

Gestational diabetes mellitus: In search of better screening and diagnostic pathway for Sri Lankan women

Herath HMM

Department of Medicine, Faculty of Medicine, University of Ruhuna, Galle, Sri Lanka.

Correspondence: Dr. HMM Herath
e-mail: herathp@gmail.com

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Introduction

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance resulting in hyperglycemia of variable severity, with onset or first recognition during pregnancy. It is associated with increased risk of several adverse infant and maternal outcomes, and its early clinical recognition can reduce these risks (1).

With the exponential rise in the prevalence of Type 2 Diabetes Mellitus (T2DM) during past few decades especially in Indian Subcontinent, there is a dramatic increment in the incidence of GDM (2). The prevalence of GDM varies widely across the globe ranging from 3-11% and in Sri Lanka it was reported to be around 11% in 2010 (3,4). As the age at onset of T2DM and pre-diabetic state is moving downwards, the possibility of pregnant women having impaired glucose tolerance at much younger age has also increased. Higher prevalence of obesity associated with sedentary life style and changes in dietary practices have contributed to insulin resistance, thus making them susceptible to gestational diabetes and T2DM later in their life (5).

GDM is associated with a number of adverse perinatal outcomes, such as neonatal hypoglycemia, macrosomia with increased risk for shoulder dystocia, and the need for neonatal intensive care (6). Maternal complications of GDM include an increased risk of caesarean delivery and pre-eclampsia. Furthermore, women with GDM have up to 60% risk of developing T2DM within 5-15 years of delivery, and it has been suggested that children prenatally exposed to a diabetic milieu have an increased risk for the development of T2DM later in life (6, 7). There are several studies showing a

significant reduction of these adverse effects when prompt and proper interventions were taken to diagnose and treat GDM early (1, 6).

However, there is a dilemma over the best diagnostic approach for GDM. Some advocates universal testing (testing everybody) while others recommend limiting testing to women having risk factors for GDM (8). The American Diabetes Association (ADA) guideline recommends to screen only the high risk women having one or more risk factors for GDM (9). However, one of the risk factors given in this guideline is South Asian ethnicity. Approach of International Association of the Diabetes and Pregnancy Study Groups (IADPSG) is more flexible and it recommends either the universal or the selective approach on the basis of the background prevalence of abnormal glucose metabolism in the population (10). At present there is no consensus over the most suitable method to screen GDM in Sri Lanka.

In addition, there is also a lack of international consistency with regard to the most sensitive and practical test to diagnose GDM. While a 75g glucose tolerance test (GTT) is considered as the gold standard test to diagnose GDM, fasting glucose challenge test (GCT) with different cutoff values is also widely used throughout the world. Diabetes in Pregnancy Study Group India (DIPSI) has recommended non-fasting 75g GCT with diagnostic criterion of 2h PG ≥ 7.8 mmol/L based on several studies conducted in India (11, 12). Nirogi Lanka diabetes prevention task force in Sri Lanka and Sri Lankan College of Obstetricians & Gynecologists (SCOG) too has recommended non fasting GCT with the same cutoff value to

diagnose GDM in Sri Lanka (13). However, this recommendation is based on few studies done in India and this method as well as the cutoff values has not been validated for Sri Lankan women.

In addition to lack of consensus over the best approach and best test in GDM, the diagnostic process is further impeded by the lack of agreement on the best method of GDM diagnosis. The two steps method with combination of GCT and GTT is widely accepted as the best method. In this method, all pregnant women are screened with GCT followed by GTT for those with positive GCT. However, complexity of this procedure is a limiting factor (11, 14). One-step approach using GTT has been recommended by IADPSG based on results of the landmark study, Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) (6). Several professional bodies including American Diabetes Association (ADA) had endorsed this approach (3, 7). As mentioned previously, one step approach using non fasting GCT has been recommended by DIPSI and the recommendation of Niroggi Lanka diabetes prevention task force and SCOG is also similar to the recommendation of DIPSI.

As there is lack of uniformity in GDM screening, diagnostic tests and methods used in Sri Lanka, author of this oration conducted a series of research in order to answer the following questions.

