Original Research Article

Evaluation of suitability and clinical applicability between two different methods in the measurement of serum albumin levels in oncology patients

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Abstract

Background: Albumin is the maximum plentiful circulating protein determined with inside the plasma. In oncology establishments, the commonly assessed parameter for the benefit of the patients like the liver function, renal function, nutritional status, and overall protein status and gastro intestinal assessment remains to be serum albumin. This study is a comparative evaluation of the results of serum albumin levels in oncology patients estimated by two different methodologies and thereby emphasizing the suitability and clinical applicability of the method to evaluate this acute phase reactant serum albumin.

Materials and Methods: In this analytical retrospective study, samples received in the laboratory of all Oncology patients (non specific to type of malignancy) of all age groups and gender was included in the study to estimate serum albumin by two different methods Bromocresol Green and Bromocresol purple. The results were compared for further evaluation.

Results: For a sample size of 200, it was observed that 169 samples (84%) shows albumin levels are lower by BCP than BCG method, 11 (6%) were higher and 20 (10%) were equal. Among the 11 samples where albumin estimation was evidences high using the BCP method, 5 samples had values greater than 6 gm/dl.

Conclusion: This study helps in comparison of results of serum albumin by two different methods and determining an effective method to use.

Keywords: Albumin, BCG Bromocresol green, BCP Bromocresol purple

1. Introduction

Serum albumin is the maximum plentiful plasma protein and is produced with inside the liver. Albumin makes up extra than 1/2 of the overall protein found in serum. In healthy human subjects, albumin measures to almost half of the total plasma protein concentration. Albumin is synthesized by the liver hepatocytes approximately 12 g per day with a molecular weight of 69k Da and half-life of approximately 20 days. About 40 % of the body's albumin circulates in plasma where it accounts for roughly three –fifths of total plasma protein by weight (3.4-4.7 g/dl). Approximately 30 to 40% of the body's overall albumin pool is determined with inside the intravascular compartment. The remainder is extra vascular and is located in the interstitial spaces, mainly of the muscles and skin.[1] Albumin is also found in small amounts in a variety of body tissue fluids such as sweat, tears, gastric juice, and bile. It is essential for retaining plasma colloid osmotic pressure, transporting endogenous compounds, scavenging loose radicals, regulating immune responses, and different metabolic processes. After synthesis, it's far immediately flooded into hepatic blood and, hence, in movement from wherein it disappears inside 30–forty days (half-lifestyles 20 days). Distribution of plasma albumin takes place over hours and involves 30–40% of the albumin pool. Serum albumin is a significant modulator of plasma oncotic pressure and transporter of endogenous and exogenous ligands that may include free fatty acids, calcium, steroid hormones, and variety of drugs. It is a traditional biomarker used to assess the nutritional status. In humans, serum albumin is a significant modulator of plasma oncotic pressure and transporter of endogenous and exogenous ligands that may include free fatty acids, calcium, steroid hormones, and variety of drugs.[2] Albumin is usually requested by the clinicians to assess the nutritional status of the subjects.[3] It is also well established that albumin levels fall in patients with

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inflammatory disorders and other acute or chronic diseases by suppressing synthesis, increases the breaks down or combination of the both.

The simplest scientific state of affairs that reasons an elevation in serum albumin is acute dehydration. A variety of clinical entities results in a decreased albumin level, either from depressed synthesis or increased losses. A lower in albumin synthesis is resulting from end-level liver disease, intestinal malabsorption syndromes, and protein-calorie malnutrition. Examples of albumin loss are nephrotic syndrome and severe burns because the skin is the most important extra storage pool for albumin. Albumin is usually measured through a dye-binding approach that makes use of the cap potential of albumin to shape a strong complicated with bromocresol inexperienced dye. The BCG-albumin complicated absorbs mild at a one-of-a-kind wavelength from the unbound dye. This approach can also additionally overestimate albumin through binding to different proteins.4 The total globulin fraction is generally determined by subtracting the albumin from the total protein.

2. Materials and Methods

2.1. Inclusion criteria

Sample size calculated on the basis of non-random purposive sampling (quota). Samples of all Oncology patients (non-specific to type of malignancy) attending the OP of all age groups and gender who fit into the inclusion criteria received in the laboratory were included in the study. It includes first onco diagnosis samples requesting for albumin tests. Around 200 samples that are received in laboratory in the period of September to November 2024 were included in this study.

2.2. Exclusion criteria

Health checks up subjects and subjects on dialysis are excluded in the study.

Patients were excluded if they were treated only for relapsed disease or second malignant neoplasm and for missing albumin data or test not requested.

2.3. Methodology

Samples were centrifuged at 4500 rpm and the serum separated is used for albumin is estimation by two different methods Bromocresol Green and Bromocresol purple. BCG was tested in auto analyzer Dirui CS 480 and BCP was tested in auto analyzer Siemens Dimension RXL. The results were compared for further evaluation. The data collected from study group subjects were entered separately in Microsoft Excel sheet of windows 2007 and values were expressed as Mean $\pm$ SD and linear regression analysis is used for the statistical analysis. With 95% confidence interval, p-value of less than 0.05 was considered statistically significant.

