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Full Length Research Paper

Effectiveness of Diabetes in Pregnancy Study Group of India (DIPSI) criteria in detecting Gestational Diabetes among women attending a Tertiary Care Hospital in Sri Lanka

Jayawardena G.R.M.U.G.P[1,2], Guruparan K[1,2], Sumathipala W.L.D.S[3], Ratnasiri U.D.P[2] and Senanayake H.M[4]

[1]Post Graduate Institute of medicine, University of Colombo, Sri Lanka.
[2]Desoysa Hospital for Women, Colombo, Sri Lanka.
[3]Facultyof Medicine, University of Colombo, Sri Lanka.
[4]Department of Obstetrics and Gynecology, Faculty of Medicine, University of Colombo, Sri Lanka.

Abstract

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The aim of this prospective descriptive cross sectional study was to investigate the utility of a single value non fasting glucose tolerance test as described by the Diabetes in Pregnancy Study Group of India (DIPSI) in detecting GDM. Sample of 165 pregnant women between 24-28 weeks of gestation was recruited from a tertiary care maternity hospital in Sri Lanka. All women had the DIPSI and standard OGTT tests performed within a one week and results compared using standard non parametric tests. According to the IADPSG criteria 20% (33/165) had GDM, compared to 22.4% (37/165) detected by DIPSI. Sensitivity of DIPSI criteria was 64% while specificity was 88%. The area under receiver operator curve was 0.8. The mean satisfaction for DIPSI was of 8.9 ± 0.4, compared to 4.7 ± 1.3 for OGTT (p<0.001). Analysis of false positives showed that it was mainly due to elevated fasting values in the IADPSG criteria. Although DIPSI has a low sensitivity compared to the IADPSG criteria, area under the ROC curve is 0.80 indicating its utility for diagnosing GDM. It has additional advantages of allowing a diagnosis of GDM in a single visit and high acceptability among women.

Key words: Gestational Diabetes Mellitus, Diabetes in Pregnancy Study Group India, Oral Glucose Tolerance Test.

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first appearance during pregnancy (NICE, 2015). Women diagnosed to have GDM are at increased risk of future diabetes as are their children (Moore, Voaklander et al., 2020), affecting up to one in six pregnancies (Hod et al., 2015).

In 2015, the International Federation of Obstetrics & Gynecology (FIGO) published a guide to the diagnosis and management of GDM. This recommends a menu of three screening tests, to be used depending on the available resources (Hod et al., 2015). The cut-off values for glucose tolerance test (GTT) has been the subject of debate for some time (McIntyre et al., 2014; Tutino et al.,

Corresponding author. Email: udarajayawardena@gmail.com
Tel: +94772987746

2014). The Hyperglycemia and Pregnancy Outcome (HAPO) study set cut-offs for defining GDM by determining the risk of an individual developing an adverse pregnancy outcome (Metzger, 2008). Using the HAPO study, the International Association of the Diabetes and Pregnancy Study Group (IADPSG) Consensus Panel recommended diagnostic values for GDM at an odds ratio of 1.75 for adverse neonatal outcomes (Metzger et al., 2010). The World Health Organization (Diagnostic criteria 2014) and the FIGO have recommended the IADPSG criteria as a screening method. This method has therefore become the current 'Gold Standard' for diagnosing GDM. However, it entails the taking and testing of three blood samples and the women must report in a fasting state. These are requirements that are difficult to enact in developing countries.

Against this backdrop, the Diabetes in Pregnancy Study Group India (DIPSI) suggested a non-fasting, 75-gram glucose challenge as a diagnostic test. They challenged the commonly held notion that a diagnostic test for GDM needed to be carried out in a fasting state, on the basis that this did not affect the glucose levels significantly (Rani, 2016). A test that could be performed in a non-fasting state holds an advantage in developing countries, where women travel long distances to reach a healthcare facility. This single stop approach whereby women could be assigned a diagnosis on site could be invaluable.

