Research article

Is it HAPO/IADPSG and NICE/ National Consensus Document criteria for diagnosis of GDM best suit for Sri Lanka; Outcome-based comparative study

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Abstract

Objective: Our aim in this study is to compare pregnancy and fetal outcomes following the diagnosis of gestational diabetes according to HAPO/IADPSG, NICE criteria or when using both criteria.

Methods: Diagnosis of GDM was made using the lowest recommended cut off values of HAPO/IADPSG criteria and NICE criteria. NICE diabetes in pregnancy guidelines were used in management once GDM was diagnosed. The outcomes of the three groups were compared, Group A: the patients diagnosed using any criteria, Group B: only from HAPO/IADPSG criteria (patients fasting value within 92-100 mg/dL and other values with in the normal). Group C: only from NICE criteria (patients with 2nd hour value within 140-153 mg/dL but the rest were normal)

Results: Out of all women with GDM 70% were in group A, 25% in group B, and only 4% in group C. 62% of women needed metformin or insulin apart from Medical nutrition therapy in Group A, and 50% in group B and only 17% in group C. Average period of gestation at the delivery in Group A was 37 weeks and 3 days , and it is 37+5 for group B and 38+4 for group C. Induction rate in Group A was 56%, 14% in Group B and 4% in Group C.LSCS rate was 48% in Group A, 41% in group B and 36% in group C. 7% of babies were macrosomic in Group A, 2% and 1% respectively in groups B and C. Special Care Baby Unit (SCBU) admission rates were 11% in group A and 1% in group B. The average birth weights of Group A were 2.93kg, Group B 2.900kg and group C 2.818kg.

Conclusion: HAPO/IADPSG criteria diagnosed more women with gestational diabetes than NICE criteria. Only 4% of mothers will be missed if HAPO/IADPSG criteria is used. Pregnancy outcomes of the Group B is similar to that of Group A and 50% of women needing further intervention apart from MNT could have prevented adverse pregnancy outcome in a significant number of patients compared to the few number of patients in group C. It was observed that IADPSG criteria provide better diagnostic cut-off values for our population compared to NICE.

Limited number of patients especially in group C is a limitation of this study to evaluate further since this is an on-going observational study and will be able to provide more information in the future.

Key words: gestational diabetes, oral glucose tolerance test, NICE, HAPO/IADPSG, pregnancy and fetal outcomes

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Introduction

There has been an exponential increase in the prevalence of diabetes throughout the world, with South Asia being its focal point. In comparison to continents such as North America, Australia and Europe, there has been a 111% increase in the number of diabetes cases in the past 15 years[1]. Therefore making Sri Lanka a high risk population, with gestational diabetes mellitus (GDM) emerging as a common medical complication associated with pregnancy and a parallel rise in the number of type 2 diabetes mellitus cases[4,5,6]. GDM affects approximately 7% of the all pregnancies and up to 14% of pregnancies in high-risk populations while pregestational diabetes mellitus (PGDM) is estimated to affect about 1.3%[2,3].

GDM is defined as glucose intolerance initially detected during pregnancy[4,8]. This results in hyperglycaemia of variable severity, short term and long term morbidity to mother and offspring. It has been associated with significantly increased risk of fetal macrosomia, shoulder dystocia, birth injuries as well as neonatal hypoglycaemia and hyperbilirubinemia. Borderline GDM has also been associated with risk of perinatal complications, with the maternal glycaemia demonstrating a continuum effect on perinatal outcome[4,6,8]. From previous researches conducted, it has been found that pregnancies complicated by GDM have had higher rates of caesarean sections and induction rates and having 10-30% risk of developing pre-eclampsia[6,8].

The commonly known risk factors for GDM are advanced age (≥ 35 years), ethnicity, obesity, excessive gestational weight gain, excessive central body fat deposition, family history of diabetes, short stature, hypertension or preeclampsia in the current pregnancy, history of recurrent miscarriages, offspring malformation, fetal or neonatal death, macrosomia, GDM during previous pregnancies and polycystic ovarian syndrome (PCOS)[9]. Obesity and family history of diabetes are two of the major risk factors identified by previous studies. Adequate pregnancy weight gain has been identified critical for optimal outcomes for both the mother and the infant[10]. However excessive weight gain during pregnancy has been found to be a contributing factor for GDM[10].

