AN APPRAISAL OF THE SCREENING AND DIAGNOSTIC CRITERIA OF GESTATIONAL DIABETES IN SOUTH INDIAN WOMEN: A SINGLE CENTER EXPERIENCE IN AN URBAN SETTING

R H Lakshmi (Ravanasamudram Hariharan Lakshmi)

MBBS; MD (Internal Medicine)

Orchid ID :0000 -0002-4769-8608

Associate Director

Hariharan Diabetes and Heart Care Hospitals

no.13 ; 29th street ; Nanganallur

Chennai 61

Corresponding Author: J V Balasubramaniyan (Jayanty Venkata Balasubramaniyan)

MBBS ; MD ; DNB (Cardiology)

Orchid id :0000 0002 6181 3828

Assistant Professor of Cardiology

Sri Ramachandra Institute of Higher Education and Research

Porur ; Chennai 116

Abstract

Introduction: The debate over the criteria to screen and diagnose gestational diabetes mellitus

(GDM) has been incessant over the last five decades.This study is particularly directed towards evaluating the one-step approach of oral glucose tolerance test (OGTT) versus the two-step process with a screening test of oral glucose challenge test (OGCT) followed by the OGTT as screening and diagnostic criteria in South Indian women. The study also aimed to determine

the normal glucose tolerance range in the study population. Materials and Methods: In a study sample of 1200 women, one and two-step diagnostic criteria were applied to 600 women each. After exclusion of those who satisfied the criteria for the diagnosis of GDM, the remaining were evaluated for determination of the normal study population followed by comparative and statistical analysis. We analysed the prevalence of GDM based on more than one abnormal value versus more than two abnormal values. Results: Out of the 600 women subjected to one-step test, 56 (9.33%) were diagnosed with GDM with a sensitivity and specificity of 80.36% and 95.77%, respectively. For the two-step test, 10 (1.67%) were found to have GDM with sensitivity of 90%; and specificity of 66.27% & 53.9 %. Conclusion: Though the one-step screening process is extremely effective, this study has revealed various advantages of the two-step protocol. The prior screening test in the two-step method reduces the burden of testing by oral glucose tolerance test, thereby diminishing laboratory load to a great extent.

Introduction

The World health Organization (WHO) recommends that hyperglycemia first detected at any time during pregnancy should be classified as either Gestational Diabetes Mellitus (GDM) or diabetes mellitus in pregnancy.(1)However, the precise method for screening and diagnosing gestational diabetes has remained a controversial topic for over five decades now. (2) Different organizations have proposed a myriad of screening and diagnostic methods forGDM.

Several studies have repeatedly suggested that using a selective screening based on historical and clinical risk factors such as BMI, lipid profile, PCOS, maternal age etc.results in missing a large number of GDM cases(3). The International Association of the Diabetes in Pregnancy Study Group (IADPSG),following Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) (4)study, recommended new diagnostic criteria for GDM based on the two hour 75 g Oral Glucose Tolerance Test (OGTT). The WHO(1) adopted these criteria in 2013, however, there have been several debates on this universal approach of screening patients.

Concerns with a single-step diagnostic criterion include the need for a fasting state in pregnant women, increased laboratory workload and increased medicalization of pregnancy(5).

The Diabetes in Pregnancy Study Group of

India (DIPSI)(6) recommended a singleglucose estimation 2 hour after a (potentially non-fasting)75g load consideringits observation thatpredominant abnormality in

the Indian population is in the post –load glucose test. Table 1(2,7–13) describes select screening and diagnostic criteria currently in recommended by various bodies worldwide.

Aim of the Study

The principal aim of the study was to appraise the existing one and two-step criteria for the screening and diagnosis of GDM in South Indian pregnant women. Another goal was to determine the normal glucose tolerance in South Indian pregnant women and if possible, derive cut off values for the diagnosis of GDM based on these values.

Ethics

This study was approved by the institutional ethics committee of Hariharan Diabetes Care Center, Chennai. All participants were included in the study after obtaining an informed consent.

Materials and Methods

One thousand two hundred pregnant women between 24-28 weeks of gestation who visited a tertiary care hospital in Chennai, India formed the material of this study. We included pregnant women without prediabetes or diabetes detected in early pregnancy. After an informed consent, we randomized these women into two parallel screening groups.