Southern Asians constitute almost one quarter of the world's population and are a recognized high-risk group for gestational diabetes, with its prevalence shown to vary from 3.8 to 21%, depending on the geographical location and diagnostic method used (Lee et al., 2018). With this increased prevalence, there is a desperate need for a cost-effective method of screening in these resource-poor settings. This study aims to evaluate the test characteristics of the DIPSI method against the IADPSG criteria in a cohort of pregnant females selected from a tertiary care hospital from Sri Lanka.

METHOD

A prospective descriptive cross sectional study was conducted over 1 year in a tertiary care maternity hospital in Sri Lanka. Women between 24 to 28 weeks of gestation attending an antenatal clinic and consented to undergo a glucose challenge test (GCT) followed by an oral glucose tolerance test (GTT) within a space of one week, were eligible for recruitment. Women with preexisting diabetes mellitus, on whom GDM was already diagnosed or with any chronic medical illness or chronic infection were excluded.

The sample size of 165 was calculated based on an assumed prevalence of GDM in this population of 11.7% (Katulanda P 2008), with an absolute precision of 5% in an infinite population and a 0.86 power for the study. This study received ethical clearance from the Ethics Review Committee (EC-14-163) of the Faculty of Medicine, University of Colombo Sri Lanka. Participants were recruited by convenience sampling following informed written consent.

Women were subjected to a GCT as described by DIPSI by administering a 75g oral glucose load irrespective of the timing of their last meal[10]. A venous blood sample was collected two hours later into a fluorated bottle and plasma glucose assayed within 2 hours of collection, using an enzymatic colorimetric assay (Hitachi, Roche). A 2-hour plasma glucose value of ≥140 mg/dl was considered diagnostic of GDM (DIPSI criteria). Study participants were recalled within one week and subjected to the 75g GTT using the standard method[3]. Three venous blood samples (fasting, 1 hour, 2 hour) of 2 ml each were collected and glucose levels assayed as described above. Qualified medical laboratory technicians using standard protocols carried out sample collection and analysis. Criteria used for diagnosing GDM by each method are shown in Table 1.

Clinical data of the women was collected using an interviewer-administered questionnaire. Descriptive statistics were used to describe the study sample while inferential statistics were used to understand associations between variables. Statistical significances were calculated using the chi-square test. Sensitivity and specificity of tests was assessed using a receiver operated characteristic (ROC) curve and a p value less than 0.05 considered to be statistically significant.

The IADPSG criteria were used as the standard against which the DIPSI test was assessed.

Maternal satisfaction regarding the two methods (GCT against standard OGTT) for GDM assessment was recorded. A scale of 1 – 10 was utilized (1= extremely unsatisfied, 10 = extremely satisfied).

RESULTS

A total of 182 women were included in the study, out of whom data was available on 165 (90.7%), giving a dropout rate of 17/182 (9.3%). Table 2 shows the baseline characteristics of the women included in the study.

There were 37 women testing positive according to the DIPSI and 33 by the IADPSG criteria. The test results according to IADPSG and DIPSI criteria are shown in Table 3. Thus, DIPSI showed sensitivity and specificity rates of 64% and 87.8% respectively, when compared with the IADPSG criteria.

The receiver operator curve (ROC) for the DIPSI test compared with reference value of OGTT values according to IADPSG criteria is shown in Figure 1. The area under the curve was 0.80 (0.706 – 0.893) with a standard error of 0.48 and a significance level of 0.0001.

The accuracy of a test is assessed by the area under the

Table 1. Values are given in mg/dl (mMol/L).

Test name	Fasting	1st hour	2nd hour
DIPSI[5]	-	-	140 (7.8)
IADPSG[13]	93 (5.1)	180 (10)	153 (8.5)

Table 2. Baseline characteristics in subjects with and without GDM.