Table 1: Serum Albumin distribution in the comparative methods

Serum Albumin values	High	Equivalent	Low	Total
BCP to BCG	11	20	169	200
%	6%	10%	84%	-

This table indicates the distribution of albumin values by comparative analysis of two methods. Based on the values the subjects were divided into three groups' high value, same value and low value. The BCP against BCG method was compared 11 (6%) were in high value, 20 (10%) same values and 169 (84%) had low values.
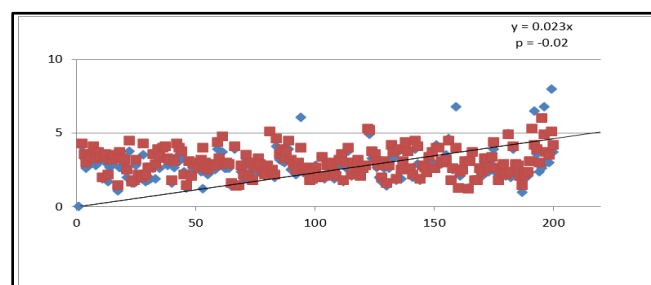

Figure 1: Distribution of the 200 data points to show the significant p value of 0.02

This shows that 200 samples were used for the analytical comparison of serum albumin by BCP and BCG methods and significant p value was obtained by the linear regression analysis to show the lower albumin levels in the BCP method.

Table 2: Impact of value estimation on methodology based biological reference interval.

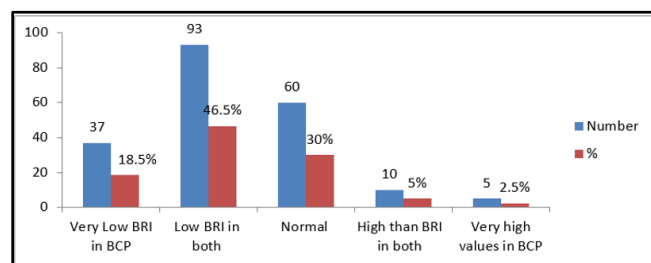| Interpretation	Number	%
Very Low BRI in BCP	37	18.5
Low BRI in both	93	46.5
Normal	60	30
High than BRI in both	10	5
Very high values in BCP	5	2.5

Figure 2: Bar diagram to show the Impact of estimation by BCP method on the biological reference interval

Impact of low serum albumin by BCP with lower values was reflected at the cutoff of the biological reference range, where in 37 numbers that 18.5% was in the hypoalbuminemia range where there was no clinical evidence or clinical application to support the same while the other method the value was within the biological reference range.

3. Discussion

Albumin in serum is a commonly requested parameter among the biochemical assays. There are many conventional methods available to estimate albumin levels in serum. Though there are studies performed in normal subjects, dialysis patients and even in nephrotic syndrome to understand the results of serum albumin by comparing the two dye binding methods. This is the first study performed in the oncology patient's samples. Albumin concentrations from serum samples in general population were analyzed using the dye binding methods. Influence of globulins on albumin concentration discrepancies between methods was estimated as well as the impact of the albumin method concentrations. Med calc was employed for statistical analysis, setting a value of P < 0.05 as significant.[5] According to this study Albumin results from the BCP and BCG methods resulted in unacceptable differences and clinical confusion, especially at lower albumin concentrations. As a result it was noticed that overestimation of the albumin concentration using Bromo Cresol Green method. Precipitation, which influences the BCG method, turned into now no longer discovered with BCP. Blank corrections have been negligible, salicylates did now no longer interfere, and bilirubin affected the technique best if found in very excessive concentration. The approach gives a method to the terrible accuracy of current BCG techniques whilst maintaining lots of their perfect features.[6] Albumin consequences from the BCP and BCG strategies can also additionally bring about unacceptable variations and medical confusion, in particular at decrease albumin concentrations. Serum acute phase proteins contribute to overestimating the albumin concentration using Albumin BCG.[7] In Nephrotic syndrome, α2-macroglobulin is a major factor for positive bias of Albumin in BCG, especially in patients with severe hypoalbuminemia. The BCP assay is useful for measuring albumin concentrations in Nephrotic syndrome.[8]

The bromocresol green (BCG) and bromocresol purple (BCP) assays frequently yield discordant serum albumin results. This take a look at seeks to check the speculation that bias in albumin effects are inspired via way of means of the awareness of serum globulin subtypes. Among the 197 have a look at participants, people with nephrotic syndrome had an appreciably better degree of alpha2-globulin as compared to the ones in different categories. Thus, the authors conclude that serum globulins contribute to the bias seen in the BCG and BCP assays, with the greatest effects observed for a-globulin on the BCG assay where higher concentrations contributed to a higher bias. In the elderly Non Squamous lung carcinoma patients, serum albumin tiers also can moreover help understand certain affected man or woman populations more likely to attain a survival benefit of systemic chemotherapy.[9]

