

ORIGINAL RESEARCH ARTICLE

Establishing reference intervals of serum albumin levels in the apparently healthy Caribbean population by gender, age, ethnicity, and body mass index

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Abstract

Serum albumin (SA) is often used in research and clinical settings as a biomarker of nutritional status. This report documents SA reference intervals (RIs) in an apparently healthy Caribbean population by age, gender, ethnicity, and body mass index (BMI). The study included 105 subjects (41 males, 64 females) aged 17–83 years residing in Trinidad and Tobago. Fasting blood samples were collected, and SA concentrations were measured using a multi-channel chemistry auto-analyzer. The 95% RIs for SA, stratified by age, gender, ethnicity, and BMI, were then established. The Statistical Package for the Social Sciences was used for statistical analysis. The results are expressed as mean $\pm$ standard deviation. RIs were established for the two gender groups as 35.95–43.91 and 34.87–41.73 for males and females, respectively. Because the mean SA levels differed significantly ($p < 0.05$) across age subgroups, age-related RIs were also established for each subgroup. However, no significant difference in mean SA levels was observed across ethnic groups ($p = 0.413$), which warrants establishing a unified RI of 35.21–42.65. RIs established for gender, age, ethnicity, and BMI categories have provided a platform for establishing RIs for other biochemical parameters routinely used in the population of Trinidad and Tobago.

Keywords: Biomarker; Body mass index; Caribbean; Gender; Nutrition; Protein; Serum albumin; Reference intervals

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1. Introduction

Serum albumin (SA) is widely used in research and clinical practice as a biomarker of nutritional status.¹ SA is also the most abundant circulatory protein and represents half of the total protein pool of the body.² It is synthesized in the liver and then secreted into the bloodstream and has a half-life of 20 days. Albumin has a molecular weight of 66.5 kDa and consists of 585 amino acids arranged into three repeated homologous domains and two separate sub-domains, A and B.² It has several vital physiological functions that include maintenance of oncotic pressure and microvascular integrity, regulation of metabolic and vascular functions, provision of binding ligands for substances, antioxidant activities, and anticoagulant effects.^{2,3} Moreover, it is inversely related to inflammatory processes by modulating neutrophil adhesion and cell signaling

moieties.^{2–3} Importantly, it is present in large quantities⁴, and the effect of a temporary decrease in protein intake on its concentrations is limited.⁵ The total albumin pool in the body is about 3.5–5.0 g/kg body weight, of which 40–45% is present in the intravascular space³, while the remaining is present in the interstitial space³, while the reference range for albumin in serum is approximately 35–50 g/L.⁶ Therefore, individuals with a concentration below 35 g/L are usually considered to be hypoalbuminemic.⁶ In this light, several studies have supported that lower SA concentration is associated with an increased risk of mortality.^{6–9} In one of the largest surgical Medication-Related Osteonecrosis of the Jaw cohorts to date, the researchers reported a statistically significant association between lower preoperative SA levels and poor outcome.¹⁰ Furthermore, another previous study has reported that a higher albumin-to-globulin ratio (AGR) is associated with a reduced risk of multiple cerebral atherosclerotic stenosis. This study reported that AGR levels were significantly associated with the presence of specific stenosis subtypes and could therefore be hypothesized to be a marker for risk stratification; however, the researchers cautioned that this utility may require validation in prospective cohorts.¹¹

A population-based, prospective cohort study aimed at evaluating the correlation between SA concentration and mortality was conducted by Phillips *et al.*⁶ in 1989. The study comprised 7,735 middle-aged men with or without a pre-existing disease. The result of an average of 9.2 years of follow-up in the study shows that SA concentration was inversely correlated with all-cause mortality, cardiovascular mortality, and cancer mortality in both groups with and without a pre-existing disease.⁶

Hence, establishing a reference interval (RI) for this important biomarker in a population that has undergone a nutritional transition is important. This is because the nutrition transition witnessed in Trinidad and Tobago has impacted on the nature and trend of several biochemical parameters, including SA, which was previously considered a marker of nutritional status.¹

Trinidad and Tobago is a country in the Caribbean, which consists of two islands separated by the Caribbean Sea. The population in the country is multi-ethnic, composed of East Indians, Afro-Caribbeans, and Chinese people, in addition to people of European descent. The country has one of the modest economies in the Caribbean region, supported by its large oil and gas reserves, and its gross domestic product was USD 21.53 billion in 2020. This has therefore made it easy for the population to thrive on a modest lifestyle associated with a rich, balanced diet. As stated earlier, the population in Trinidad and Tobago comprises of various ethnic groups, and studies have shown

that there are variations in the RIs of several biochemical parameters, both within and between populations, due to important factors, such as age, sex, race, dietary habits, environment, and genetics.^{11–14} These differences were especially evident in the values of certain biochemical parameters established in developing countries compared to those in developed countries.^{11–14} Thus, it is important for developing countries, including Trinidad and Tobago, to establish RI for their populations across the various biochemical parameters routinely used in the country, as this can help improve the quality of health care delivery. Therefore, the aim of the present study is to establish the RI for SA, one of the most commonly measured biochemical parameters and an important marker of nutritional status. The established RI can assist future studies in establishing Clinical and Laboratory Standards Institute (CLSI)-compliant RIs to support appropriate clinical decision-making.