		Total	Positive by DIPSI (%)	Positive by IADPSG (%)
Age in years	< 20	21	1	3
	20 - 25	33	9	6
	26 - 30	42	14	9
	31 - 35	39	12	11
	> 35	30	1	4
Parity	1	73	10	11
	2	54	18	10
	3	26	5	6
	≥ 4	12	4	6
BMI	<18kg/m2	0	0	0
	18 - 24.9 kg/m2	86	13	12
	25 - 30 kg/m2	70	17	13
	>30 kg/m2	9	7	8
Total positive (%)		-	37 (21.6)	33 (19.3)

BMI – body mass index, Positive by DIPSI ≥ 140mg/dl or 7.8mmol/L, Positive by IADPSG ≥ 92mg/dl and/or ≥180mg/dl and/or ≥153mg/dl

Table 3. The sensitivity and specificity of detecting GDM using DIPSI compared IADPSG guidelines (TP = true positives, FP=false positives, FN=false negatives, TN=true negatives).

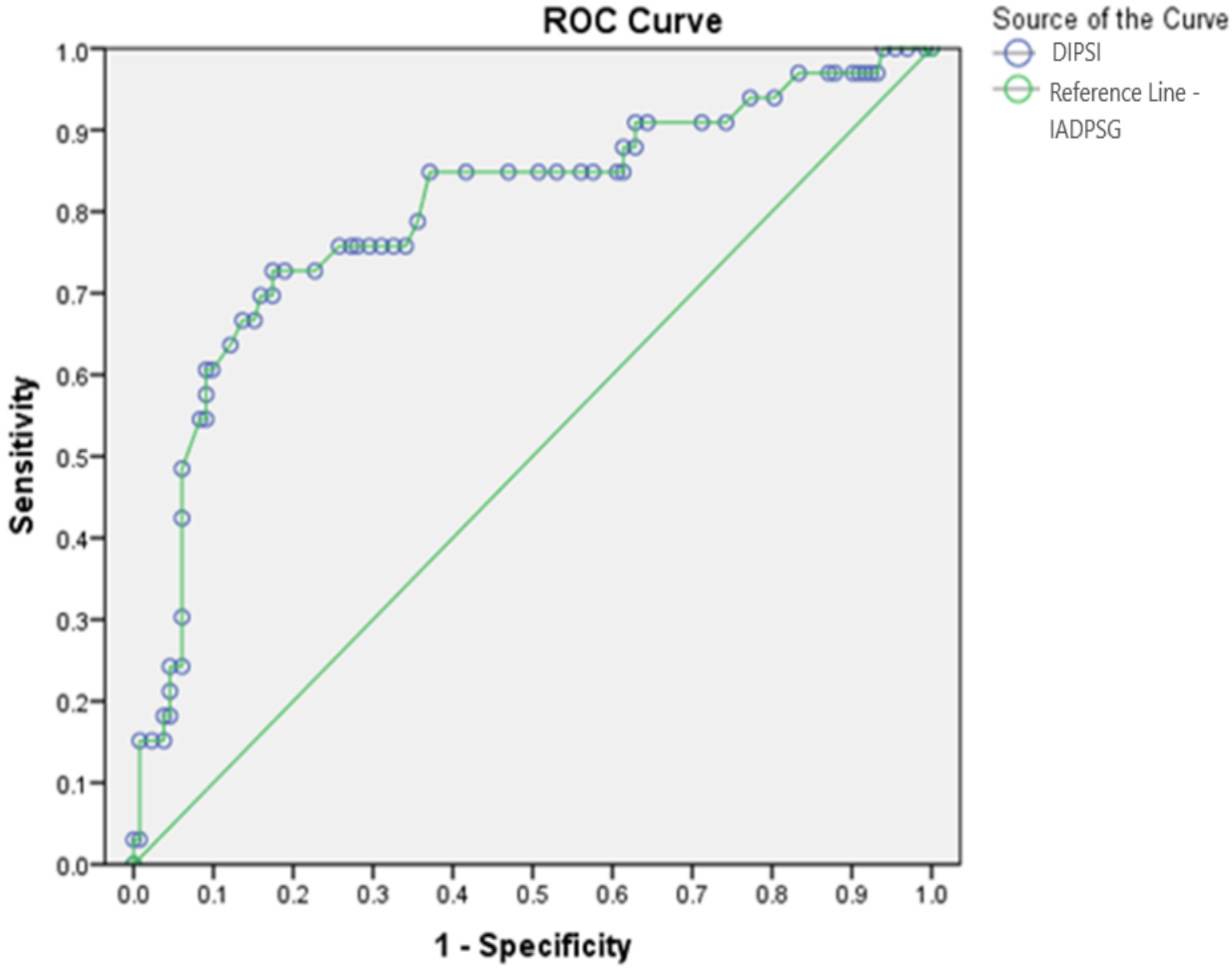
		IADPSG		
		Positive	Negative	Total
DIPSI	Positive	21 (TP)	16 (FP)	37
	Negative	12 (FN)	116 (TN)	128
	Total	33	132	165

