

Full Length Research Paper

Impact of American diabetes association criteria on the frequency of impaired fasting glucose

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In 2003 the American diabetes association (ADA) suggested to lower diagnostic criteria for impaired fasting glucose (IFG) from 110mg/dl (6.1mmol/l) to 100mg/dl (5.6mmol/l). However the World Health Organization (WHO) remains to maintain lowered threshold criteria as 110mg/dl due to a lack of evidence of any benefit in terms of reducing progression to diabetes mellitus and cardiovascular disease. The aim of the present study was to evaluate the impact of ADA criteria with respect to the frequency of IFG. Institutional based cross sectional study from December 2012 to February 2013 was conducted to assess the impact of the ADA diagnostic criteria in prevalence of IFG. 422 subjects from five institutions at Bishoftu town were involved. Blood sample after fasting for ≥ 8 hours was collected and serum was assayed for glucose. Prevalence of IFG showed that the ADA diagnostic criteria increased the prevalence of IFG from 15.4% to 45.3% compared with the current WHO criteria. The proposed diagnostic criteria for IFG by ADA will lead to a dramatic increase in the prevalence of IFG. Therefore further studies are needed to evaluate the change of the frequency in nationwide and among various sample populations along with the benefits as compared to WHO criteria.

Key words: ADA, Bishoftu, IFG, institutions, prevalence, WHO.

INTRODUCTION

Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) has received growing consideration for their tendency to become diabetes mellitus (Wen *et al.* 2005). These abnormalities of glucose metabolism are the most commonly diagnosed with the threshold criteria for fasting glucose or glucose tolerance established by the American diabetes association (ADA) and the World Health Organization (WHO) (Petersen and Mcguire, 2005).

ADA defined IFG in 1997 as a means of classifying individuals who had fasting glucose levels between normal and diabetes (Diabetes care, 1997). It was meant to be analogous to IGT but based on the FPG. The original FPG range was 110-125 mg/dl (6.1-6.9 mmol/l) which later in 2003 changed to 100-125 mg/dl (5.6-6.9 mmol/l) so that the population risk of developing diabetes with IFG would be similar to

that with IGT (Diabetes care, 2003). IFG was also adopted by WHO in 1999 report as fasting plasma glucose 110–125mg/dl (6.1-6.9 mmol/l). The criterion was once more recommended to be retained in 2006 (WHO and IDF, 2006).

As measures of future risk of diabetes; the annualized relative risk of people with isolated IFG progressing to diabetes mellitus compared with people with normal glucose tolerance showed a 4.7 fold increase in the three studies included in the review by the McMaster group (Diabetes Res. Clin. Pract., 2008). IFG was also associated with increased risk of adverse outcomes with a relative risk ranging from 1.19-1.28 for non-fatal myocardial infarction, non-fatal cardiovascular disease, cardiovascular mortality and all-cause mortality (Santaguida PL *et al.*, 2005).

The diagnostic criteria of IFG are likely to have variable effects on the prevalence of IFG in different population. A number of studies reported a two to threefold increase in IFG prevalence using the ADA criteria compared with WHO, highlighted by data from the evaluation of scre-

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Table 1. Institutions versus distribution of individuals participated in the study.

Institutions	No of staff	Proportional allocation	Final sample size
Agricultural Research Center	270	70	102
National Veterinary Institute	215	55	81
Zuquala Steel Production	200	52	76
Kalehiwot Kuriftu Center	130	33	49
College of Veterinary Medicine	300	77	114
Total	1115	287	422

ening and early detection strategies for type 2 diabetes and impaired glucose tolerance (DETECT-2) study (Borch-Johnsen *et al.*, 2004). Although numerous studies have documented worldwide regarding IFG, there is scarcity of study in Ethiopia. Hence, this study was aimed to assess the difference between ADA and WHO criteria on the frequency of IFG in selected institutions at Bishoftu town.

MATERIALS AND METHODS

Study design, area and period: Cross-sectional study was conducted from December 2012 to February 2013 to determine the burden of IFG using ADA and WHO criterion in selected institutions at Bishoftu town, East Shoa, Ethiopia. The institutions were National Veterinary Institute, Agricultural Research Center, Zuquala Steel Production Factory, Kalehiwot Kuriftu Center and College of Veterinary Medicine.

