Consensus Evidence-based Guidelines for Management of Gestational Diabetes Mellitus in India

V Seshiah*, Samar Banerjee**, V Balaji*, A Muruganathan***, Ashok Kumar Das****

Abstract
Gestational diabetes mellitus represents both a clear pathological condition of glycaemic dysregulation and a factor aggravating the risk of future diabetes in both the mother and child. Thus it is of paramount importance to control and manage pregnancy complicated by diabetes to improve the health and well-being of the mother and avert the risk of diabetes across generations. Currently, a wide variety of national and international guidelines address clinical questions pertinent to diabetes management during pregnancy. Of them, the pioneering Diabetes in Pregnancy Study Group India (DIPSI) guideline for the management of diabetes during pregnancy has previously set new standards for quality diabetes care in India and around the world. The advent of insulin analogues, pen delivery devices and insulin pumps, has enriched our armamentarium to manage diabetes and thus warrants our due attention. The current guideline is an attempt to present an overview of current knowledge relating to the management of diabetes in pregnancy and to update available guidelines in view of advances in insulin therapy. These guidelines represent the amalgamation of updated clinical evidence with expert inputs in the context of Indian clinical practice.

Introduction

History

Until 1922, the time of discovery and commercial availability of insulin, in young women diagnosed with type 1 diabetes pregnancy was positively discouraged. Before 1922, there are reports of fewer than 100 pregnancies in diabetic women. These cases of diabetes with pregnancy had an infant mortality rate more than 90% and a maternal mortality rate of 30%. There was almost universal perinatal mortality and a very high maternal mortality. In 1947, the perinatal mortality rate in pregnancies complicated by pre-existing diabetes was about 40% in Europe and the United States. In the early 1950s, the concept of specialty clinics for pregnancies complicated by diabetes was introduced and resulted in a decrease in the perinatal mortality rate from 177.4 per 1000 births in 1967-68 to 60.7 in 1975-1976. Improvement in infant and maternal mortality rates finally occurred after 1980, when treatment strategies could achieve better control of maternal plasma glucose levels when, self-monitoring-blood glucose (SMBG) and glycated haemoglobin estimation and ultra sonography because available. Though the absolute risk of perinatal mortality has declined in both the general population and in women with diabetes, the relative risk remains approximately 3 times higher in the diabetes subgroup.

Pathophysiology

Complicated changes in maternal metabolism, to accommodate the needs of a developing foetus have a major impact on maternal health and physiology. Normal pregnancy is characterized by insulin resistance and maternal inability to up-regulate insulin secretion to compensate for such incipient insulin resistance could lead to the development of gestational diabetes mellitus (GDM). Normal pregnancy is characterized by “facilitated insulin action” during 1st half of pregnancy and “diabetogenic stress” in the 2nd half of pregnancy. These changes are a result of high hormone levels (elevation of progesterone, oestriol, oestradiol, oestrone and HCS), decreased glucose disposal rate, increased fasting serum insulin levels, and decreased insulin secretion after meals. GDM is defined by the International Association of Diabetes and Pregnancy Study Group (IAFPSG) and the Diabetes in Pregnancy Study Group India (DIPSI) as “any degree of glucose/carbohydrate intolerance with onset or first recognition during pregnancy”. The results from the landmark Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) study demonstrated that maternal hyperglycaemia, even at a level below that diagnostic of diabetes, is associated with a strong and continuous trend of increased birth weight and increased cord-blood serum C-peptide levels. Pregestational diabetes mellitus (pre-GDM) is the condition in which pregnant women have preexisting diabetes mellitus (type 1 or type 2). Pre-GDM has a significant perinatal impact with worse outcomes (combined perinatal loss and malformation) for babies born to Asian mothers compared with Caucasian mothers. The most debilitating impact of pre-GDM and GDM is an increased foeto-maternal risk of developing diabetes mellitus and metabolic syndrome later in life, thus posing a trans-generational diabetes risk.