ROC curve, where 0.90-1 is considered excellent, 0.80-0.90, good, 0.70-0.80 fair, 0.60-0.70 poor and 0.50-0.60 as a failed test.

The women who had false negative results (negative according to the DIPSI criteria results, but testing positive by IADPSG criteria) were analyzed further to assess the severity of derangement of the values. There were twelve women in this group. Most of these women (n=9) had elevated FPG values, while 4 had elevated 1 hour values and 3 had elevated 2nd hour values. The values of the women who showed false negative and false positive results are further explored in Table 4.

Table 4 shows the mean values in the fasting, 1 hour and 2 hour values of the women who had false negative and false positive results according to the DIPSI method. (Values are given in mg/dL).

Fig. 1. Receiver operator curve of DIPSI test against the IADPSG criteria as the reference line.



Results of patient satisfaction and acceptability which was assessed by using a scale from 1-10 showed a mean satisfaction level for DIPSI was 8.9 ± 0.4, while the OGTT recorded a mean satisfaction level of 4.7 ± 1.3. The difference was statistically significant ($p<0.001$).

DISCUSSION

Main Findings

There are many studies that have compared the DIPSI criteria with GTTs. One of the main limitations with these is that the comparison has been done against GTTs that had their own problems. For example, the fasting value of the WHO criteria of 1999 (Diagnostic criteria 2014) has been shown to have an extremely poor sensitivity (Imoh, 2017).

This study aimed to compare characteristics of the DIPSI against the IADPSG criteria, which is widely regarded as the gold standard for the diagnosis of GDM. The IADPSG values have the unique advantage of being based on pregnancy outcomes (Metzger, 2008).

The comparison showed DIPSI to have a low sensitivity (64%) in diagnosing GDM compared to IADPSG. Roughly a third of women who would have been diagnosed as GDM on the IADPSG criteria were missed by DIPSI (Table 3). However, the specificity was high at 87.8%.

The area under the ROC was 0.80, categorizing it as a good/fair test compared to the gold standard (Figure 1).

Strengths and Limitations

The main contribution to the low sensitivity of the DIPSI method was that it does not have a fasting component. The majority who were false negatives according to the DIPSI method had elevated fasting values on the IADPSG method. This emphasizes the main drawback of the DIPSI method. Fasting hyperglycaemia has been shown to influence pregnancy outcomes (Rani, 2016).

Several studies done in South Asia have shown that the non-fasting GCT has poor sensitivity and specificity (Mohan et al., 2014; Herath 2017; Tripathi et al., 2017).

Table 4. Plasma glucose values of women who showed false negative and false positive results with the DIPSI method.

	Fasting value mean, SD, (range)	**1-hour value mean, SD, (range)**	**2-hour value mean, SD, range**
False negative N = 12	101.1±7.8 (92-120)	171.5±22.9 (148-207)	119.7±18.5 (98-145).
False positive N = 16	89.1±2.8 (79-92)	164.5±14.9 (148-178)	131.7±5.5 (106-138)