Study population, sampling procedure and sample size: Study participants were recruited using convenient sampling method from the staffs of the institutions and the sample size was calculated using formula for estimating single population proportion with an assumption of 50%, 0.05 precision and 95% confidence interval (CI) giving 384. However the sample was taken from a relatively small population ($n < 10000$, ie $n=1115$); the sample size is adjusted using finite population correction to give a total of 287. Nevertheless by considering the resources, participant's response and to increase precision the size was inflated proportionately to 422. **The** sample size was distributed to selected institutions by using proportional allocation related to staff size of the institutions (Table 1). **Exclusion Criteria:** Individuals with diagnosed diabetes mellitus, pregnant women and those taking any drugs with possible impact on glucose metabolism were excluded from the study.

Measurement and data collection: 3ml venous blood using plain vacutainer tubes was obtained after an

overnight fast (≥ 8 hrs). The blood samples were left at room temperature to allow clotting for 15-20 minutes and centrifuged at 3000 rpm for 10 minutes. Then sera were transferred into 2ml Eppendorf tubes and stored at $+4^{\circ}\text{C}$ for 1-2 hours at sampling sites and transported to biochemistry laboratory of College of Veterinary Medicine (CVM), Addis Ababa University (AAU). The level of glucose was measured using enzymatic colorimetric assay using Humastar 80 chemistry analyzer (Human diagnostic Germany). Unique code number was given to the study participants so that confidentiality was kept well throughout the study.

Diagnostic criteria: According to WHO and ADA diagnosis of IFG categorized as fasting blood glucose value of 110-125mg/dl (6.1-6.9 mmol/l) and 100-125 mg/dl (5.6-6.9 mmol/l) respectively (Diabetes care, 1997 and 2003).

Data collection procedure: Ethical clearance (DRERC 03/12/MLS) was collected from research and ethics review committee of the department of medical laboratory sciences, school of allied health sciences, college of health sciences, Addis Ababa University. An information handbill on purpose of the study was made and given to individuals in the selected institutions, prior to data collection.

Quality assurance: After blood collection serum was separated within 30 minutes and prior to analysis samples were placed at -20°C . The instrument Humastar 80 chemistry analyzer was calibrated using calibrator (Autocal) and quality control samples both normal (Humatrol N) and pathological (Humatrol P) were run each day before running samples for tests.

Statistical Analysis: Data entry and analysis was performed using STATA (Version 11, USA). Descriptive summary of the study participants was presented in terms of mean, range, Standard deviations, proportions and the percentage of IFG was calculated as number

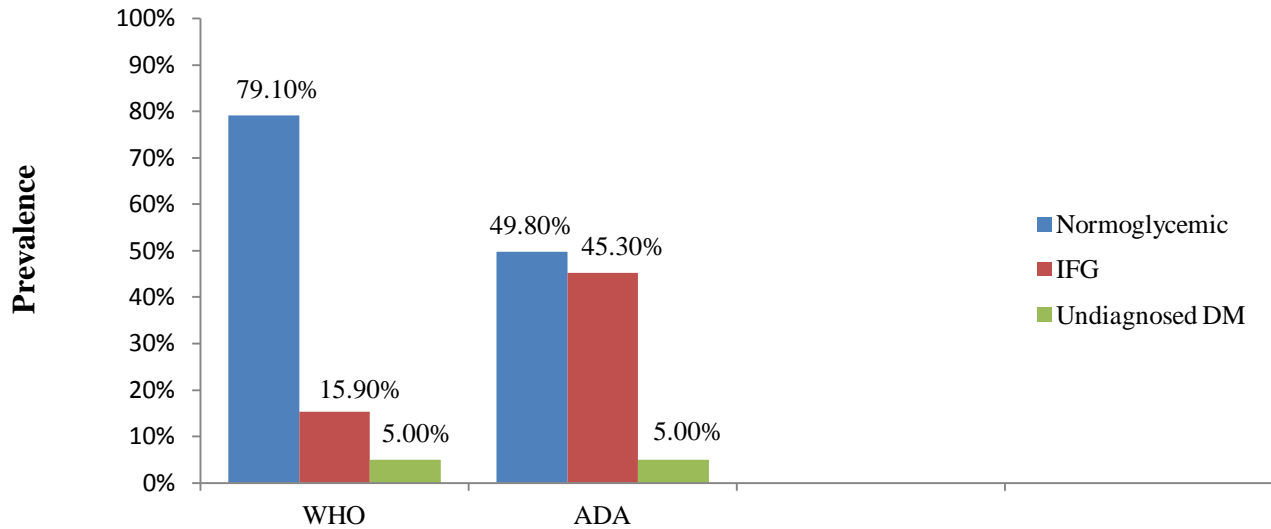


Figure 1. Prevalence of IFG using WHO and ADA criteria

subjects with IFG divided by the total number of study subjects.

