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RESEARCH ARTICLE

Assessing impaired fasting blood glucose criteria for high-risk dysglycaemic populations: an experience from a European population state

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Abstract

Purpose Discrepancies exist between international bodies for the diagnosis of impaired fasting glucose (IFG). The aim of this study was to establish the IFG characteristics and evaluate the best diagnostic IFG criteria in a high risk dysglycaemic population.

Methods An IFG population ($n = 451$) was identified from a national representative cross-sectional survey using a fasting blood glucose (FBG) ranging from 5.60 to 6.99 mmol/L. These participants were invited for a follow-up oral glucose tolerance test (OGTT). Both FBG results (health survey & OGTT) were evaluated in relation to different diagnostic IFG criteria (≥5.6 mmol/L vs. ≥6.1 mmol/L) while comparing to the final OGTT glycemic diagnosis.

Results Out of the total survey population ($n = 1861$), 24.34% was diagnosed with IFG. Approximately 50% of the IFG's ($n = 227$) attended for the OGTT. The majority of the IFG population were male with an overweight-obese status. If the FBG cut-off point of 6.1 mmol/L was followed, more than a quarter of the population attending the OGTT would have had a missed dysglycaemic status.

Conclusion High-risk dysglycaemic and body mass populations may establish a more accurate dysglycaemia diagnosis and outcome when following an FBG cut-off point of ≥5.60 mmol/L for IFG.

Keywords Type 2 diabetes · Oral glucose tolerance test · Glucose intolerance · Impaired fasting glucose · Malta

Introduction

Intermediate hyperglycaemia or pre-diabetes occurs when the plasma glucose is above the normal glucose level but is not high enough to be classified as type 2 diabetes mellitus (T2DM) [1]. Considering that T2DM is an established global epidemic, identification of the precursor stage of T2DM might be an ideal public health strategy with an eventual positive health economic outcome.

The differing diagnostic cut-off points for the identification of this precursor stage have resulted in a number of disagreements between international bodies. Although consensus had been agreed upon for diagnosing T2DM between both major international bodies, discrepancies still exist between the American Diabetes Association (ADA) and the World Health Organization (WHO) on the cut-off points for impaired fasting glucose (IFG). In fact, the ADA recommends the fasting blood glucose (FBG) cut-off point for IFG as being more or equal to 5.6 mmol/L following a number of studies reporting that the best sensitivity and specificity for FBG as a predictor for future diabetes was lower than 6.1 mmol/L [2]. Conversely, the WHO expressed concerns on lowering of the FBG levels to 5.6 mmol/L [3]. It was reported that if this cut-off point had to be adopted, there would be an increase in IFG prevalence and a greater impact on health systems. Therefore, the WHO cut-off point for IFG was set to be beyond or equal to 6.1 mmol/L [3]. Such discrepancies leave examining bodies in a conundrum as to which diagnostic criteria need to be used for a specific population and when to undergo repeat testing or further management.

Malta is a small European state with an established high type 2 diabetes rate [4, 5] Such a high risk dysglycaemic

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population is the perfect candidate to establish which IFG criteria should be used, especially for small islands and high-risk neighboring countries. The aim of this study was to evaluate the phenotypic characteristics of the IFG Maltese population along with their glycaemic status after an oral glucose tolerance test. Furthermore, to explore whether the American Diabetes Association (ADA) or the World Health Organization (WHO) criteria were a better diagnostic measure of dysglycaemic state in Malta. Considering that no previous studies had been conducted in Malta covering the impaired fasting blood glucose status, this study was considered to be of a medical and public health importance.

Material and methods

Study design and sampling

A cross-sectional health examination survey was conducted in Malta between 2014 and 2016. The detailed protocol can be found elsewhere [6] In brief, a single stage random population sample stratified by age, sex and locality was obtained from a national register. The sample population (18 to 70 years) represented approximately 1% of each Maltese town for each sex and age. An informed written consent was obtained from each participant. All residents in Malta for at least 6 months were eligible however, pregnant women and those too ill to attend for the health survey were excluded. A health examination hub was set up every weekend in each towns' governmental clinics. A fasting blood glucose (FBG) test and a lipid profile (LDL-C, Triglycerides, HDL-C, Total Cholesterol) were performed as part of the health examination survey. Participants scoring an FBG between 5.60–6.99 mmol/L were considered to suffer from impaired fasting glucose (IFG) provided they did not have a previous history of diabetes or were already on oral hypoglycaemic agents [7].