2. Materials and methods

2.1. Data collection

The study retrospectively reviewed data from a previous study conducted between January 2014 and December 2014.¹⁵ This previous study recruited 105 apparently healthy individuals living in Trinidad and Tobago. The subjects comprised 41 males (mean age 45.17 ± 13.59) and 64 females (mean age 40.75 ± 13.80); all were aged 17–83 years. The subjects were either civil servants working with the Waste and Sewage Authority, St Augustine, Trinidad, or staff/students of the University of the West Indies, St Augustine Campus, Trinidad, or of the Eric Williams Medical Science Complex (EWMSC), Mount Hope, Trinidad. Prior to recruiting the subjects, an advertisement was posted at the University of the West Indies Main Campus in St. Augustine and at the EWMSC, Mount Hope, Trinidad. Informed voluntary consent to participate in the study was obtained from all subjects after the research team explained the nature and benefits of participation. The study protocol (Approval date: 23 Jan, 2014) was reviewed and approved by the Ethics Committees of the University of the West Indies, St Augustine, and the North Central Regional Health Authority, Trinidad.

2.2. Eligibility criteria

All the subjects recruited for the study had no prior history of a non-communicable disease, as indicated by either a fasting plasma glucose of <7.0 mmol/L¹⁶ or a blood pressure of $<135/90$ mmHg¹⁷ or an established glomerular filtration rate of >90 mL/min/1.73 m² (calculated using the Chronic Kidney Disease–Epidemiology Collaboration equation).¹⁸ Subjects excluded from the study were those

diagnosed with conditions such as cancer, infectious, or inflammatory conditions, or were taking medications for such conditions, and those who declined voluntary consent.

2.3. Statistics and calculations

The data collected were first entered into Excel (2013, Microsoft Corporation, USA), and the statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS 20.0, IBM, USA). Differences in categorical variables for the male and female groups were determined using Student's *t*-tests, and $p < 0.05$ was considered statistically significant. The RIs were established from the obtained 95% confidence intervals. A similar approach was used for other subject categories, including age, ethnicity, and body mass index (BMI).

2.4. Variables

2.4.1. Ethnicity

Ethnicity was recorded via either self-definition from the subject or as documented in the subject's medical folder: African, East Indian, or Mixed.

2.4.2. Body mass index

The BMIs of the participants were categorized according to the World Health Organization criteria (Table 1).¹⁹

3. Results

Results are expressed as mean $\pm$ standard deviation as appropriate. Table 2 shows the calculated gender-related intervals for the two groups: 35.95–43.91 for males and 34.87–41.73 for females. Gender-specific RIs were warranted because the mean SA level in males (39.93 ± 3.98 g/L) was significantly higher than in females (38.30 ± 3.43 g/L, $p < 0.05$). Table 3 presents age-specific RIs for SA. Significant differences ($p < 0.05$) were observed between several age groups, notably between 20–29 and 40–49, 50–59, and 70–79; 30–39 and 70–79; 40–49 and 50–59; 50–59 and 60–69; and 60–69 and 70–79. However, no ethnicity-related differences were recorded in the mean SA concentration among the various ethnic groups ($p = 0.413$; Table 4). In addition, Table 5 shows the SA intervals for the subjects by BMI category. The table also shows significant differences in mean SA between the underweight and obese groups ($p < 0.05$), the normal weight and obese groups ($p < 0.05$), and the overweight and obese groups ($p < 0.05$).

