

# The Glycohemoglobin (HbAlc) Distribution in EDTA-Chelation-Eligible Patients

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The present norms for Hemoglobin Alc are based on a few subjects, approximately 50 people. Additionally, there is a wide difference of opinion as to what constitutes the physiologic range. Finally, what is especially interesting is that, whatever criterion one wishes to utilize, somewhere between one in six to one in five, according to Koenig, to about four out of five, if one grants the Gabbay norm, who appear, in our opinion, to be EDTA-chelation-eligible are within the pathologic range.

There is no question but that the recent published body of scientific literature attests to the increasing awareness of the primary and secondary contributions of diabetes mellitus, particularly the maturity-onset type, to the common killing and crippling conditions. Hence, it is not surprising that there is progressively more interest in the development of more sophisticated, more sensitive, and more simple tests of carbohydrate metabolism. The area presently

enjoying the greatest attention is the glycohemoglobins, also called hemoglobin A, and especially HbAlc.

Two points to be emphasized in this report have escaped scrutiny. First, there is, as far as we can determine, no substantial indication of the incidence and prevalence of abnormal HbAlc in the general population. Second, and more relevant here, the distribution of HbAlc in a group of patients deemed to be EDTA-chelation-eligible is not available.

## Review of the Literature

Koenig and his colleagues (1976), from a study of HbAlc during diabetic control, concluded that a mean of 5.8 percent (range 4.2 to 7.6) concentration appeared to reflect the average blood glucose content best over previous weeks and months in five hospitalized diabetic patients. Gabbay et al. (1977) studied HbAlc in a diabetic population (n = 28) and concluded a normal range of  $4.9 \pm 0.7$  percent. Cole (1978) contends that HbAlc values below 5 percent are physiologic. Ellul (1980) from a review of the literature, suggests a consensus of 3 to 7 percent for so-called normal subjects. Finally, Tze, Thompson and Leichter (1978)

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from a study of 16 presumably nondiabetic people (4 to 24 years), claimed a physiologic range of 3.1 to 6.3 percent (mean and S.E.  $4.33 \pm 0.39$ ).

### Methods

We selected 334 patients at the McDonagh Medical Center who met the following specifications. First, all of the subjects had been previously treated by one or more practitioners elsewhere. Secondly, as far as we can determine, all patients suffered with one or another form of chronic degenerative disease, mostly cardiovascular, and very few were known diabetics. Third, in the opinion of these patients, their therapy elsewhere had been unsuccessful. Finally, in our clinical judgment, based on our earlier treatment of several thousand subjects, all of the subjects were thought to be EDTA-chelation-eligible. In our sample were 178 males ( $59.2 \pm 12.1$  years) and 156 females ( $60.8 \pm 12.4$  years). The initial examination included an HbA1c measurement (MET-PATH method). The distribution is summarized in the table. There was no statistically significant sex difference ( $t = 1.3648, p > 0.100$ ).

### Results

Utilizing the Koenig (1976) criterion for diabetes mellitus, 26 males (15 percent) and 29 females (19 percent) of our group exceeded 7.6 percent and therefore could be viewed as potentially, if not actually,

diabetic. Parenthetical mention should be made that 1 female (0.3 percent) fell below the minimum of 4.2 percent (the significance of low glycosylated hemoglobins has not been clarified). Employing the Gabbay standards (4.2 to 5.6 percent), 140 males (79 percent) and 126 females (81 percent) could be viewed as having elevated levels and, therefore, possibly diabetic. Again, only 1 female is below the acceptable lower limit. On the basis of the conclusions by Ellul ( $< 7$  percent), then 44/178 (25 percent) of the males, 49/156 (31 percent) of the females, and 93/334 (28 percent) of the total group in our series display elevated glycohem-oglobins. Cole indicated a cutoff point of 5 percent. Thus, 320/334 (96 percent) of our group may be viewed as, at least potentially, diabetic. Finally, according to Tze et al., about 46 percent (154/334) of our group demonstrated elevated scores.

A word of caution should be appended to these preliminary observations. The various methodologies for measurement and the relationships to blood glucose require additional investigation as has been so ably pointed out in recent reviews (Bunn, 1981; Jovanovic and Peterson, 1981). We hope that this brief communication will catalyze additional interest by others to reexamine, and in greater detail, the incidence and prevalence of abnormal glycosylated hemoglobins and especially A1c in the general and specialized populations.

**Table Hemoglobin A1c Distribution**

HbA1c groups	male group	female group	total group
3.0- 3.9	0	1	1
4.0- 4.9	6	7	13
5.0- 5.9	53	42	95
6.0- 6.9	75	57	132
7.0- 7.9	21	24	45
8.0- 8.9	13	10	23
9.0- 9.9	6	6	12
10.0 - 15.9	4	9	13
totals	178	156	334
mean	6.6	6.8	6.7
S.D.	1.4	1.8	1.6
minimum	4.3	3.2	3.2
maximum	15.7	15.0	15.7
range	11.4	11.8	12.5

**References**

- BUNN, H.F.: Nonenzymatic Glycosylation of Protein: Relevance to Diabetes. *Amer. J. Med.* 70,2,325-330, February, 1981.
- COLE, R.A.: The Significance of Hemoglobin A1c in Diabetes Mellitus. In: *Current Concepts*. The Upjohn Company, Kalamazoo, Michigan, 1978.
- ELLUL, D.A.: Glycosylated Hemoglobin: A Literature Review. *Amer. J. Med. Technol.* 46, 9, 657-661, September, 1980.
- GABBAY, K.H., HASTY, K., BRESLOW, J.L., ELLISON, R.C., BUNN, H.F. and GALLOP, P.M.: Glycosylated Hemoglobins and Long-Term Blood Glucose Control in Diabetes Mellitus. *J. Clin. Endocrinol. Met.* 44: #5, 859-864, May 1977.
- JOVANOVIC, L. and PETERSON, C.M.: The Clinical Utility of Glycosylated Hemoglobin. *Amer. J. Med.* 70, 2, 331-338, February, 1981.
- KOENIG, R.J., PETERSON, C.M., JONES, R.L., SAUDEK, C, LEHRMAN, M. and CERAMI, A.: Correlation of Glucose Regulation and Hemoglobin A1c in Diabetes Mellitus. *N. Eng. J. Med.* 295, 8, 417-420, 19 August, 1976.
- TZE, W.J., THOMPSON, K.H. and LEICHTER, J.: HbA1c - An Indicator of Diabetic Control. *J. Pediat.* 93, 1, 13-16, July, 1978.