The diagnosis of GDM is based on the results of a 75g oral glucose tolerance test. Cut off values for the diagnosis of GDM is provided by Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study and its implementation through International Association of Diabetes in Pregnancy Study Group (IADPSG) and National Institute of Health and Clinical Excellence (NICE). There are significant differences in the cut-off values for the diagnosis of gestational diabetes mellitus (GDM) based on the above two criteria[6,7]. IADPSG has a lower cut off value of 92mg/dl for fasting blood sugar compared to that of NICE recommendation (100mg/dl) and NICE recommend a lower 2 hour value of 140mg/dl compared to that of IADPSG (153mg/dl)[6,7]. However there is consensus on the 1st hour value (180mg/dl). This leads to three groups of patients depending on the criteria used for diagnosis, those patients with diabetes according to any criteria, GDM only for IADPSG and GDM only for NICE criteria. Depending on the criteria selected to diagnose gestational diabetes, there will be over or under diagnosis of GDM as in both criteria contains lower value than the other. This study is designed to compare pregnancy and fetal outcomes of the three groups in order to develop local recommendations. Hence we have taken the lowest values in both criteria to analyse the pregnancy outcomes of women diagnosed with GDM, as our final aim is to compare the pregnancy outcomes of women diagnosed with GDM using two main critera (IADPSG vs NICE) and this will invariably lead to diagnosis of more women than using either one criteria mentioned above.

The main purpose of treating mothers with gestational diabetes is to prevent fetal, maternal and neonatal complications. A randomized control study conducted on 1000 women with GDM showed that treating GDM was associated with a reduction of all neonatal complications such as birth injuries, shoulder dystocia, perinatal morbidity and mortality. It also reduced the rate of development of preeclampsia by 6%[11].

Method

An on-going outcome based observational study from June 2015 to June 2019 was conducted on 315 pregnant women who were diagnosed as GDM in the university obstetrics unit, Colombo South Teaching Hospital, Sri Lanka. Diagnosis of GDM was made using the lowest recommended cut off values of HAPO/ IADPSG criteria and NICE criteria. NICE diabetes in pregnancy guidelines were used in management once GDM was diagnosed. The outcomes of the three groups were compared, Group A: the patients diagnosed using any criteria, Group B: only from HAPO/ IADPSG criteria (patients fasting value within 92-100 mg/dL and other values with in the normal). Group C: only from NICE criteria (patients with 2 hour value

within 140-153 mg/dL but the rest were normal). The group A and B together is the group of women with GDM when used HAPO/ISDPSG and Group A and C together forms the group of women with GDM when used the NICE criteria.

Patients who diagnosed using lowest cut off values in both criteria were included in the study and managed according to the NICE guidelines of managing diabetes in pregnancy. All were counselled regarding the foetal and maternal outcomes and educated regarding the follow up. Both verbal and written information were provided. Medical nutrition therapy was initiated in all and depending on the blood sugar series (BSS) values and serial ultrasound scan findings further management decisions were made.

Results

As per the results collected for the 315 pregnant women, majority of the mothers were diagnosed using both the criteria that is HAPO and NICE (70%), 25% using HAPO only and 4% using NICE criteria only (Figure 1).

62% of women needed metformin or insulin apart from medical nutrition therapy in Group A, and it is 50% in group B and only 17% in group C. In reference to Table 1, there is no statistical significance between the glucose lowering drugs prescribed across the three groups since the p value >0.05 at 95% confidence interval. Average period of gestation at the delivery in Group A was 37 weeks and 3 days , and it is 37+5 for group B and 38+4 for group C. Induction rate in Group A was 56%, 14% in Group B and 4% in Group C. LSCS rate was 48% in Group A, 41% in group B and 36% in group C. 7% of babies were macrosomic in Group A, 2% and 1% in groups B. SCBU admission rates were 11% in group A and 1% in group B. The average birth weights of Group A were 2.93kg, Group B 2.900kg and group C 2.818kg. In reference to Table 2, when comparing the correlation between the pregnancy and fetal outcomes in the three different groups, it was found there was no statistically significant correlation.