Study instruments

Data collection

This sub-group (IFG diagnosed during the survey) was invited to undergo a second glucose testing through an oral glucose tolerance test (OGTT) within 2 weeks of the initial IFG diagnosis. A validated socio-demographic questionnaire was used to gather self-reported data on the district these participants lived in; their highest education level; their employment status (Employed, Unemployed, Student, Retired or Housewife) and whether they smoked or consumed alcohol. The categorical definition for education followed the ISCED-1999 criteria [8]. Hence, education was categorised into no formal education, primary education level, unfinished secondary level, finished secondary level, tertiary level, university level and postgraduate level. Smoking was defined as having smoked at least one cigarette packet in a week over a period of 12 months. Alcohol consumption was defined as the consumption of at least one unit of an alcohol beverage in a week over a period of 12 months.

As part of the initial health examination survey, participants had their body weight (in kilos) and their height (in meters) measured using a calibrated digital scale with a height rod. Participants were asked to remove all heavy clothing, hats, jewelry and shoes, while maintaining privacy, before stepping on the scale. They were advised to stand straight while looking away from the height rod when measuring their height. The body mass index (BMI) was then calculated by dividing the weight (in kilos) by the height (in meters) squared.

Participants invited for an OGTT were requested to be fasted for at least 8 h and refrain from any physical activity or smoking for at least an hour preceding the test [9]. A glucose sample (FBG) at 0 h was taken followed by the ingestion of a 75 g glucose load. After 2 h, another glucose serum sample (2nd hour glucose) was taken.

Definitions and analysis

Isolated impaired glucose tolerance (i-IGT) was defined as those participants with an initial normal fasting glucose (FBG), but with a 2nd hour glucose ranging between 7.8–11.0 mmol/L.

Isolated impaired fasting glucose (i-IFG) was defined as an initially elevated FBG (>5.6 mmol/L but <7 mmol/L) with a return to normal glucose level (<5.6 mmol/L) at the 2nd hour glucose. Combined IFG and IGT (IFG + IGT) was defined as those participants with an elevated FBG ($\geq$ 5.6 mmol/L) and a 2nd hour glucose between 7.8–11.0 mmol/L [10]. Those with a 2nd hour glucose above 11.1 mmol/L were labelled as diabetic (T2DM) irrelevant of the initial FBG level [3].

The results of the lipid profile measurements taken during the health examination survey were considered. Dyslipidaemia was defined as having a combination of elevated LDL-C and triglyceride levels along with a low HDL-C level.

The BMI was divided into 4 categories, where a BMI of <= 18.40 Kg/m^2 was labeled as underweight, 18.41–24.99 Kg/m^2 as normal; BMI 25–29.99 Kg/m^2 as overweight and BMI >30 Kg/m^2 as obese [11].

Statistical analysis

Descriptive and statistical analyses were done by using IBM SPSS version 21. The socio-demographic and the phenotypic characteristics (BMI and dyslipidaemia) were categorically compared between the IFG population males and females. Proportions out of the total IFG males and females

(respectively) for each categorical variable was established. The IFG population that accepted the OGTT invitation was compared to those that rejected the invitation by median age, age groups, education level and sex categories. All categorical statistical testing was done using the Chi squared test while Mann-Whitney-U test was used for continuous variables. A p value of less than 0.05 was considered as significant.

The initial FBG results obtained during the health survey and the subsequent FBG performed as part of the OGTT, were analyzed in relation to the different diagnostic criteria (ADA and the WHO) and the final OGTT diagnosis. This was performed by categorizing the OGTT participants according to their FBG results and their final OGTT diagnosis. The proportion (%) making up each subdivision was calculated out of the total participating OGTT population. This process was followed for the (i) FBG obtained during the initial survey and (ii) the OGTT FBG at 0 h, while using the WHO cut-off points (6.1–6.99 mmol/L) [3]. As well as for the OGTT FBG at 0 h using the ADA cut-off points (5.60–6.99 mmol/L) [7].

Ethical considerations

This survey was granted ethical approval by the 'University of Malta Research Ethics Committee' and data protection clearance by the 'Commissioner for Data Protection Office'. All participants were provided with a unique code in order to maintain anonymity and confidentiality throughout the study and the study analyses.

Results

Out of the total attending population ($n = 1861$), the examination survey identified a total of 450 participants (24.23% CI 95%: 22.34–26.23) having a FBG between 5.60–6.99 mmol/L without any previous history of T2DM or on oral hypoglycaemic agents. These were labeled as IFG. Table 1. Illustrates the socio-demographic and phenotypic characteristics of the IFG population. The majority of the IFG population were either overweight or obese and followed a non-smoking habit. Of note, the female IFG population predominantly followed a non-alcohol habit to the contrary of the male IFG population.