4. Discussion

The CLSI guidelines²⁰ recommended that all laboratories establish their own RIs from the local population, or validate those established from a different population and

setting before use. Nevertheless, reference values derived from European and North American populations remain widely used in most developing countries, including Trinidad and Tobago. The importance of population-specific reference values cannot be overstated. First, they are more appropriate for the specific population in clinical decision-making, especially as indicators of good health or pointers to an ongoing disease process. Secondly, they can be used as a tool to screen for physiological and pathological conditions in that population. In addition, and more importantly, they can be used for the routine health assessment and management of disease conditions, especially those that may be more peculiar to that population. Hence, RI established for the local population can assist physicians in accurately interpreting laboratory data, thereby aiding them in developing a comprehensive clinical perspective for the diagnosis and management of their patients.²¹

We observed gender-related differences in the mean of SA in this study. This, therefore, necessitated the establishment of a separate RI for each gender group. Gender-related differences in the mean values of SA have been reported in studies by Indrayan *et al.*²², Sairam *et al.*²³, and Weaving *et al.*²⁴, in which higher mean values were observed in males than in females. However, another study reported no significant differences in mean SA between the two gender groups.²⁵ Several previous studies have suggested that gender differences in SA levels may be influenced by the use of hormonal contraception among some female participants.²⁶ This observation was supported by a previous study that reported SA values that were approximately 2 g/L lower in women on contraception than those who were not, thus supporting a hormonal basis for the differences between the two gender groups. Furthermore, McPherson *et al.*²⁶ reported that the liver may play a role by expressing distinct gene subsets that could affect the organ's ability to mobilize certain hormones.²⁶ Nevertheless, our finding in the present study underscores the need for separate RI for male and female gender groups in the population of Trinidad and Tobago for SA.

Table 1. Body mass index (BMI) categorization according to the World Health Organization criteria

BMI (kg/m ²)	Nutritional status
<18.5	Underweight
18.5–24.9	Normal weight
25.0–29.9	Overweight
≥ 30.0	Obese

Table 2. Gender-related distribution of serum albumin of the study cohort (Student's *t*-test)

Parameters (mean ± standard deviation)	All subjects (<i>n</i> = 105)	Male (<i>n</i> = 41)	Female (<i>n</i> = 64)
Age (yrs.)	42.50 ± 13.82	45.17 ± 13.59	40.75 ± 13.80
Albumin (g/L)	38.93 ± 3.72	39.93 ± 3.98	38.30 ± 3.43
95% confidence intervals	38.218–39.642	38.712–41.148	37.460–39.140

Table 3. Age-related distribution of serum albumin of the study cohort (Student's *t*-test)

Age categories (years)	<i>n</i>	Albumin (g/L)	
		Mean ± standard deviation	95% confidence intervals
17–19	2	–	–
20–29	16	40.69 ± 3.88 ^{ac} ; ad [†] ; af [†]	38.789–42.391
30–39	36	38.49 ± 3.45 ^{bf}	37.363–39.617
40–49	15	37.73 ± 4.70 ^{cd}	35.352–40.108
50–59	23	38.78 ± 3.45 ^{de}	37.370–40.190
60–69	8	39.50 ± 4.17 ^{ef}	36.610–42.390
70–79	5	38.00 ± 2.00	36.247–39.753
Total	105	38.93 ± 3.72	38.218–39.642

Notes: **p* < 0.05; a: 20–29; b: 30–39; c: 40–49; d: 50–59; e: 60–69; f: 70–79. Alphabet indicates groups with a significant difference.

Table 4. Ethnicity-related distribution of serum albumin of the study cohort (Student's *t*-test)

Parameter (mean ± standard deviation)	All subjects (<i>n</i> = 105)	African (<i>n</i> = 48)	East Indian (<i>n</i> = 39)	Mixed (<i>n</i> = 18)
Albumin (g/L)	38.93 ± 3.72	38.58 ± 3.97	39.56 ± 3.45	38.50 ± 3.62
95% confidence intervals	38.218–39.642	37.457–39.703	38.477–39.703	36.828–40.172

Table 5. Body mass index (BMI)-related distribution of serum albumin of the study cohort (Student's *t*-test)

BMI category (kg/m ²)	<i>n</i>	Albumin (g/L)	
		Mean ± standard deviation	95% confidence intervals
Underweight	9	39.89 ± 2.47 ^{ad}	38.276–41.504
Normal weight	37	39.19 ± 4.18 ^{bd}	37.843–40.537
Overweight	26	39.38 ± 3.06 ^{cd}	38.204–40.556
Obese	33	38.03 ± 3.90	36.699–39.361

Notes: **p* < 0.05; a: Underweight; b: Normal weight; c: Overweight; d: Obese. Alphabet indicates groups with a significant difference.

In addition, several studies have attributed the difference to age. It was reported that SA concentration decreases with age, with reductions of up to 10% observed across the age range of 18–65 years among 1,000 blood donors.²⁶ Moreover, values were lower by approximately 2 g/L in females at ages associated with the menopause. In support of the effect of age on SA concentration, the data in Table 3 of the present study showed significant differences

across almost all age subgroups, except for those aged 17–19 years. This may be due to the small sample size (*n* = 2) in that subgroup. Other findings were also noted in support of this observation. Furrugh *et al.*²⁷ reported a decline in albumin concentration with age in Bangalore, India. Other researchers, including Weaving *et al.*²⁴ and Kim *et al.*²⁸, reported that SA concentration declined with age. However, Kim *et al.*²⁸ reported that the decline in

albumin concentration in the subjects was possibly related to deteriorating liver function with advancing age, which is caused by reduced hepatic blood flow in older subjects. These studies underscore the importance of establishing RIs for different age subgroups to account for the effect of age on the decline in SA concentration with advancing age in the population.