- 1) What is the current practice with regards to GDM screening in a tertiary care setting in Sri Lanka?
- 2) As suggested by some local professional bodies, can non-fasting GCT be used effectively in diagnosing GDM in Sri Lankan women?
- 3) What is the best screening strategy to diagnose GDM; Universal screening or selective risk factor based screening?
- 4) What is the current prevalence of GDM using the newer diagnostic criteria in a tertiary care setting in Sri Lanka?
- 5) What is the reliability of GTT as a diagnostic test over a decade?
- 6) In addition to the traditional risk factors, can other clinical parameters especially gestational weight gain be used to predict GDM?

As the first step towards finding an ideal screening and diagnostic strategy for GDM, author of this oration was interested to know the current practices of GDM screening in a tertiary care setting. The first study which is presented here was undertaken to investigate the adequacy of GDM screening in a Tertiary Care Hospital.

STUDY 1

Adequacy of Gestational diabetes mellitus (GDM) screening in a tertiary care hospital; are we missing GDM in big ways?

Aim

Aim of this study was to investigate the adequacy of GDM screening in a tertiary care hospital and to assess the prevalence and predictors of macrosomia.

Methods

This was a hospital based cross sectional study carried out in Teaching Hospital Mahamodara from 15th March to 15th May 2015. The data were gathered from post-partum women using an interviewer administered questionnaire. Data on GDM screening were collected from hospital and patients records.

Results

Out of 254 women studied, prevalence of GDM was 26.4% (67/254). Of the type of GDM screening tests, the most commonly used test was PPBS 38.6% (98/254) followed by GTT (19.3%). Urine sugar was the only screening test in 13% (33/254) of women. Prevalence of macrosomia was 18.5% (47/254) and of women who delivered macrosomic babies, only 36% (17/47) were found to have GDM with the available tests. GDM screening with the gold standard GTT was performed only in 25% (11/47) women who delivered macrosomic babies.

Conclusions

For screening GDM, a variety of tests are used in Teaching Hospital, Mahamodara. Surprisingly only 20% of women had undergone GTT as a screening test. There was higher prevalence of macrosomia which may indicate that GDM was missed in some women.

The finding of this study was presented at annual academic session of Galle Medical Association in 2015 (15).

A previous community based study conducted in Anuradhapura district too showed similar findings of inadequate screening of GDM at community level (16). In this study urine dipstick was the main screening method in majority of women (97%) and GTT was performed only in 1% of the study sample. This suboptimal practice was against the recommendation of Ministry of Health and Nutrition of Sri Lanka. The practice guideline of Ministry of Health and Nutrition recommends two hour postprandial blood sugar (2h PPBS) as the screening test at booking visits for those with risk factors for GDM. It further states that if 2h PPBS is >130 mg/dL to proceed to 75g glucose tolerance test (GTT) at 24-28 weeks of gestation. However, it is clear that this guideline was not followed in managing majority of these women. One would expect the screening method to be better at tertiary care settings. Even though the findings of our study was not as bad as one conducted in Anuradhapura district, it was far below the standard practice.

We believe practices observed in our study epitomize the inadequate screening practices for GDM at all levels in Sri Lanka. ADA as well as many other professional organisations do not recommend urine testing for glucose as a screening method. However, around 13% (33/254) of women in our study had only urine testing as the sole screening method. Our study also revealed that only 25% of women who delivered macrosomic babies had undergone proper GDM screening with GTT. Previous studies had shown that women especially of Asian ethnicity had a trend towards increased odds of macrosomia in the presence of GDM compared to those without GDM. This may indicate that some women with macrosomia in our study might have undiagnosed GDM. The finding of this study will be a real eye opener for health authority to take necessary action to improve the GDM screening strategies.

After having the understanding about current practices of GDM screening and methods used, the author of this oration was interested in finding the most suitable screening test for GDM in local setting. Out of many screening tests, glucose challenge test (GCT) is considered as the preferred test by professional organizations such as DIPSI and Nirogi-Lanka in Sri Lanka. Both of the organisation have recommended non-fasting GCT over gold standard GTT to screen GDM.

Therefore, the second study was undertaken to ascertain the validity of non-fasting GCT to diagnose GDM in pregnant women in Sri Lanka.

STUDY 2

Is non-fasting glucose challenge test sensitive enough to diagnose gestational diabetes mellitus?

Aim

The aim of this study was to investigate the sensitivity and specificity of GCT when compared to GTT for diagnosing GDM.