We subjected every alternate woman to either a one-step or a two-step screening protocol resulting in 600 women in each group. Figure 1 provides details of the study protocol in each arm.

Our National Accreditation Board for Testing and Calibration Laboratories (NABL) certified laboratory analysed the Plasma Glucose (PG) values via glucose hexokinase spectrophotometry in a fully automated analyser. We made the diagnosis of GDM made if any two of the values on OGTT were met or exceeded as recommended by Carpenter and Coustan.(8)

We determined the prevalence of GDM using the screening thresholds as mentioned in Figure 1. We also determined the sensitivity and specificity of the screening test with the different screening thresholds.

We calculated the normal glucose distribution after excluding the women who were diagnosed with GDM. We calculated the mean +2 SD values at the various time intervals of   the OGTT to determine the upper limit of normal at the respective time intervals. These values then constituted the cut-off values for abnormal blood glucose values based on the present study population.

We analysed the prevalence of GDM based on more than one abnormal value versus more than twoabnormal values.Similarly, we evaluated the reliability of basing the diagnosis of GDM on each of the time intervals of the OGTT.We carried out the statistical analysis using the Student's 't' test and considered a p value >0.05 statistically significant.

Results

 We enrolled a total of 1200 women in the study with an equal distribution of 600 women in each of the study arms. We carried out the OGTT in the second trimester(24-28 weeks) which minimized the chances of nausea and vomiting and ensured higher compliance rates to the protocol.

Of the 600 women, who underwent the OGTT, 56 (9.33%) women were diagnosed   to have GDM. Thus, the prevalence of GDM among the 600 women who were subjected to the 75G 2-hour OGTT in this study was 9.33%. Figure 2a shows the comparative results of the 75 g glucose load one-step test between the screening and the diagnostic tests.(Figure 2a)

We found that the normal glucose tolerance in this study arm after excluding the 54 women who were diagnosed with GDM. It was a fasting blood glucose level of   84.55 $\pm$ 3.25 mg/dl, 1-hour OGTT value of 130.45 $\pm$ 25.36 mg/dl and 2-hour OGTT   value of   101.74 + 17.89 mg/dl.

The cut off values for the diagnosis of GDM rounded off to the nearest 5mg whole number were a fasting PG of 90mg/dl, 1-hour value of 180mg/dl and 135mg/dl at 2 hours.

In the second study arm, two different cut - off values were employed to determine the positive screenees, viz., 140 mg/dl and 130 mg/dl.The prevalence   of GDM among the 600 women whowere subjected   to the 100G 3-hour OGTT in this study armwas 1.67% with 10 women diagnosed to have GDM. Figure 2b and 2c show the results of 50g Oral

Glucose Challenge Test (OGCT) Vs 100 g OGTT with a cut-off   value of 140mg/dl and 130mg/dl.

We determined that the normal glucose tolerance in this study arm after excluding the 10 women who were diagnosed with GDM. It was a fasting blood glucose level of   78.74 + 6.13mg/dl 1-hour OGTT value of 129.02 + 25.61 mg/dl, 2-hour OGTT value of 114.88 + 18.40 mg/dl and 3-hour OGTT value of 89.91+ 15.94 mg/dl.

The cut off values for the diagnosis of GDM rounded off to the nearest 5mg whole number were a fasting PG of 90mg/dl, 1-hour value of 180mg/dl, 150mg/dl at two hours and at three hours 120mg/dl.

Discussion

We intended to evaluate the existing criteria for the screening and diagnosis of Gestational Diabetes in South Indian women. The study also provided an opportunity to determine the normal glucose tolerance in the study population and thereby determine the cut-off   values for the diagnosis of GDM in this population.

Screening for GDM

The need and method of screening for GDM remains a conscientious topic for over several decades now. O Sullivan and Mahan(9) first proposed a 50 g Oral Glucose Challenge test in the year 1964 followed by a 1-hour plasma glucose measurement to screen for GDM.   Several controversies exist over the need for selective vs universal screening as well the time for screening (first or second trimester).(14)

Crowther et al. suggested that the serious perinatal outcomes namely death, shoulder dystocia, bone fracture and nerve palsy were lower when GDM was identified and treated. (15) This has led to an agreement amongst certain groups that screening is essential.