Oral glucose tolerance test

The OGTT invitation was accepted by 50.33% (CI 95%: 45.73–54.92; $n = 227$) of the eligible participants ($n = 451$), with a male predominance (59.91% CI 95%: 53.42–66.07; $n = 136$).

On comparing the IFG population who attended the OGTT session to the IFG population who declined the invitation, no statistically significant difference was present between both cohorts, as follows. This non-significance held true when comparing the age groups of both cohorts ($p = 0.06$). The median age of those attending the OGTT was significantly similar to those who declined the invitation ($p = 0.47$) even on comparing median age by sex (female $p = 0.73$; male $p = 0.39$). No educational level difference was evident between the attendees and the non-attendees ($p = 0.92$). This held true even on comparing the education level by gender (female $p = 0.62$, male $p = 0.72$) and age groups (20–29 years $p = 0.36$; 30–39 years $p = 0.15$; 40–49 years $p = 0.35$; 50–59 years $p = 0.77$; 60–69 years $p = 0.96$) respectively.

The majority of those who attended the OGTT (*OGTT sub-population*) were found to have an isolated IFG (48.02% CI 95%: 41.61–54.50) after the 2 h OGTT test, as seen in Fig. 1.

Analysis of the oral glucose tolerance test sub-population

The *OGTT sub-population's* initial fasting blood glucose (FBG) obtained during the health examination survey was analyzed in accordance with the World Health Organization IFG criteria ($\geq$ 6.10 and $\leq$ 6.99 mmol/L) and to the eventual OGTT diagnosis, as seen in Table 2.

It was observed that if the WHO criterion was used as part of the study's protocol to define IFG, around one third of the *OGTT sub-population* (34.80% CI 95%: 28.90–41. 21) would have had a missed dysglycaemia diagnosis since their initial FBG was below 6.10 mmol/L but higher than 5.60 mmol/L.

As part of the oral glucose tolerance test (OGTT) process, an initial FBG sample at 0 h was withdrawn. This FBG result was categorized using both the ADA criteria and WHO criteria, and compared to the eventual OGTT diagnosis, as seen in Tables 3 and 4 respectively.

If the *OGTT sub-population* had just a repeat FBG only (instead of the 2 h OGTT), according to the ADA criteria, 3.52% (CI 95: % 1.68–6.91) of this sub-population would have had a missed dysglycaemic diagnosis since the FBG fell within normal limits. However, if the FBG WHO criteria were applied, 37.44% (CI 95%: 31.40–43.90) of the *OGTT sub-population* would have had a missed dysglycaemic diagnosis, based on just the FBG result. As expected, a higher proportion of IFG diagnosed participants by the WHO criteria were found to have an eventual T2DM diagnosis following an OGTT.

Discussion

Small state countries, such as Malta, have geographical and cultural stressors that predispose the population to a number of metabolic diseases including diabetes mellitus [12]. The pre-diabetes state usually occurs prior to the full onset of type 2 diabetes. Both impaired fasting blood glucose (IFG) and impaired glucose tolerance (IGT) states make up pre-diabetes

Table 1 Phenotypic and socio-demographic characteristic of the IFG population, by gender

		IFG population		Chi squared *p* value
		Female (*n* = 198)	Male (*n* = 253)	
Age (years)	20–29	4%	4%	0.17
	30–39	8%	15%	
	40–49	18%	18%	
	50–59	34%	35%	
	60–69	32%	25%	
	70	4%	4%	
Locality (districts)	Southern Harbour	17%	16%	0.59
	Northern Harbour	25%	28%	
	Southeastern	16%	15%	
	Western	12%	15%	
	Northern	13%	13%	
	Gozo	19%	13%	
Highest Education Level	No formal education	0%	0%	0.15
	Primary	17%	10%	
	Unfinished secondary	10%	8%	
	Finished secondary	45%	44%	
	Tertiary	14%	19%	
	University	12%	15%	
	Post-graduate	2%	4%	
Employment	Employed	38%	72%	<0.01
	Unemployed	1%	2%	
	Student	1%	0%	
	Retired	14%	26%	
	Domestic	46%	0%	
Smoking habit	Non-smoker	86%	76%	0.01
Alcohol habit	Smoker	14%	24%	
	No alcohol intake	79%	41%	<0.01
	Alcohol intake	21%	58%	
BMI (Kg/m^2)	Underweight (<=18.40)	1%	1%	<0.01
	Normal (18.41–24.99)	22%	11%	
	Overweight (25–29.99)	30%	45%	
	Obese (> = 30)	47%	42%	
DM dyslipidaemia*	Yes	7%	9%	0.36
	No	93%	91%	

