

Title : Validity of using HbA1c for diagnosing diabetes mellitus and mean values at Diagnosis across IFG,IGT and Diabetes at Diagnosis

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Primary Aim : To find the sensitivity and specificity of HbA1c of 6.5% as recommended by ADA to Diagnose new onset of Diabetes in our patient population.

Secondary Aim: Mean HBA1c values at diagnosis across the natural course of IFG,IGT and Diabetes

Methodology & Study Design: Retrospective Analysis of a pooled data of 949 asymptomatic subjects with or without a positive family history and who volunteered to rule out diabetes for the first time between April 2007 and February 2012. Analysis included subjects who had undergone OGTT along with HBA1c simultaneously. NGSP certified Biorad equipment was used for HbA1c estimation and Cobas Integra was used for estimation of Plasma Glucose values. SAS statistical system was used for statistical analysis & results reported.

Results: HbA1c level of 6.4% had an optimal combination of sensitivity and specificity of 77% and 78% for diagnosing diabetes in our population. ADA's recommended cut off HbA1c level of 6.5% had sensitivity and specificity of 76% and 82% respectively for diagnosis of newly detected diabetes mellitus as per WHO/ADA criteria using OGTT values. Specificity & Sensitivity table at various levels of HBA1c(Table 1) and Mean HBA1c at various levels of Diabetes(Table 2) are given as tables below:

A1c	Sensitivity (%)	Specificity (%)
6.1	85.02	61.51
6.2	82.76	66.55
6.3	81.07	71.76
6.4	77.01	78.03
6.5	75.98	82.18
6.6	74.57	86.05
6.7	70.62	89.07

	HbA1c (Mean ± SD)	95%CI
Normal	5.99±0.39	5.95-6.01
IFG	6.56±0.84	6.47-6.65
IGT	7.17±1.82	7.04-7.29
DM	7.87±2.03	7.68-8.03

Conclusion: HbA1c of 6.4% had best possible specificity & sensitivity for Diagnosing Diabetes in our study. ADA's cut off value of 6.5 for diagnosis of newly detected Diabetics is acceptable. Mean HBA1c at diagnosis among asymptomatic subjects studied in this cohort across IFG,IGT & Diabetes is above the ADA's recommended cut off of 6.5% . If replicated in larger studies, our data will have important implications for screening, evaluation, prevention and public health measures.