The American Diabetes Association (ADA) recommends selective screening of women who have high-risk factors for GDM, while the American Congress of Obstetricians and Gynecologists (ACOG) suggest a universal screening irrespective of the presence of risk factors (10).NICE guidelines (16) recommend screening of all women of South Asian ethnicity. Several

clinical risk factors have been identified and listed by these groups. High BMI, advanced maternal age, prior history of macrosomia or still birth, known impaired glucose metabolism, family history of diabetes mellitus are some of the key risk factors. The DIPSI guidelines suggest repeating the screening test during the third trimester (32-34 weeks) in patients who remain undetected at 16 weeks.*(12)*

The 50g OGCT with a cut-off point of 140mg/dl is the most commonly evaluated screening test in the literature (17).It showed a sensitivity of 55% to 98% and a specificity of 30% to 96% in   9 observational   studies reported(18).In the present study, the sensitivity of this screening   test was 90% whilethe specificity was 66.27%. It is reported that only 11% of the patients who had a positive test developed GDM according to Carpenter and Coustan' s criteria(19). In   the   present study population,itwasfound that4.33%who had a positive test were ultimately diagnosed with GDM.

Similarly, with the cut-off point of 130mg/dl, various authors have reported a sensitivity of 54-100% and a specificity of 69-90% (18). In the present study, the sensitivity of the 1- hour 50g OGCT with 130mg/dl cut-off point, was 90% and specificity 53.90%. Only 3.20% of the   patients who had a positive test developed GDM according to the Carpenter and Coustan' s criteria.

75g two-hour test with a   cut-off point of $\geq$ 140mg/dl   is yet another screening test recommended by DIPSI.(14) This test carried a sensitivity of 80.36% and a specificity of 95.77% in the present study. 66.18% of the positive screens were found to   have GDM with this criteria.

Prevalence of GDM

Prevalence estimates of GDM are highly variable based on the screening and the diagnostic criteria used to determine them.Li et al in a recent metanalysis reported a prevalence estimate of 19.9% using the IADPSG diagnostic criteria, 10.13% with the WHO 1999 criteria and 7.37% using the DIPSI criteria in India. (17)

A 4.7% increase in the prevalence (from 7%-11.7%) has been reported by Fuller and Borgidawhen using a one- step versus a two-step screening criteria for GDM(20). In the present

study the one-step criteria showed a prevalence of 9.33% versus a 1.67% in the two-step study arm.

Diagnostic Criteria for Gestational Diabetes

We derived the criteria for GDM diagnosis based on the normal glucose tolerance values. Irrespective of the glucose load (75g or 100g) and the reliance on >1 or≥2 abnormal values on OGTT, this study's criteria showed a significantly higher prevalence of GDM. All criterianaturally identified a greater number of women with GDMif the diagnosis is based on > 1 abnormal value rather than on ≥ 2 abnormal values. (2,7–13)

Table 2 compares the prevalence of GDM in the study population using different diagnostic criteria. (2,7–13)

Plasma glucose levels at different time intervals

The primary comparative criteria for the present studywith 75g OGTTwas IADPSG (21)criteria that recommends 75g OGTTand any one abnormal value. Reliance on elevated fasting blood sugar alone or one-hour OGTT value alone identified similar number of women with GDM. On the other hand, reliance on two-hour OGTT value alone identified significantlyhigher percentage of women with GDM by the present study criteria p value.

We also compared Carpenter Coustan' s criteria with the 100 g OGTT study arm. Relying on elevated fasting blood sugar alone or one-hour OGTT value alone   identified similar number of women with GDM. On the other hand, reliance ontwo-hour OGTT value alone or three-hour OGTT value alone the present study criteria identify significantly higher percentage of   women with GDM. Table 3 provides a comparative analysis of prevalence of GDM based on plasma glucose levels at different time intervals.

Therefore, if only one OGTT value was tobe recommended for the diagnosis of GDM, the two-hourOGTT value of 135 mg/dl with 75G OGTT and 150mg/dl with 100G OGTT would be considered most suitable.

Though there is ambiguity   in the literature as to whether the screening cut- off value is >=130 mg/dl or > 130 mg/dl or >=140 mg/dl or > 140 mg/dl when the respective   cut off values mentioned are 130 mg/dl and 140mg/dl, the prevalence rate of GDM based on either

of the interpretation   was not statistically significant. However, lowering the threshold from 140mg/dl to130mg/dl significantly improves the sensitivityof the screening test and, is therefore recommended.