*LDL-C > 2.59 mmol/L + Triglycerides > = 1.69 mmol/L + HDL-C < =1.03 mmol/L for males or HDL-C < =1.29 mmol/L for females

and have been associated with an increased risk for hypertension, dyslipidemia, cardiovascular risk and type 2 diabetes [1]. Examining bodies are faced with a challenge when defining IFG due to discrepancies between the two main bodies, WHO and ADA, unlike when defining IGT [3, 9]. In fact, the International Diabetes Federation (IDF) defines pre-diabetes as IGT [13]. However, in order to establish a diagnosis of IGT, an oral glucose tolerance test (OGTT) needs to be performed. The OGTT is a laborious and uncomfortable test that requires an individual to drink a 75 g glucose load with a 2 h waiting time for the test to finish. Although the OGTT is claimed to be the "gold standard" for the diagnosis of diabetes mellitus since fasting plasma glucose levels alone fail to identify approximately 30% of those with undiagnosed diabetes [14, 15]. Of note, in this study, a much smaller prevalence rate of undiagnosed diabetics would have been missed if only FBG was

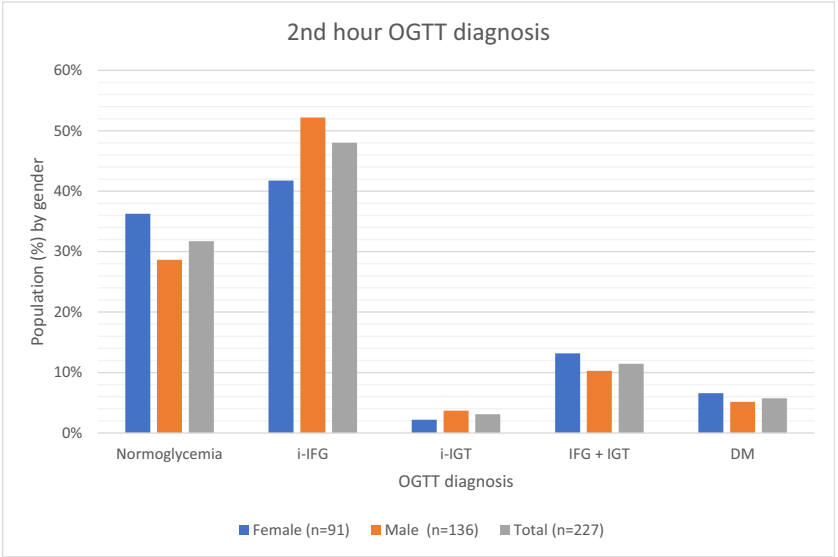

Fig. 1 Demonstrates the 2nd hour OGTT diagnosis by gender

used as a diagnostic test. Nevertheless, both FBG and OGTT have pre-analytic and analytic variability. This predispose both diagnostic tests to possible variable results when repeated. It is thus important that analytic precautions are taken. In fact, in this study the blood samples were collected in sodium fluoride tubes and transported to the laboratory within 2 h of bloodletting in order to try to reduce such analytic variabilities. One needs to appreciate that this was only possible due to the short distances between each Maltese town and the general hospital.

Epidemiological studies usually base the diagnosis of T2DM on a single fasting blood glucose or oral glucose tolerance test, [16] which was the case in this study. This may have an impact on the actual dysglycaemic prevalence rates of the country. It has been reported that approximately 20% of the OGTT diagnosed diabetics had an FBG below 6.1 mmol/L. In fact, such an observation was established in this study, although at a smaller population proportion. However, almost a tenth of this study's population with an initial FBG below 6.1 mmol/L were found to have an established isolated-IGT or a combination of IFG and IGT after the 2 h OGTT. Hence, these are at higher risk for the development of metabolic complications later on and would have been missed if the WHO criteria were followed. Our findings coincide with another European study conducted in Spain [17]. Suggestions have been put forward that individuals with an established IFG should have a follow-up OGTT since 5 to 20% of these would have already developed T2DM [10]. Indeed, this was observed in this study. It was also reported the IFG state provides a better predictive indication for the development of overt diabetes rather than IGT since IFG reflects the presence of hepatic insulin resistance [18]. Hepatic insulin resistance also forms part of obesity pathophysiology [19]. Considering that a large proportion of the IFG population understudy were also obese, the lower FBG cut-off point may have been found to be a better identifiable marker for dysglycaemia possibly due to the concurrent presence of excess adiposity. Hence, the identification of an earlier IFG stage through the use of a lower cut-off point especially in the presence of adiposity, as seen in this study, may prevent the development of silent diabetes complications. As well as it may be possible to halt the transition to overt diabetes through preventive measures. In fact, it was reported that the introduction of lifestyle interventions led to the reduction of 40–70% of pre-diabetes from converting to diabetes [20]. Nonetheless, the identification of early IFG can increase the psychological