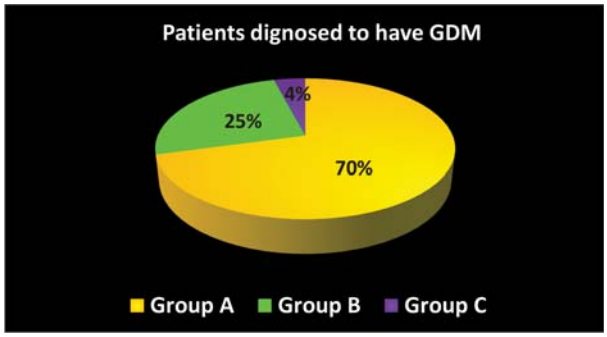

Figure 1. **The proportion of patients diagnosed as per the three different groups.**

Table 1. Type of glucose lowering drug and its correlation to the different diagnostics groups

Type of glucose Lowering drug	Group	N	Mean dose	Standard deviation	P-Value
Metformin	A	39	1505	364	0.670
	B	9	1444	300	
	C	3	1333	288	
Soluble Insulin	A	25	34.64	29.15	0.295
	B	2	74.00	87.68	
	C	1	37.43	33.86	
Lente Insulin	A	10	12.20	9.45	0.829
	B	1	10.00		
	C	11	12.00	8.99	

Table 2. Pregnancy, fetal outcomes and its correlation to the three different groups

Pregnancy outcomes	P-Value
NICU admissions	0.365
Induction use	0.230
Primary CS	0.636
Fetal outcomes	**P-Value**
BW weight > 90th percentile	0.808
SCBU admission	0.260

Discussion

World Health Organization (WHO) recommends OGTT as the universal screening and confirmatory test for GDM[3]. Hence OGTT is the screening test used for GDM in the current hospital setting between 24 to 28 weeks of gestation. The HAPO study demonstrated a linear association between the increasing levels of maternal hyperglycaemia and adverse perinatal outcomes with no obvious threshold[3]. New diagnostic thresholds were proposed by the IADPSG based on the HAPO study, however the South Asian representation to the population of mothers studied in HAPO study is minimal. NICE guideline continued to recommend different criteria which is usually followed in Sri Lanka. While over diagnosis causes anxiety and additional cost whereas under diagnosis may give rise to increased morbidity and neonatal mortality. The detection rate of GDM using HAPO or NICE criteria showed a significant difference in this study (25.4% and 4.1%). That is if the HAPO criteria is used only 4.1% women will be excluded but using NICE criteria 25.4% will be missed. This was consistent with the results from the various studies conducted in South East Asia which also compared the two different GDM criteria for diagnosis[3,5,7,8]. This may be due to the ethnic variation, however it may be because using lower fasting blood sugar value seems to detect more women with impaired glucose tolerance than the lower second hour value[10,11].

When comparing the pregnancy outcomes of the three groups, the rate of NICU admissions was the same between Group B and C (in reference to Figure 2). However, the rate was higher for Group A (11%) in comparison to the group B (1%) and C (1%). Whereas the need for induction was higher in Group A mothers followed by Group B (Figure 3).

From the previous studies conducted, it was found that GDM diagnosed by either criterion were at a higher risk for both LSCS and large for gestational age but macrosomia was found to be associated with GDM mothers only diagnosed using NICE criteria[12,13,14,15]. As per the results obtained in this study, the group C showed had no macrosomia where as 2% of babies in Group B showed macrosomia. The 7% in Group A is expected as it uses all the higher values of the OGTT[13,14,15]. This shows using HAPO criteria alone can detect all the macrosomic babies but NICE misses 2% of them.

A slight difference in the birth weights were observed when comparing the three groups. Where group A and B had a birth weight of greater than or equal to 2.900kg whereas for patients diagnosed with HAPO only had a slightly lower birth weight of 2.818Kg. The difference of 0.082kg in birth weight could be due the fact the 62% of Group A and 48% of Group B were started on glucose lowering drugs meaning that these mothers were controlled using diet and lifestyle modification. In a study conducted by Ovesen et al., it was found that the fetal birth weight in mothers who were treated on diet and lifestyle modification had a normal birth weight compared to the patients who have been receiving treatment[16]. As per Table 2, it must be noted that there was no correlation and statically significance between the different GDM diagnosis criteria and the risk of macrosomia (p=0.808).