There is an assumption by the DIPSI guidelines that performing an OGTT might be difficult in pregnant women due to high incidence nausea and vomiting(14)(22).However, we observed a 100% compliance in our study population. This could be attributed to the testing being done during 24-28 weeks of gestation when these symptoms are minimal.

Limitations of the study

The current study did not evaluate the maternal and fetal complications with respect to the screening and diagnostic criteria. This however was out of the scope of the present study.

Conclusion

The various   existing   diagnostic criteria marginally differ from each other with regard to the cut-off values for the diagnosis of GDM.When recommending a preferred protocol, it is observed that theone-step test protocol requires all subjects to be submitted to OGTT thatis diagnostic.

On the other hand, two-step test protocol hasa preceding screening test with 50g glucose load, followed by a1-hour   screening   cut-off value of 130mg/dl or 140mg/dl. Irrespective ofthe cut-off value used, it is seen that the screeningtest canreduce the burden of testing forGDM by OGTT by nearly 50%, and hence is to be recommended.The cut-off values derived from the present study population are lower at two and three-hour OGTT values thus requiring different diagnostic criteria in this population.

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Table & Figures

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Tables

Table 1 Screening and Diagnostic Criteria for Gestational Diabetes Recommended by Various Study Groups						
Guidelines	**50 g Glucose screen PG** (mg/dl)	**OGTT Fasting (mg/dl)**	**Glucose load (g)**	**1hour (mg/dl)**	**2hour (mg/dl)**	**3hour (mg/dl)**
ADA/ACOG: one step		$\geq$92	75	$\geq$180	$\geq$153	
ADA/ACOG: two step*	$\geq$130	$\geq$95	100	$\geq$180	$\geq$155	$\geq$140
Brazilian health Ministry		$\geq$110	75		$\geq$140	
Carpenter and Coustan		>95	75	>180	$\geq$155	

Carpenter and Coustan	≥130	≥95	100	≥180	≥155	≥140
CDA	≥140(7.8)	≥95	75	≥191	≥ 160	NR
DIPSI		NR	75	NR	≥140 (7.8)	NR
IADPSG		≥92	75	≥180	≥153	
Sacks et.al		≥ 105	75	≥ 200		
Sacks et.al		≥96	100	≥172	≥152	≥131
NICE		≥ 126			≥ 140	
WHO one-step	None	≥ 126	75	NR	≥ 140	NR

*PG: Plasma Glucose; OGTT: Oral Glucose Tolerance Test

ADA: American Diabetes Association; ACOG: American College of Obstretics and Gynecology; CDA: Canadian Diabetes Association; DIPSI: Diabetes In Pregnancy Study Group of India; IADPSG: international Association of Diabetes and Pregnancy Study Group; NICE: National Institute of health and Care Excellence; WHO: World Health Organization

Table 2: Comparative prevalence of GDM* with various diagnostic criteria							
Study	75g OGTT with >2 abnormal values		75g OGTT with >1abnormal value		100 OGTT with >2 abnormal values		100 OGTT with >1 abnormal value	
	Prevalence	p value	Prevalence	p value	Prevalence	p value	Prevalence	p value
Carpenter and Coustan	9.33%	Ref	25%	Ref	1.67%	Ref	14.33	Ref
Brazilian Health Ministry	9.33%	Ns	7.67%	p<<0.001				
CDA	7%	0.317>p>0.1	23.17%	0.317 > p > 0.1				
WHO (1998)			11.67%	p<<0.001				
ADA			30%	0.1 > p > 0.5				