Table 2 Distribution of the OGTT sub-population according to their initial health survey FBG measurement following the WHO criteria and compared to their final glycaemic diagnosis (2nd hour glucose)

	OGTT sub-population initial health survey FBG (mmol/L)	
2nd Hour OGTT diagnosis	<6.10 ($n = 139$)	6.10–6.99 ($n = 88$)
Normoglycemia	43%	14%
i-IFG	45%	53%
i-IGT	3%	3%
IFG + IGT	6%	19%
Diabetes Mellitus	3%	10%

Table 3 Distribution of the 0-h FBG measurement obtained during the OGTT categorized by the ADA criteria and compared to the final OGTT diagnosis

	OGTT sub-population		
	0-h FBG (mmol/L) - ADA criteria		
2nd Hour OGTT diagnosis	<5.60 ($n = 80$)	5.60–6.99 ($n = 139$)	> = 7 mmol/L ($n = 8$)
Normoglycemia	90%	0%	0%
i-IFG	0%	78%	13%
i-IGT	9%	0%	0%
IFG + IGT	0%	15%	63%
DM	1%	7%	25%

stress onto the diagnosed individual along with an increased burden on the country's economy and healthcare system [21]. Therefore, before implementing a lower IFG cut-off point, one needs to consider the related pros and cons in accordance with the population phenotypical characteristics. In this case, it appears that in this highly diabetic and obesogenic prevalent country, considering the lower IFG cut-off point may be beneficial and would enable the prevention of more overt dysglycaemic states from developing.

This study had several strengths. Firstly, the sample was drawn from a national register and was nationally representative. Second, the study sample population included both young adults and elderly, hence the study's results and interpretations incorporated a wide range of the adult population. However, the sex distribution of OGTT participants was not equal and hence this may provide a challenge in establishing data on the sex susceptibility to dysglycemia. The majority of the data was obtained from a health examination survey, hence minimizing self-reporting or data re-collection biases, although the socio-demographic data was obtained through a self-reported questionnaire. Finally, although not every IFG diagnosed individual during the survey accepted the invitation to undergo further testing with an OGTT, no statistically significant differences were established between both sub-groups (OGTT responders vs. OGTT non-responders). Our study had also some limitations. Firstly, the design was cross-sectional hence temporal relationships could not be inferred. Secondly, the sample size was small and may have had an effect on the study power, results and interpretation. It is therefore recommended that a larger study is carried out along with the evaluation of the sensitivity and specificity of the OGTT as a screening tool for the Maltese population while comparing to the diagnostic ability of FBG for both pre-diabetes and diabetes.

Conclusion

This study provides a snapshot of the IFG population characteristics. The majority of this population were males having a high body mass index. Even though there are a number of controversaries as to the ideal cut-off point for IFG, in this study it was observed that following a FBG cut-off point of 5.60 mmol/L, higher dysglycaemic diagnostic outcome was obtained. A number of dysglycaemic individuals would have been missed if the higher cut-off point (6.1 mmol/L) was used. Such findings put forward the suggestion that in high-risk dysglycaemic and high body mass populations, the lower FBG cut-off point (> = 5.60 mmol/L) may act as a better diagnostic index. However, it is recommended that a larger population study is conducted to further evaluate this finding.

Table 4 Distribution of the 0-h FBG measurement obtained during the OGTT categorized by the WHO criteria and compared to the final OGTT diagnosis

	OGTT sub-population		
	0-h FBG (mmol/L) - WHO criteria		
2nd Hour OGTT diagnosis	<6.10 ($n = 157$)	6.10–6.99 ($n = 62$)	> = 7 mmol/L ($n = 8$)
Normoglycemia	46%	0%	0%
i-IFG	45%	61%	13%
i-IGT	4%	0%	0%
IFG + IGT	4%	23%	63%
DM	1%	16%	25%

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Compliance with ethical standards

Conflict of interest The authors declare that they do not have any conflict of interest.

Ethics approval Ethical approval was granted from the University of Malta Research Ethics Committee (UREC), with the reference number 19/2014 and dated 30th May 2014.

Consent to participate All participants provided informed written consent to participate in the survey and oral glucose tolerance testing.

Consent for publication All participants gave their informed consent to have non-identifiable results published.

Availability of data and material Data and material are available on request to the corresponding author.

Code availability Statistical data is available upon request to the corresponding author.

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