A study by Tripathi et al. involving 900 pregnant women in India concluded that DIPSI cannot be recommended for screening (Tripathi et al., 2017). It is worthwhile noting that in their study as well, like in ours, DIPSI was compared with the IADPSG criteria. Initial evaluations on DIPSI showed great promise (Anjalakshi et al., 2009; Rashmi, 2016), however, more recent studies have cast doubts on its utility (van et al., 2012; Vij et al., 2015; Saxena et al., 2019). This illustrates another aspect of the diagnostic conundrum of GDM. The test characteristics of any new tests will be influenced by the test criteria against which they are compared. The studies that showed the DIPSI test in positive light (Anjalakshi et al., 2009; Rashmi, 2016) were those that compared it against the WHO criteria of 1999 (Diagnostic criteria 2014), whereas the ones that questioned its utility (van et al., 2012; Vij et al., 2015; Saxena et al., 2019), used the IADPSG. A single-center study from Southern India by Anjalakshi et al. (2009) reported a 100% sensitivity and 100% specificity for the DIPSI compared to WHO 1999 criteria. This enhanced the reputation of the DIPSI, which was proposed as a single-step, definitive, diagnostic test for GDM based on similar studies carried out in India (Anjalakshi et al., 2009; Seshiah et al., 2009). However, the utility of the WHO 1999 criteria too has been challenged (Imoh et al., 2017). This finding of 100% specificity is also interesting, since the two-hour cut offs for both WHO 1999 and DIPSI are identical and the finding that fasting does not alter the way the body would handle a glucose load (Senanayake et al., 2010). It is probable that this was the reason for the 100% sensitivity and specificity, which would normally be considered biologically implausible. For the pregnant woman, the GTT has the drawback of having to fast for eight to ten hours. Many women will find this difficult during pregnancy and especially when they must travel long distances to reach a healthcare facility (Anjalakshi et al., 2009; Yadav, 2019). This is the reality in many Southern Asian and other developing countries. Further, the requirement of having to draw blood more than once and to assay glucose levels on them would place an additional load on human and laboratory resources that are already under strain. The administration of two stage testing with an initial non-fasting screening test followed by a diagnostic test in these settings results in high drop-off rates (Anjalakshi et al., 2009; Yadav, 2019). The test characteristics of simpler approaches such as fasting and postprandial glucose do not make them suitable for routine screening (Senanayake et al., 2006).

Interpretation

While our study confirms the low sensitivity of the DIPSI, its 'area under the curve' in the ROC curve reaches the threshold of 0.8 for screening test. As shown in our study, the test has a high acceptability among women. As highlighted in the study by Anjalakshi et al. (2009) and Yadav (2019), this is invaluable in resource-poor settings. The DIPSI method places a lower load on resources, which are usually under strain in many countries that require their women to be screened for hyperglycemia in pregnancy.

A unique feature of our study is that we further analyzed the reported values of false negatives and false positives. This showed that in general, these have only mildly deranged values compared to the cut-offs. Except for the fasting values in the false negatives, this is particularly true. Based on this finding, the area under the ROC and the high specificity, we would still argue that the DIPSI method still has a value in settings that have limitations of resources and where a one-stop diagnosis for GDM has applicability. One must understand its limitation in sensitivity mainly due to not having a fasting value, but it is reassuring to have a test that has special advantages in a setting where a formal GTT is difficult to do.

CONCLUSION

When compared to the IADPSG criteria, the DIPSI method has a sensitivity of 64% and a specificity of 87.8%. The 'area under the ROC curve' reaches the critical threshold of 0.80, indicating its worth. On analyzing the women who had false negative and false positive results, we found that the derangement of the values in the OGTT in them to be relatively minor. We found that the test had a high acceptability among women. The advantage of being able to provide a diagnosis in one visit while reducing the strain on human and laboratory resources are features that would strengthen its applicability in resource-challenged settings. However, there is no doubt that the DIPSI test

cannot replace the formal GTT, but given its characteristics, in the situations of limited resources, it could still have applicability.

Disclosure Statement

Authors' contributions

UJ, UDPR and HMS designed the study. UJ collected the data and performed the statistical analysis, with support from WLDSS, KG and UDPR. UJ wrote the article. HMS and UDPR revised the article. All authors read and approved the final manuscript.

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Availability of data and materials

All relevant data are presented in the manuscript. Our original data are coded and the key is available with UJ.

Declaration of Interest

The authors report no conflict of interest

Ethical Clearance

This study received ethical clearance from the Ethics Review Committee (EC-14-163) of the Faculty of Medicine, University of Colombo Sri Lanka on 19th December 2014.

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