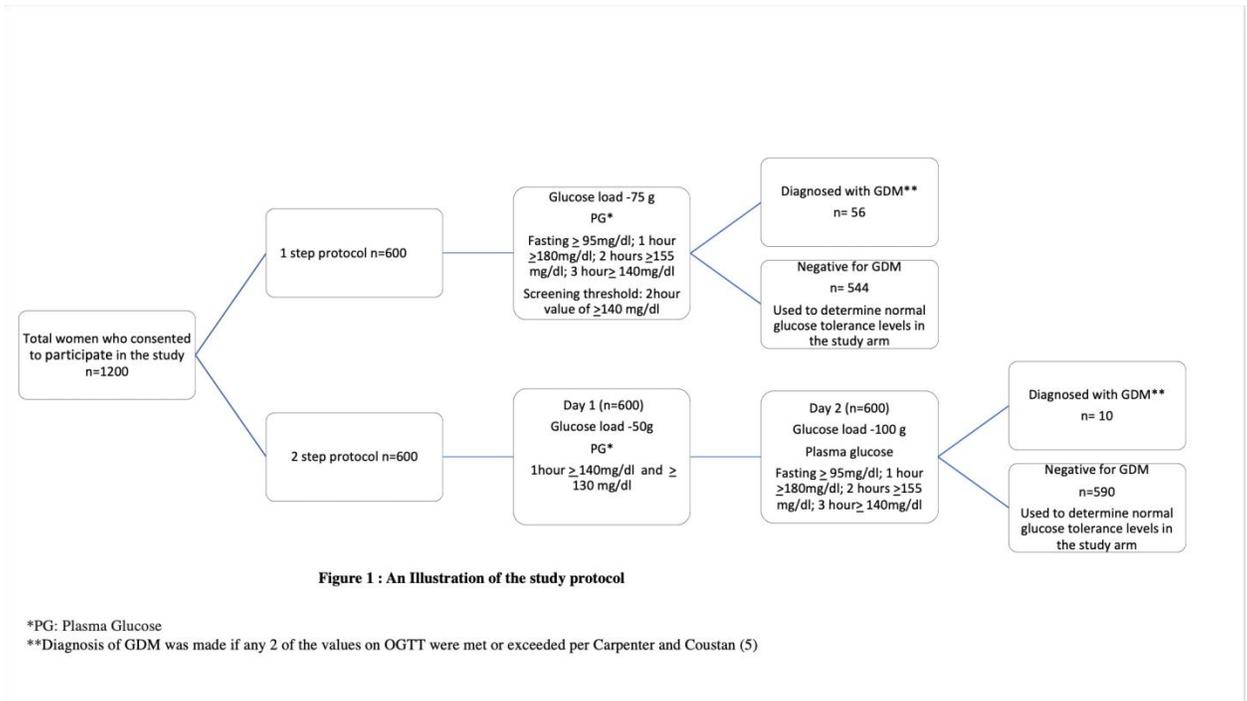|								
IADPSG (2010)		30%	0.1 > p > 0.5					
Sacks et. al		7.83%	p<<0.001		2.67	0.317 > p > 0.10		
DIPSI		30%	0.1 > p > 0.5					
ACOG				1.67%	p > 0.50			
NICE							10.33	0.046 > p > 0.001
Present Study	13.33%	0.046 > p > 0.001	36.83%	p<<0.001	4.33%	0.1 > p > 0.0027	18	p < 0.5

GDM: Gestational Diabetes Mellitus, OGTT: Oral Glucose Tolerance Test, Ref: Reference Standard , WHO : World Health Organization, ADA : American Dental Association, IADPSG : International Association of Diabetes and Pregnancy Study Group, DIPSI: Diabetes In Pregnancy Study Group of India, CDA: Canadian Diabetes Association; ACOG: American College of Obstetricians and Gynecologists, NICE: National Institute of health and Care Excellence.

Table 3 : Comparative prevalence of GDM based on plasma glucose levels at different time intervals								
Diagnostic Plasma Glucose level	**Present Study**		**IADPSG**			**Carpenter Coustan**		
	Cut off value(mg/dl)	Prevalence	Cut off value(mg/dl)	Prevalence	p value	Cut off value(mg/dl)	Prevalence	p value
75 g OGTT								
FBS value alone	90	30	92	26.33%	0.317 >p>0.10	95	21.80%	p<<0.001
2hour value alone	135	12.50%	153	7.33%	p<0.0027	155	6.50%	p<<0.001
100 g OGTT								
FBS alone	90	13.83%				95	13.83%	
1hour	180	1.50%				180	1.50%	

value alone					
2hour value alone	150	4.17%	155	1.67%	0.01>p>0.0027
3hour value alone	120	5.83%	140	0.50%	p<<0.001

