structured questionnaire form adopted and modified from the hospital donor recruitment form. Five milliliters of blood samples were obtained from each enrollee into plain vacutainers for serum extraction. Serum samples obtained by centrifuging clotted blood samples were stored frozen in plastic vial at ≤−18˚C till analysis.

2.3. Experimental Procedures

The biochemical tests were done on fully automated, HUMASTAR, 600® analyzer. The analyzer was quality controlled using trilevel controls (low, normal and high) for each analyte. The reagents for: ALT, AST, ALP, GGT, T.Bil, D.Bil, TP, ALB, CRT and UREA were positioned in the analyzer. The analyzer mixed the samples and the reagents, incubated, read the absorbance at appropriate wavelength, displayed the results and printed them automatically. Test serum sample were run after commercial controls met the manufacturer's recommended ranges (**Appendix 1**).

2.4. Statistics

The raw data was entered into excel computer data base for cleaning and verification. The data was then transported into statistical package for the social sciences (SPSS) version 21 for analysis. The fit of the observed distribution was determined using Shapiro-Wilk tests with $P > 0.05$ being considered significant. Bootstrap parametric and non-parametric methods were used to calculate means and medians to raise the power of the low sample sizes [10]. Medians were used to describe non-parametric parameters, while means and standard deviations were used to describe data with Gaussian distribution. Wilcoxon rank-sum test was used to compare male and female median values.

3. Results

The enrollees were majorly in business and held tertially level of education as shown in Table 1.

Males demonstrated significantly higher median values than females in AST

Table 1. Social demographic characteristics of the study participants.

Gender	Variable									
	Age	Education				Vocation				
	Mean (±SD)	None F (%)	Primary F (%)	Secondary F (%)	Tertially F (%)	None F (%)	House/wife F (%)	Student F (%)	Business F (%)	Employed F (%)
Combined (n = 202)	31.88 (9.25)	1 (1)	25 (12.3)	81 (39.9)	95 (46.8)	3 (1.5)	12 (5.9)	53 (26.2)	81 (40.6.6)	53 (26.2)
Male (n = 94)	31.91 (9.66)	0	7 (7.4)	39 (41.5)	48 (51.1)	0	0	28 (29.8)	33 (35.1)	33 (35.1)
Female (n = 108)	31.85 (8.92)	1(1)	18 (16.7)	42 (38.9)	47 (43.5)	3 (2.8)	12 (11)	25 (22.9)	49 (45)	20 (18.3)

F = Frequency.

(26 u/l vs 24 u/l, $p = 0.001$), ALT (18 u/l vs 13 u/l, $p < 0.001$), ALP (99 u/l vs 84 u/l, $p < 0.001$), T.Bil (7.01 μmoles/l vs 5.49 μmoles/l, $p = 0.004$), D.Bil (3.42 μmoles/l vs 2.5 μmoles/l, $p < 0.001$), ALB (45 g/l vs 41 g/l, $p < 0.001$) and CRT (97 mmoles/l vs 86 mmoles/l. $p = 0.001$). Females demonstrated significantly higher TP median values than males (77 g/l vs 69 g/l, $p < 0.001$). This is shown in Table 2.

4. Discussion

Significantly higher median values in males than in females demonstrated in AST, ALT, ALP, T.Bil, D.Bil and ALB and CRT in the current study have been reported also by Kibaya *et al.* (2008) among 1020 males and 521 females from different ethnic people groups residing in Kericho situated 2042 m above sea level and lying 260 km northwest of Nairobi. The results of UREA were however, not comparable in the two studies as gender-based significant difference was only demonstrated in the current study [11]. These findings clearly show that the observed gender-based differences in biochemical parameters were not tagged to the studied sample sizes or altitude. Sex hormones play major roles in the various aspects of reproduction, differentiation, growth and homeostasis in influencing development of specific gender-traits and consequently, influencing the regulation of structure and function of nearly all tissues and organs [12]. Thus their role in the observed differences in the biochemical parameters may not be exonerated. Specifically, estrogen has been reported to have protective role against cardiovascular diseases in premenopausal females when compared to age-matched males, and to postmenopause females [13]. Moreover, there are reported increases in urea, Lactate dehydrogenase and ALP values in Caucasian females above 48 years which is considered as menopausal transition period [14] [15] when levels of estrogen start declining compared with the values of those below 45 years [16]. This observation supports the role of sex hormones in influencing the levels of biochemical parameters. Contradicting reports of insignificant differences between males and females in ALT, AST ALP and TP values

Table 2. Means, medians, SD, modes, Ranges, 2.5 - 97.5 percentiles Z-value, p-value of females and males AST, ALT, G-GT, ALP, T.Bil, D.Bil, TP, ALBUREA & CRT values.