Methods

Pregnant women in period of gestation between 24-28 weeks were recruited by simple random sampling method. Non fasting 75g GCTs were performed in all followed by fasting 75g GTTs within a week's time. IADPSG criteria of GTT were used as the reference test to diagnose GDM and 2h values of GCT were compared.

Results

Table 1 shows the baseline characteristics of the 274 women who completed the study. On average, pregnant women were relatively old with mean age of 31.4 ± 6.7 years and of average pre-conception BMI (21.7 ± 4.6 kg/m²). The differences of the baseline characteristics between subjects with and without GDM (based on IADPSG criteria) and GCT ≥ 140 and <140 are shown in table 1.

According to IADPSG criteria of the 75g GTT, 21.5% (59/274) subjects in the sample were diagnosed to have GDM; however, only 13.1% (36/274) were detected to have GDM with GCT using 2h cutoff value ≥ 140 mg/dL. Out of the 36 cases detected by 2h value ≥ 140 mg/dL, 12 women were found to have normal GTT (false positive). Thus, only 24 cases of GDM were diagnosed by GCT with 2h value of ≥ 140 mg/dL, giving the sensitivity of 40.6% and specificity of 94.4%. Close to 60% (35/59) of patients with true GDM were missed by GCT.

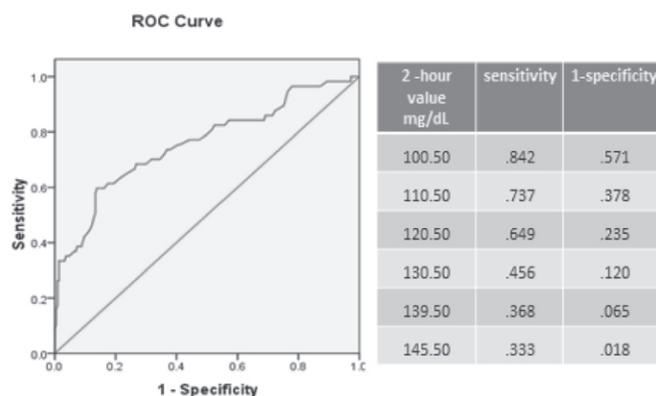
Table 1: Baseline characteristics of subjects with and without GDM

		GCT =140	GCT <140	with GDM*	without GDM*
Age in years	<20	2	11	2	11
	20 - 30	9	77	8	78
	>30	24	151	49	126
Parity	1	11	72	12	71
	2	8	69	18	59
	=3	16	98	29	85
POG ¹		26.86 ± 3.9	25.93 ± 4.7	25.56 ± 4.73	26.19 ± 4.42
BMI	<18	4	47	8	43
	18 - 24.9	20	149	35	134
	25 - 29.9	10	35	15	30
	>30	1	8	1	8
Past history of GDM		3	6	4	5
Family Hx. of GDM		17	66	23	60
Past Hx. of macrosomia		6	28	8	26

Table 2: Comparison of GCT with GTT using IADPSG criteria in diagnosing GDM

GCT = 140 mg/dL	GTT using IADPSG criteria as gold standard		Total
	Positive	Negative	
Positive	24	12	36
Negative	35	203	238
Total	59	215	274

The area under the ROC curve for the ability of GCT to predict GDM detected by GTT was 0.758 (SE 0.039) (Figure 1). The best cut-off point of 2h value to predict GDM occurred at 120 mg/dL (sensitivity of 64.9%, specificity 76.5%) (Figure 1). If the cut-off of 2h value of GCT is increased to 140 mg/dL, sensitivity dropped 37% and specificity increased 96% and this is a clear indication that GCT with cut-off 2h value of 140 is not sensitive enough to diagnose GDM compared to the gold standard GTT (Figure 1).

**Figure 1: ROC curve of 2h value to predict abnormal FBS and 1h value**

Conclusions

GCT with 2h cutoff value 140 mg/dL is not sensitive enough to diagnose GDM recognised by GTT.

The finding of this study was published in International Archives of Medicine (IAM), a peer reviewed indexed medical journal, in 2015 (17).