GDM: Gestational Diabetes Mellitus; IADPSG: International Association of Diabetes in Pregnancy Study Group; OGTT: Oral Glucose Tolerance Test; FBS Fasting Blood Glucose
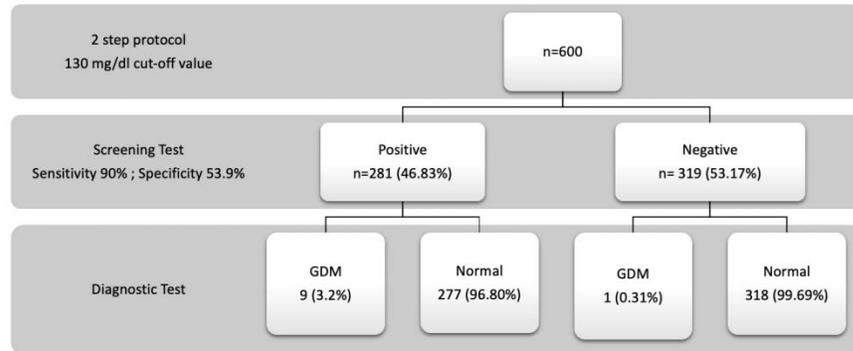

Figure 1 : An Illustration of the study protocol

*PG: Plasma Glucose
**Diagnosis of GDM was made if any 2 of the values on OGTT were met or exceeded per Carpenter and Coustan (5)

Figure 2c : Results of the 50 g OGCT* with a cut-off value of 130mg/dl Vs 100 g OGTT**
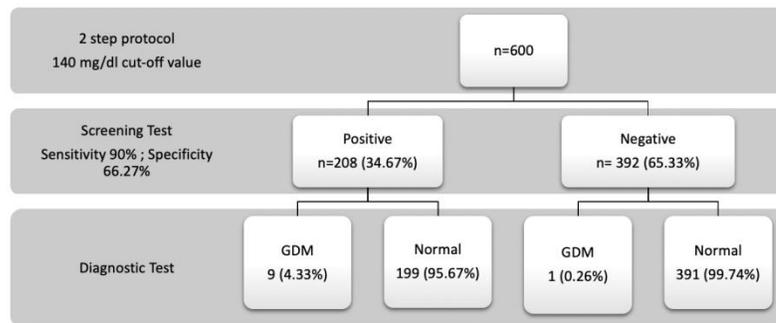

Figure 2b : Results of the 50 g OGCT* with a cut-off value of 140mg/dl Vs 100 g OGTT**

*OGCT-Oral Glucose Challenge Test
**OGTT- Oral Glucose Tolerance Test

| 1 step protocol with 75 g glucose load | n=600 | | | |

| Screening Test Sensitivity 80.36% ; Specificity 95.77% | Positive n=68 (11.33%) | | Negative n=532 (88.67%) | |

| Diagnostic Test | GDM 45 (66.18%) | Normal 23 (33.22%) | GDM 11 (2.07%) | Normal 521 (97.93%) |

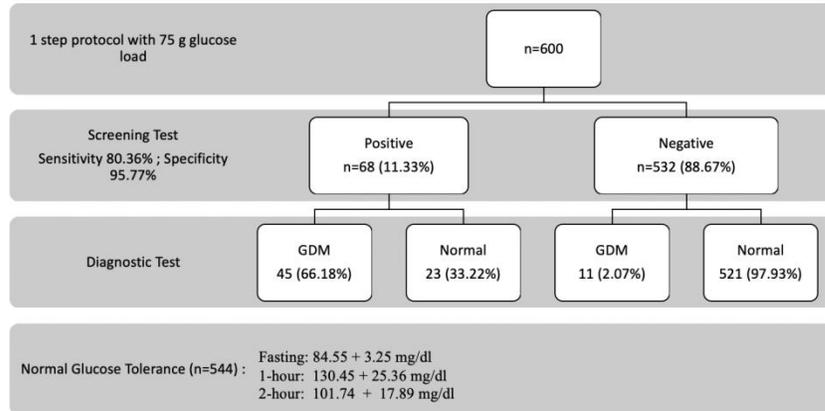| Normal Glucose Tolerance (n=544) : | Fasting: 84.55 + 3.25 mg/dl 1-hour: 130.45 + 25.36 mg/dl 2-hour: 101.74 + 17.89 mg/dl |

Figure 2a : Results of the 75 g glucose load 1 step test: Comparison between the screening and diagnostic tests