Regarding ethnicity-related differences in SA, ethnicity appeared to play a minimal role in the reference values established for SA in this study. This could be attributed to the similarity in the participants' dietary habits and economic status. Hence, this warranted the establishment of a single RI for all ethnic groups in Trinidad and Tobago. Nevertheless, a study by Koh *et al.*²⁹ reported higher mean values of several biochemical parameters, including SA, in whites compared to blacks, but these differences could also be explained by economic factors and race.

Finally, BMI is a simple anthropometric measure of nutritional status and an important mortality indicator among hospitalized patients³⁰, and the combination of BMI and serum or urinary albumin levels may predict all-cause mortality in the general population.³¹ This assertion could be supported by the findings in the present study. As shown in Table 5, the obese group had the lowest mean SA concentration, which was significantly lower than all other BMI categories ($p < 0.05$). Notably, large cohort studies of elders in Australia³² and Europe³³ have shown that being underweight is associated with higher all-cause mortality risk. In contrast, overweight and obesity have also been implicated with the development of insulin resistance, as well as the development of hyperfiltration—a condition that may likely predispose subjects to kidney impairment.^{34,35} Therefore, this calls for close monitoring of subjects, particularly at both extremes of the BMI, as both conditions are associated with mortality risk. In addition, the established RI for each BMI group in this study can assist in close monitoring to track trends in the prevalence of underweight, overweight, and obesity in the population.

5. Conclusion

The RIs established for gender, age, ethnicity, and BMI categories have provided a platform on which RIs for other biochemical parameters routinely used in the population of Trinidad and Tobago could be established in future studies.

In the present-day context, a modern laboratory database provides a valuable option for establishing RIs for different biochemical parameters. The use of this resource is particularly helpful, especially when practical constraints make a traditional RI study difficult or impossible.³⁶ Therefore, retrospective data can be used to undertake such a task using an indirect method, which

utilizes existing subject data in the database.

This study was conducted using an indirect method to establish RIs. One significant advantage of this indirect method for establishing RI is that it reduces interindividual variability by partitioning intervals as much as possible. Although stratification by age and gender is the minimum prerequisite for such an undertaking, other approaches may be used, including stratification by race and dietary habits (e.g., vegetarians).³⁶

The indirect method relies on results stored in a database for purposes other than deriving RIs.³⁷ Therefore, results from routine clinical pathology testing that were stored in laboratory databases are the most often used. This approach has significant practical advantages over the traditional RI method. Most notably, the method is considerably less time-consuming and more cost-effective. Moreover, the direct method becomes impractical, especially when multiple partitions are necessary, because it requires at least 120 subjects per partition.³⁷ Hence, if partitioning adults by decade of age from 20 to 80+ years, a minimum of 840 subjects is required. If partitioning by sex is also performed, at least 1,680 subjects are required.³⁷

Another advantage of the indirect method to establish RIs is that it reflects routine laboratory operating conditions. In contrast, the direct study method may be conducted under ideal pre-analytical and analytical conditions that are difficult or impossible to replicate in routine practice. Finally, there are also ethical advantages to the indirect approach, as participants are not subjected to venesection solely for an RI study, and it avoids the dilemmas that arise in direct studies when apparently healthy subjects have extreme results.³⁷

One limitation of this study is that the analysis was based on retrospective data collected in 2014 for the establishment of the Reference Intervals (RIs). As the data were obtained from an earlier time period, changes in population characteristics, healthcare practices, lifestyle factors, and laboratory methodologies over time may affect the current applicability and generalizability of the established reference intervals. Therefore, periodic re-evaluation and validation using more recent data may be warranted.

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Conflict of interest

The author declared no conflicting interests.

Author contributions

This is a single-authored article.

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Ethics Committees of the University of the West Indies, St Augustine, and the North Central Regional Health Authority, Trinidad (Approval date: 23 Jan, 2014). Informed consent was obtained from all individual participants included in the study.

Consent for publication

The requirement for informed consent for publication was waived by the Ethics Committees of the University of the West Indies, St Augustine, and the North Central Regional Health Authority, Trinidad, due to the retrospective nature of the study and the use of de-identified patient data. No identifiable personal information is included in this manuscript.

Availability of data

Data are available upon reasonable request from the corresponding author.

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