DIPSI and some of the experts in Sri Lanka have recommended non-fasting GCT to diagnose GDM based on studies carried out in India (12, 13, 18). However, in these studies GCT was not compared with standard GTT and the cut-off value was justified on the basis of equal prevalence of macrosomia in GDM group and non GDM group. Equal prevalence is thought to be due to appropriate recognition and treatment of GDM cases in these studies. However, prevalence of macrosomia as the surrogate marker to diagnose GDM is not accurate as many factors including success of the treatment can confound the prevalence of macrosomia. There are other studies showing poor sensitivity of GCT in diagnosing GDM (19, 20). A recent study conducted by V Mohan, *et al.* in India showed a very low sensitivity of non-fasting GCT when compared to the IADPSG criteria (sensitivity 22.6%, specificity 97.8%) (21). Other studies done in South Asian ethnicity as well as in Caucasians too have revealed poor sensitivity of 50g and 75g GCT (19, 22, 23).

In summary, the results of the second study clearly indicated that the non-fasting GCT has a poor sensitivity (40.6%) when compared to gold standard GTT. Therefore, the current recommendation of using non-fasting GTT with 2h cut-off of 140 mg/dL as a screening and diagnostic test for GDM may need to be revisited. In order to obtain international standardisation, we recommend that, wherever possible, a single-step fasting GTT using the IADPSG criteria be used, with the two-step procedure remaining a viable option.

Having observed the poor sensitivity of GCT against the gold standard GTT, author of this oration was interested to know the most appropriate method to screen GDM in local setting. A community based study conducted in 2012 in Anuradhapura district showed inadequacy of the risk factor based approach to detect GDM (4). However, the most appropriate method to detect GDM depends largely on underlying prevalence of risk for GDM. In a cross

sectional community based study one would expect to find both pregnant women with and without risk factors for GDM. However in practice, pregnant women are screened at antenatal clinic, not at the community level. It is a known fact that women with no or minimal risk are followed up in community clinics whereas high risk women are followed up in tertiary care clinic settings. Therefore, the author argues that the best setting to study the most appropriate method for GDM screening should be at antenatal clinic settings rather than at the community settings. With that in mind, the third study was carried out to evaluate the best method to screen GDM in a tertiary care clinic setting.

STUDY 3

Screening for gestational diabetes mellitus (GDM) in a Tertiary Referral Center in Sri Lanka; Universal versus Selective approach

Aim

To evaluate whether universal screening is superior to that of selective risk factor based screening for GDM.

Methods

This study was conducted as a clinic based cross sectional study in a tertiary care hospital. Pregnant women with period of gestation between 24 to 28 weeks were recruited by convenience sampling method. Data on their demography and risk factors for GDM was collected using a predesigned questionnaire. All those who selected for the study underwent 75g Oral Glucose Tolerance Test (OGTT) during 24-28 weeks of gestation. Diagnosis of GDM was made according to IADPSG (International Association of the Diabetes and Pregnancy Study Groups) criteria.

Results

Out of all 452 pregnant women, 105 were found to have GDM and thus if universal screening was adopted, 23.2% (105/452) would have been detected as having GDM. For the selective risk factor based screening, 356 women with at least one risk factor for GDM were selected. Among them, 91 women were found to have GDM with the overall

prevalence of 20.1% (91/452). Compared to universal screening, the selective risk factor approach missed 14 cases (3%) of GDM who did not have any of the risk factors for GDM.

in a community antenatal clinic where majority has no or few risk factors for GDM it is likely that many women will be spared from GDM screening.

Table 3: Prevalence of risk factors in the study population

Risk factor	N	%
Past history of GDM	15	3.3
Maternal age \geq 35 years	179	39.6
Pre conceptional BMI \geq 23 kg/m ²	178	39.3
Bad obstetric history- miscarriages, still births, IUD etc.)	108	23.8
Delivering large babies (>3.5 kg)	42	9.2
History of T2DM / GDM among first degree relatives	138	30.5

Of the risk factors of GDM assessed, the commonest risk factor was maternal age \geq 35 years followed by BMI \geq 23 kg/m² at booking visit (Table 3).

Conclusions and recommendations

Even though, risk-based screening will reduce the necessity of screening by 20% (from 452 to 356), the detection rate of GDM would drop by 3% (from 23% to 20%). Based on this study we can recommend universal screening as the best strategy to detect GDM at tertiary level. However, if the facilities are limited, selective risk factor based screening also can be used with success in community clinics where women are less likely to have multiple risk factors for gestational diabetes mellitus.

Findings of this study were presented at annual academic session, Ceylon College of Physician in 2013 and published in International Journal of Preventive Medicine in 2016 (24).