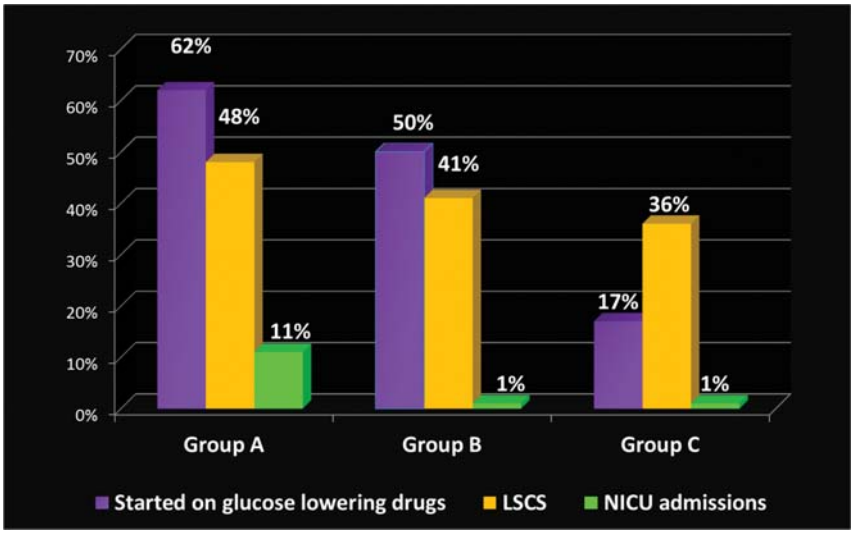

Figure 2. **Comparison of the pregnancy outcome across the three different groups.**

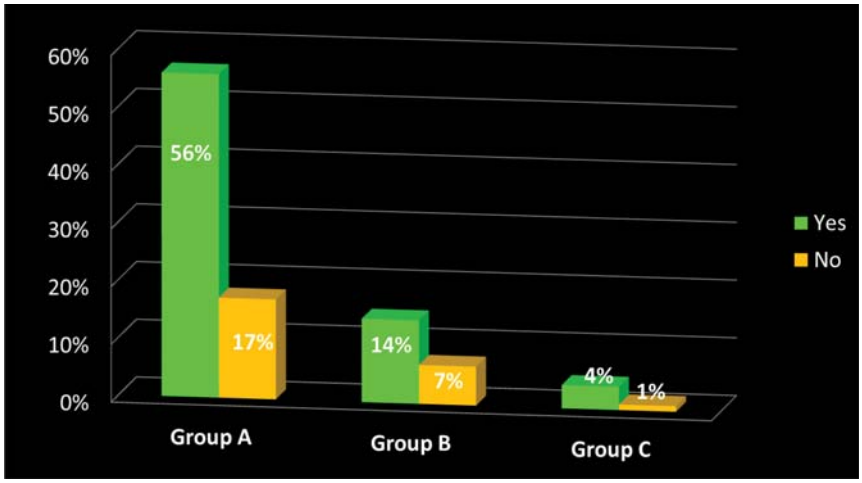

Figure 3. **Comparison of induction for the three different groups.**

SCBU admission was needed by the babies of the mothers in Group A and B only ie Diagnosed using HAPO criteria. However when analysing the correlation between the diagnosis criteria and the risk of SCBU admissions, there was no statically significance between the two with a p value of 0.260 (refer to Table 2). As per the study conducted by Watson et al., it was found that neonatal morbidity is a common occurrence in infants of mothers who have had GDM especially in a population with high prevalence of type 2 diabetes mellitus[17]. Though there is no statistical significance Group C contribute to less SCBU admission, no macrosomia and needed less interventions apart from medical nutrition therapy.

Conclusion

HAPO/IADPSG criteria diagnosed more women with gestational diabetes than NICE criteria. HAPO/IADPSG criteria, only miss 4% of the mothers. Pregnancy outcomes of the Group B is similar to that of Group A and 50% of women needing further intervention apart from MNT could have prevented adverse pregnancy outcome in a significant number of patients compared to the few number of patients in group C. It was observed that IADPSG criteria provide better diagnostic cut-off values for our population compared to NICE.

Limited number of patients especially in group C is a

limitation of this study to evaluate further and this is on-going observational study and will be able to provide more information in the future.

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