Indian Scenario

Seshiah et al. reported in 2008 that GDM was detected in 17.8% women in urban, 13.8% in semi urban and 9.9% in rural areas in a study which prospectively screened for GDM. By World Health Organisation criteria of 2 hr. plasma glucose ≥ 140 mg/dl, the prevalence of GDM in our country was 16.55% in 2004. Among ethnic groups in South Asian countries, Indian women have the highest frequency of GDM. The prevalence of GDM corresponds to the prevalence of impaired glucose tolerance (IGT) within a given population. The ICMR-INDIab study estimates the prevalence of IGT to be between 8.3-14.6% varying according to the state. This high rate implies that Indian population with higher incidence of diabetes mellitus and IGT is more predisposed to GDM and is at a relatively greater risk of GDM. GDM manifests in all trimesters of pregnancy, with
an Indian study showing that out of all women diagnosed for GDM 16.3% were diagnosed at ≤ 16 weeks of gestation while 22.4% were diagnosed between 17-23 weeks and 61.3% were diagnosed after 23 weeks of gestation.18 The incidence of GDM is considerably affected by demographic characteristics; adjusted odds ratio of GDM incidence in patients aged ≥ 25 years was 2.10 [95% CI : 1.87 - 2.37], P < 0.001; with BMI ≥ 25 adjusted odds ratio was 1.88 [95% CI : 1.63 - 2.16], P < 0.001; with family history of diabetes adjusted odds ratio was 1.58 [95% CI : 1.39 - 1.79], P < 0.001].12

Data from Indian studies shows that adverse antenatal outcomes such as hypertension, polyhydramnios, macrosomia, foetopelvic disproportion (P < 0.001), congenital anomalies (like cleft lip with palate, foot drop, hip dislocation, pericardial effusion, and anencephaly with meningocoele), polycythemia, hypocalcaemia, and hyperbilirubinaemia are observed to be more common (P < 0.05) in pregnancies with a diagnosis of diabetes.19 Another study from India reported that not only do women with diabetes have worse pregnancy outcomes (abortions, 0% vs. 2.7%; macrosomia, 27.6% vs. 7.1%) compared to non-diabetic women, but that pre-gestational diabetes results in worse outcomes (abortions, 10.1% vs. 2.7%, congenital anomalies 3.8% vs. 1.4%) than gestational diabetes.20

Management of GDM

The goal of diabetes management during pregnancy is to ensure safe foeto-maternal outcome, prevention or delay of diabetes and cardiovascular disease (CVD) in the mother and the child. The management of GDM must involve a team approach consisting of obstetrician, diabetes physician, a diabetes educator, dietitian, midwife and paediatrician ideal for managing GDM.21,22 Management of GDM and pre-GDM should include early referral to a specialist, collaborative effort among obstetrician/midwife, endocrinologist, ophthalmologist, registered dietitian, and nurse educator, and engagement of all team members in patient education/care prior to and throughout pregnancy. The individualized treatment plan must involve a combination of glucose monitoring, medical nutrition therapy (MNT), pharmacotherapy, exercise, weight management strategies and psychological support.21,22 Insulin is currently the mainstay of pharmacological glycaemic management during pregnancy.15

Overview of guidelines for management of GDM and pre-GDM

Currently, there are a number of country-specific guidelines on diagnosis and treatment of GDM. These include American Diabetes Association (ADA) guidelines, American College of Obstetricians and Gynaecologists (ACOG) guidelines and National Institute of Health and Clinical Excellence (NICE) guidelines and JADPSG guidelines. The high burden of GDM in the Indian scenario mandates the framing of GDM-specific guidelines for its clinical management. Thus, the current recommendations have been formulated with the framework of the pioneering DIPSI guideline to comprehensively diagnose and manage GDM in India.

Rationale for India specific guidelines

Currently existing guidelines focus on the management of hyperglycaemia in patients of their respective regions. However, the Indian population is a diverse grouping of varying genetic and demographic profiles making Indian women more predisposed to developing insulin resistance or diabetes during pregnancy. Furthermore, the incidence of diabetes in general and GDM in particular is on the upswing due to changing lifestyles, making them potential public health catastrophes without timely intervention. Existing guidelines, with the exception of DIPSI guidelines, do not specifically address the clinical questions about the considerations related to diabetes management during pregnancy in India. There has been a rapid expansion of the therapeutic armamentarium with the introduction of insulin analogues against diabetes mellitus, in general. Due to these peculiarities in the Indian scenario, existing guidelines cannot be widely used in Indian clinical practice. The current guidelines are an effort to provide an updated clinical view in light of these developments. This current consensus guideline aims to provide specific recommendations based on published data for proper management of GDM and pre-GDM in India.

Methodology

A systematic review of literature from medical databases was conducted to provide the best possible evidence base for the recommendations. Existing guidelines, meta-analyses, cross sectional studies, systematic reviews and key cited articles related to GDM and pre-GDM were reviewed by a group of doctors and recommendations relevant to Indian scenario were framed. The recommendations were discussed at the National Insulin summit held in August 2013, by an expert panel of physicians, endocrinologists and key opinion leaders. At this summit, recommendations for each section of the guidelines, and overall recommendations were agreed upon. Where there was little or no evidence, the committee relied on experience, judgement and consensus to make their recommendations. The consensus document was drafted and circulated for further feedback from the participants and others who could not attend.

