

Basic Performance of an Enzymatic Method for Glycated Albumin and Reference Range Determination

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Abstract

Background:

Glycated albumin (GA) is a medium-term glycemic control marker of diabetes and may be more sensitive to changes in plasma glucose than hemoglobin A1c. We studied where and how many fructosyl groups bind to albumin, and which glycation sites are measured by the enzymatic method for GA. We also studied the basic performance of the enzymatic method for GA.

Methods:

Glycated albumin was measured using an enzymatic method (Lucica[®]GA-L, Asahi Kasei Pharma) on a biochemical autoanalyzer. Molecular weights of purified GA and nonglycated albumin were measured by a mass spectrometry system. Two hundred one healthy volunteers with normal results of oral glucose tolerance testing were recruited to determine the reference range in Americans.

Results:

The present method measured only glycated amino acids from albumin in serum protein. We estimate that the number of glycated amino acids measured by this method was approximately two per molecule of albumin. The general performance (sensitivity, specificity, reproducibility, linearity, interference) of the method was good. The reference range of GA% in Americans with normal glucose tolerance was determined to be 11.9–15.8% (mean $\pm$ 2 standard deviations). Significant differences were not observed between the sexes; however, race differences were observed (higher levels in blacks relative to whites).

Conclusions:

The method was specific for measuring glycated amino acids in albumin and had good basic performance characteristics. The reference range in Americans was 11.9–15.8%. This method may be a useful indicator for diabetes control.

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Abbreviations: (BCP) bromocresol purple, (CV) coefficient of variation, (DCCT) Diabetes Control and Complications Trial, (DOF-Lys) N ϵ -(1-deoxy-D-fructose-1-yl)-L-lysine, (GA) glycated albumin, (HbA1c) hemoglobin A1c, (HMA) human mercaptalbumin, (HNA) human nonmercaptalbumin, (HPLC) high-performance liquid chromatography, (IDMS) isotope dilution mass spectrometry, (JSCC) Japan Society of Clinical Chemistry, (MW) molecular weight, (NGA) nonglycated albumin, (OGTT) oral glucose tolerance test, (SD) standard deviation, (TBA) thiobarbituric acid

Keywords: diabetes, enzymatic method, glycated albumin, reference range

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