RESULT

Characteristics of Study Participants

A total 422 (37.9%) subjects from a total of 1115 individuals, were involved in the study. Among the study subjects, 62.3% (n=263) were males and 37.7% (n=159) females giving a sex ratio of 1:0.6. The age of the study participants ranged from 20 to 70 years with the mean \pm SD of 40.3 ± 10.3 . Higher proportion of the study participants reside in the age group 30-49 years old.

Prevalence of IFG

Out of 422 subjects tested 4.98% (n=21) [95% CI: 3%-7%] were found to have fasting glucose value ≥ 126 mg/dl (>7.0 mmol/l) (undiagnosed diabetes). The remaining 95% (n=401) had fasting glucose value ≤ 125 mg/dl (< 6.9 mmol/l) whom 334 (79.15%) normoglycaemic, 67 (15.88%) [95%CI: 11.9%-18.7%] had IFG according to WHO criteria. Comparatively when the ADA criterion was applied the frequency of IFG increases to 191 (45.3%) [95%CI: 40.5%-50.1%] which was three times larger than the WHO criteria (Figure 1).

DISCUSSION

In the present study we assessed the impact of the ADA's proposed change on prevalence of IFG. The IFG prevalence using WHO and ADA criteria's was 15.9% and 45.3% respectively. There was a threefold increase in the prevalence of IFG using the ADA criteria as

compared to WHO. Our findings are in agreement with the prevalence of a number of studies which reported a two to three fold increase in IFG prevalence using the ADA criteria compared with WHO. The prevalence of IFG increasing from 12.6% to 38.8% in Denmark, from 16.3% to 45.7% in France, from 11.0% to 38.6% in India, from 12.7% to 28.7% in China, and from 12.1% to 32.0% in the USA (Borch-Johnsen *et al.*, 2004). In agreement with our findings the epidemiological health survey in Saudi subjects obtained 14.1% (Al-Nozha *et al.*, 2004) and in Paris 15.9% (Borch-Johnsen *et al.*, 2004) of IFG using WHO criteria. However reports in literature indicated that prevalence of IFG using WHO can be as high as 29.9% in India (Borch-Johnsen *et al.*, 2004). The study shows relatively higher prevalence of IFG compared to Ethiopia; 15% (Yemane *et al.*, 2007), Pakistan; 5.6% (Zafar *et al.*, 2011) and Congo; 9% (On 'Kin *et al.*, 2008) using ADA. The direct comparisons of prevalence rates are challenging owing to different methodologies applied and diverse characteristics of the study population.

Limitation of the Study

The study was being institutional based and it might be affected by selection bias and the conclusions might not apply to the population at large. Though a number of factors that might alter IFG; the study unable to not consider them owing to the logistic reasons.

CONCLUSION

In conclusion, our results suggested that the ADA criteria over estimates IFG as compared to WHO. This leads to

confusion, because the term pre-diabetes is used to indicate a category of subjects with very high risk of both cardiovascular disease (CVD) and diabetes mellitus.; this group should be targeted for primary prevention and intensive treatment of risk factors. Therefore further studies are needed to evaluate the change in frequency of IFG in nationwide and among various sample populations and clearly identify population at risk for developing diabetes mellitus and CVD.

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CONFLICT OF INTEREST

YC designed the study and collected data in the field, performed analysis, Interpretation of data, and draft the manuscript. **MW** assisted with the design, performed analysis, interpretation of data and the critical review of the manuscript. **SK** participated in design and helped in drafting the manuscript. **AR** participated in interpretation of data, helped in drafting the manuscript. **DY** conceived of the study and helped to draft the manuscript. All authors read and approved the final manuscript. All authors participated in critical appraisal of the manuscript.

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