The third study in this oration clearly indicated that the universal screening method is superior to the selective risk factor based screening method. Furthermore, universal screening appears to be the most practical approach for GDM screening in tertiary care settings as 80% of pregnant women had at least one risk factor for GDM. Therefore, majority (80%) would any way require GDM screening even if selective screening is chosen. On the other hand, if the selective risk factor based screening is practiced

Therefore, the pragmatic utility of applying selective risk factor-based screening will largely depend on the frequency of these risk factors in the screened population. Therefore, universal screening is the most suitable strategy for GDM screening in tertiary care setting and the selective risk factor based screening is an option for GDM screening at the community based antenatal clinics.

We also reviewed the prevalence of GDM in a tertiary care setting in this study. It revealed that the prevalence of GDM was 23.2% which is higher than the prevalence reported in previous studies in Sri Lanka (3, 5). The main reason for higher prevalence observed in this study is the setting where the study was carried out. As mentioned earlier it is likely that more patients with risk factors for GDM are followed up at antenatal care clinic in a tertiary care setting than in a community. Therefore, GDM prevalence is expected to be higher in a tertiary care setting than in a community. The rise of GDM prevalence may also reflect the substantial increase in the community prevalence of obesity and type 2 diabetes over last several years. Other reason for the dramatic rise in the prevalence of GDM in our study is the adoption of new diagnostic criteria (IADPSG). Previous studies too had reported that the change in diagnostic criteria from the previously utilised criteria to the new IADPSG criteria would increase the prevalence of GDM by 4% - 5% (25, 26).

The forth study present here was designed to evaluate the diagnostic performance of GTT over a period of 10 years. This study was conducted in Mornington Peninsula, Victoria, Australia.

STUDY 4

Change of pattern of Oral Glucose Tolerance Test (OGTT) in pregnant women with gestational diabetes mellitus (GDM) in Mornington Peninsula, Victoria over 10 year period.

Introduction

With the increased incidence of type 2 diabetes mellitus (T2DM) in the community, we predicted that the glycaemic abnormalities of the OGTT in women with GDM will have altered to favour elevations of FBS over elevations of the 2h value over last 10 years.

Aim

Aim of the study was to evaluate the changes of glycaemic abnormalities detected by OGTT over a period of a decade.

Methods

We retrospectively analysed 2h, 75g OGTT done in pregnant women in year 1994 - 1997 and 2006 -2007. Abnormal OGTT results on the basis of Australasian Diabetes in Pregnancy Society (ADIPS) criteria were selected for further analysis. Twenty seven and 84 OGTT were selected for 1994-7 and 2006-7 year period respectively. According ADIPS, FBS equal or more than to 5.5 mmol or 2h value equal or more than 8 mmol were considered as diagnostic of GDM.

Results

Even though, the mean FBS for 2006-7 (4.97) was higher than mean FBS for 1994 - 1997 (4.75) there was no significant difference between these two values ($p=0.15$). Even though there was no statistical difference ($p=0.39$), the similar increment pattern was observed for mean 2h value for 2006-2007 (8.90) in comparison to 1994-1996 (8.82). According ADIPS, 2h values of OGTT have higher sensitivity for GDM detecting 77/85 in 2006-7 and 22/27 in 1994-97. FBS has the least sensitivity, detecting only 5/27 in 1994-97 and 19/85 in 2006-7.

Although the proportion of women diagnosed on the basis of the FBS was greater in 2006-7 this difference was not significant. The mean gap between fasting and 2h values (delta) was 4.06 for 1994-7 and 3.71 for 2006-7 with no statistically significant difference ($p=0.25$) between these two values.

Conclusions

Parameters of OGTT in pregnant women diagnosed with GDM had not significantly changed over last 10 years. The baseline FBS in women with GDM did not change over last 10 years although there was a trend for this to increase. Further study with a large sample may be necessary to confirm our hypothesis further.

Finding of this study was presented at the Annual Academic Session of the Peninsula Health, Victoria, Australia (27).

This study revealed that the glycaemic abnormalities detected by GTT had not changed over a period of decade even though we postulated alteration of glycaemic abnormalities in favour of elevation of FBS over 2h value. This means that GTT can be used to diagnose GDM with more or less similar cut off values even if the underlying prevalence of T2DM and GDM has risen in recent past.