In some studies the albumin measured by a bromocresol purple dye-binding assay agrees more closely with the gold standard of immunonephelometry than bromocresol green

measurement. Both tests are in current clinical use. A technique for changing among the 2 might be useful. The capacity to transform among those measurements could be of use in scientific conditions in which absolutely the cost of the serum albumin is important, whilst facts from laboratories using extraordinary methodologies need to be combined, and with inside the software of the Modification of Diet in Renal Disease method to estimate glomerular filtration fee in sufferers whose albumin has been measured by bromocresol purple.[10] In another study performed in renal patients, the bromocresol green assay is commonly used for measuring albumin, but is affected by α1- and α2-globulins, which are elevated in systemic inflammation. The bromocresol purple assay is another dye-binding method developed to overcome non-specific reactions. Concentrations of α2-macroglobulin, a chief α2-globulin component, are expanded in nephrotic syndrome, however now no longer in inflammation. There is little direct evidence that α2-macroglobulin affects BCG or BCP assays. Some studies indicated that the BCG assay has the greatest reactivity with α2-globulin, that is a collective term for various proteins with α2-mobility on electrophoresis, and it is likely that the composition of α2-globulin changes depending on clinical conditions.

In this study for a sample size of 200, where serum albumin from oncology patients was measured by two methodologies – 169 samples (84%) shows albumin levels are lower in BCP and higher in BCG method. 11 samples (6%) showed albumin levels higher when measured by BCP method. 20 samples (10%) showed the equal results in both BCP and BCG method. Among the 12 samples where albumin estimation was evidences high using the BCP method, 5 samples had values greater than 6gm/dl. Applicability is described because the quantity to which the outcomes discovered in posted research are in all likelihood to mirror the predicted results while an intervention is implemented to broader populations under real-world conditions. Suitability and clinical applicability depends on the Population and purpose. Based on the clinical applicability and efficacy where there is no evidence for the overestimated albumin of the Bromo cresol green, it can still be considered in oncology patients to estimate the serum albumin levels as the effect of low globulin is not appropriately adequate.

This is the first study to be performed on oncology patients to compare the albumin values between two dye binding methods. Bromocresol green method showed albumin values on the higher side though within the biological reference intervals among the oncology patients. There was an overestimate in the values whereas in the Bromocresol purple method albumin values were on the lower side though within the biological reference intervals. Most of the BCG-based platforms falsely overestimate the plasma albumin concentration. This becomes crucial as albumin values are key important was assessment of liver function and nutritional status. Also globulin values were

overestimated in the Bromocresol purple method which did not correlate clinically. This becomes extremely important to decide when in moderate and severe hypoalbuminemia as severe hypoalbuminemia is considered as a marker for advanced and aggressive cancer. BCP and BCG methods can be used for the intended purpose in oncology patients however the BCG remains to be the preferred method to evaluate the albumin levels.

4. Conclusion

The level of serum albumin is an index of nourishment care and management and the most commonly requested parameter at biochemistry laboratory. This study assesses the albumin concentration in oncology patients by the two dye binding methods. Though studies have proven that bromocresol purple method may be the adequate method to assess the albumin values but the clinical applicability and efficacy amongst the oncology patients reveals that serum albumin estimation by the Bromo cresol green supersedes the effect of bias and interferences that has caused the over estimation of albumin and lower globulin levels.

5. Results

Albumin – serum a commonly requested parameter among the biochemical assays has its effect on all the systems of the body. For a sample size of 200, where serum albumin was measured by two methodologies – 169 samples (84%) shows albumin levels are lower in BCP and higher in BCG method. 11 samples (6%) showed albumin levels higher when measured by BCP method. 20 samples (10%) showed the equal results in both BCP and BCG method. Among the 12 samples where albumin estimation was evidences high using the BCP method, 5 samples had values greater than 6gm/dl. The total group of 200 samples can be divided into low value, equal value and high value sub groups based on comparative values of the two methods.

Many studies have been performed in general subjects and shows that Bromo cresol Green method has an overestimated albumin values there by lowering the globulin values relatively. In this study on oncology patients, there is a distribution of values with different interpretations in albumin assays. Though albumin was lower by the Bromocresol purple method the relative higher globulins were not supportive of any clinical applications and sustenance. However the 6 % higher albumin values by BCP method creates even more discrepancy to lower globulins.

5.1. Limitations of the study

This was a retrospective study, which could possibly introduce biases and limit the generalizability of our findings. All samples were obtained from oncology patients irrespective of age, gender and type of malignancy and staging and also therapy. Future research on specific oncology status and case scenario could benefit and a more extensive patient cohort, which would provide deeper insights.

6. Conflicts of Interest

Author agrees with the contents of the manuscript and there is no conflict of interest.

Ethical committee clearance is obtained from the Hospital committee.

7. Source of Funding

None.

8. Conflict of Interest

None.

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