Parameter	Sex	N	Mean	SD	95% CI	p-value	Mode	Median	2.5th - 97.5th
AST u/l	Combined	202	26.13	8.47	24.95 - 27.30	**0.001**	22	25	14.0 -46.62
	Female	108	24	7	23.1 - 25.6		22	24	14.0 - 42.0
	Male	94	28	10.00.	26.1 - 30.2		24	26	16.0 - 64.0
ALT u/l	Combined	202	17.87	11.28	16.31 - 19.44	**<0.001**	13	15.5	5.0 - 48.9
	Female	108	15	8	13.3 - 16.3		13	13	4.0 - 38
	Male	94	21	13	18.5 - 24.1		17	18	7.0 - 70.0
G-GT u/l	Combined	202	26.83	21.88	23.8 - 29.9	0.902	15	21	7.0 - 92.6
	Female	108	26.6	20.5	22.7 - 30.6		15	22.5	7.0 - 102.0
	Male	94	27	23.5	22.2 - 31.8		17	20	7.0 - 138.0
ALP u/l	Combined	202	92.1	35.89	87.0 - 97.0	**<0.001**	83	88	30 - 171.3
	Female	108	83.5	34.5	77.0 - 90.0		53	84	21.0 - 172.0
	Male	94	101.9	35.1	95.0 - 101.0		83	99	31.0 - 187.0
T.BIL µmoles/l	Combined	202	7.13	3.77	6.61 - 76.5	**0.004**	4.57	6.25	2.6 - 18.7
	Female	108	6.43	3.19	5.8 - 7.0		4.51	5.49	2.15 - 14.56
	Male	94	7.94	4.23	7.1 - 8.8		8.13	7.01	2.86 - 22.05
D.Bil µmoles/l	Combined	202	3.14	1.51	2.93 - 3.34	**<0.001**	1.71	2.81	1.71 -6.88
	Female	108	2.73	1.04	2.5 - 2.9		1.71	2.5	1.71 - 5.47
	Male	94	3.6	1.8	3.2 - 4.0		1.71	3.42	1.71 - 11.58
TP g/l	Combined	202	73.54	10.205	72.1 - 75.0	**<0.001**	71	72	57.0 - 96.0
	Female	108	77	11	74.9 - 79.2		71	77	58.0 - 104.0
	Male	94	69	7	68.1 - 70.9		68	69	57.0 - 87.0
ALB g/l	Combined	202	43.94	4.98	43.2 - 44.6	**<0.001**	41	44	36.0 - 53.0
	Female	108	42	5	41.5 - 43.4		41	41	34.0 - 53.0
	Male	94	46	4	47.7 - 46.6		44	45	38.0 - 55.0
UREA µmoles/l	Combined	202	39.6	1.77	3.71 - 4.20	0.133	4	3.5	2.1 - 9.15
	Female	108	3.8	1.5	3.5 - 4.1		3.1	3.4	2.1 - 8.4
	Male	94	4.2	2	3.7 - 4.6		4	3.8	2.2 - 10.8
CRT mmoles/l	Combined	202	93.33	22.92	90.1 - 96.5	**0.001**	86	90	52.2 - 146.9
	Female	108	88.2	23.2	83.8 - 92.6		86	86	50 - 173
	Male	94	99.2	21.2	94.9 - 103.6		88	97	70.0 - 159.0

Comparison of male and female parameters using Independent t-test $p < 0.05$ considered significant. Bold denotes significant. AST= Aspartate transaminase, ALT = alanine aminotransaminase, ALP = alkaline phosphatase, T.Bil = total bilirubin, D.Bil = direct bilirubin, ALB = albumin, CRT = creatinine. TP = total protein.

from a study conducted among 35 Indian females and 35 males [12] raises a question on the need of using large sample sizes when determining reference intervals of a population [17]. Significantly lower ALB values in females have been

reported elsewhere and have been attributed to increased degradation [12]. The significantly higher TP values in females than males observed in the current study concurs with the findings observed in elderly subjects aged between 60 and 75 years [18]. Nonetheless, there is a contradictory report of insignificant gender-based differences in TP levels [5]. Although there is no obvious explanation of the reported discrepancies in TP values, it would be helpful to evaluate the performance of different assay techniques using different age group subjects and from different racial backgrounds.

5. Conclusion

In health males demonstrate significantly higher biochemical median values than females and the main possible cause of the disparities is the effect in sex hormones. It is also apparent that gender-based disparities were not tagged to the studied sample sizes or altitude. Notwithstanding too low sample sizes for example that of 35 participants did not demonstrate the significant gender-based disparities in ALT, AST ALP and TP observed in larger sample sizes.

Recommendations

Localized gender-based reference intervals for ALT, AST, ALP, T.Bil, D.Bil, TP, ALB, and CRT for different age groups are established for use in clinical practice and research. The reference ranges established in the current study could be used in the interpretation of laboratory test results in the setting of the study if no other appropriate reference intervals are available.

Conflicts of Interest

The author has no conflict of interest tagged to this study work.

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Appendix 1. SERODOS 004® Commercial Control for Biochemistry Values

Parameter	Expected low limit	Control result	Expected High Limit	Remarks
AST u/l	27	37	43	Acceptable
ALT u/l	27	39	43	Acceptable
GGT u/l	27	38	42	Acceptable
ALP u/l	134	185	223	Acceptable
T.PRT g/l	57.30	65.23	71.50	Acceptable
ALB g/l	26.40	35.61	42.20	Acceptable
CRT mmoles/l	79.50	116.73	120.0	Acceptable
UREA µmoles/l	4.40	4.90	6.80	Acceptable
T.Bill µmoles/l	21.80	24.71	37.10	Acceptable
D.Bill µmoles/l	21.10	25.54	34.30	Acceptable