After knowing the reliability of GTT over a period of time, we were interested in looking for new predictors of the GDM detected by GTT. The traditional risk factors that have been associated with an increased risk of GDM include past history of GDM, hypertension, maternal age > 35 years, pre conception BMI $> 23 \text{ kg/m}^2$, bad obstetric history (miscarriages, still births, IUD etc.), history of delivering large babies ($> 3.5 \text{ kg}$), and family history of first degree relatives with diabetes mellitus or GDM. The third study presented in this oration revealed around 3% of GDM cases were detected in the absence of any of these traditional risk factors.

Previous studies have revealed that excessive gestational weight gain (GWG) was associated with abnormal glucose tolerance in GTT in the third trimester of pregnancy (28). However, it is unclear whether excessive GWG can be used as a surrogate marker of GDM among pregnant women in Sri Lanka. Therefore we designed the fifth study with a view of looking for association between excessive GWG and risk of GDM.

STUDY 5

Can Body Mass Index at booking visit and weight gain during mid-trimester predict Gestational Diabetes Mellitus?

Aim

The aim of this study was to determine whether body mass index (BMI) at 9-12 weeks of booking visit and weight gain in mid-trimester can predict glycaemic abnormalities in glucose tolerance test (GTT).

Methods

In this prospective study, 452 women underwent 75g GTT at 24-28 weeks of gestation. BMI at booking visit (9-12 weeks of gestation) and weight gain in mid-trimester were recorded. Excessive gestational weight gain (GWG) was determined using the Institute of Medicine (IOM) guidelines. Student's t-test and multivariate logistic regression were used to find associations.

Results

Mean age and BMI were 31.3 years (SD 6.3) and 22.0 kg/m² (SD 4.6). Thirty eight point nine percent had excessive GWG in mid-trimester with no statistically significant difference across BMI categories. Excessive GWG was associated with higher risk of GDM. The odds of GTT results above GDM threshold were 31% higher in the excessive GWG group [adjusted OR 1.3 (95% CI 1.1 - 1.5)]. The odds of GDM were 22% higher among women with booking visit BMI ≥ 25 kg/m² [OR 1.2 (95% CI 1.1 - 1.4)].

Conclusions and recommendations

Booking visit BMI and mid trimester excessive GWG can be used to predict GDM. We recommend to calculate BMI at booking visit and look for excessive gestational weight gain in mid trimester and consider GTT for all women with BMI ≥ 25 kg/m² or/and excessive GWG.

Abstract based on the finding of this study was presented at Annual Academic Sessions of Sri Lanka Medical Association in 2015 (29).

Identification of mid trimester excess gestational weight gain is important as it is associated with higher risk of GDM. It would also provide an opportunity for intervention early in pregnancy.

Even though most women with excessive GWG had traditional risk factors for GDM in our study, excessive GWG without traditional risk factors also had higher odds of having GDM. Therefore, it can be used as a predictor of GDM in our setting.

Summary & conclusions

From the series of clinical research on diagnostic tests and methods, author of this oration would like to draw following conclusions and would also like to argue against some of the existing management of GDM in Sri Lanka.

1. Results of our first study clearly indicated that the current GDM screening practices at tertiary care setting is far below the standard practice. Therefore, educating the health care professionals on GDM screening is an urgent need to improve maternal and child health services in Sri Lanka.
2. The second study revealed that the non-fasting GCT had a poor sensitivity (40.6%) and poor specificity when compared to GTT with IAPDSG criteria. Therefore, the current recommendation of Nirogi Lanka-diabetes prevention task force and Sri Lankan College of Obstetricians & Gynaecologists on GDM screening using a single-step non-fasting GTT with 2h cutoff of 140 mg/dL as a screening and diagnostic test for GDM may need to be revisited.
3. Instead we would suggest a single-step 75g GTT using the IADPSG criteria over GCT as the most appropriate method for GDM screening for our settings.
4. As for the most appropriate method for GDM screening, we would recommend universal screening as the best strategy at tertiary care settings. However, if the facilities are limited, selective risk factor based screening also can be used with success in community clinics where women are less likely to have multiple risk factors for GDM.
5. Booking visit BMI and mid trimester excessive gestational weight gain can be used to predict GDM. We recommend to calculate BMI at booking visit and look for excessive gestational weight gain in mid trimester and intensive look for GDM in women with BMI ≥ 25 kg/m² or/and mid trimester excessive gestational weight gain.

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