Grading system

The current guideline has been developed in accordance with the American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Recommendations are organized by topic and are assigned evidence level (EL) ratings on the basis of the quality of supporting evidence all of which have also been rated for strength. Recommendations are based on clinical importance and graded as A (strongly recommend), B (intermediate), C (weak) and D (not evidence based); The evidence levels are coupled by 4 intuitive levels of evidence: 1,2,3,4 and they have been positioned on the basis of available evidence to be used for grading recommendations as follows.21

- “1” Meta-analysis of randomized controlled trials (MRCT), randomized controlled trials (RCT)
- “2” Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT), nonrandomized controlled trial (NRCT), prospective cohort study (PCS), retrospective case-control study (RCCS)
- “3” Cross-sectional study (CSS), surveillance study (registries, surveys, epidemiologic study, retrospective chart review, mathematical modelling of database) (SS), consecutive case series (CCS), single case reports (SCR)
- “4” No evidence (theory, opinion, consensus, review, or preclinical study) (NE)
Table 1: Effect of insulin treatment on pregnancy outcomes in patients with gestational diabetes mellitus (GDM)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control (n=140), n (%)</th>
<th>GDM with treatment (n=70), n (%)</th>
<th>GDM without treatment (n=62), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirth</td>
<td>-</td>
<td>-</td>
<td>3 (4.84)</td>
<td></td>
</tr>
<tr>
<td>Preterm* &lt; 37 weeks</td>
<td>4 (2.8)</td>
<td>3 (4.2)</td>
<td>10 (16.13)</td>
<td>0.006</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>-</td>
<td>-</td>
<td>2 (3.23)</td>
<td></td>
</tr>
<tr>
<td>Macrosomia &gt; 4kg</td>
<td>4 (2.8)</td>
<td>1 (1.4)</td>
<td>6 (9.6)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Current Consensus Evidence-based Guidelines

Screening for GDM

Existing guidelines

The question of appropriate screening for GDM has been widely discussed in medical literature. Current ADA guidelines recommend selective screening of high-risk women for GDM, however the ACOG guidelines call for universal screening and NICE guideline recommends screening of all women of South Asian ethnicity. Early screening during pregnancy affords the opportunity of initiating glycaemic management modalities early during the course of GDM. Thus, ADA guidelines call for screening as early as possible. In patients who remain undetected at 16 weeks, repeating the screening during the third trimester (32-34 weeks) is suggested by DIPI guidelines. Since the diabetic status of women is known before conception, accurate categorization of individuals helps in the appropriate pre and post-conception management of glycaemia for achieving good foeto-maternal outcomes. The Australasian Diabetes in Pregnancy Society (ADIPS) recommends screening for GDM with 50 g or 75 g oral glucose challenge test (PGT) irrespective of meal intake. On the other hand, ADA and NICE recommend a 75 g and 100 g oral glucose tolerance test (OGTT) for screening while ACOG recommends a 2-step screening (50 g GCT followed by 100 g OGTT). The DIPI guideline recommends universal screening of all pregnant women.

Evidence base

In light of the 11-fold increased risk of developing glucose intolerance during pregnancy in Asian women compared to Caucasian women, universal screening is preferable in India. Women in this category have been shown to have worse postpartum outcomes (increased postpartum glycaemia, insulin resistance, and beta-cell dysfunction) than women with normal glucose tolerance. Other studies show the benefit of a pre-24 week initial screening followed by a repeat screening at 24 weeks. Women are detected to have GDM on repeat screening in subsequent visits and thus, it is ideal to perform diagnostic test in every trimester with HbA1c > 6.5% in the first trimester indicating pre-GDM. Mission et al. suggest that despite higher cost the single-step OGTT approach remains cost effective as ~2.0% of patients are additionally diagnosed and treated for GDM. A 2-hour test has been reported to predict adverse pregnancy outcomes.

Recommendation for universal screening

• Universal screening for GDM in all pregnant women is recommended to improve outcomes in women with glucose intolerance (Grade A; EL 1).

• It is recommended that GDM screening be performed at 16 weeks of pregnancy and followed up with a second screening test between 24-26 weeks of pregnancy and third after 30 weeks of pregnancy (Grade A; EL 2).

• As a pregnant woman walks into the antenatal clinic in the fasting or non-fasting state, she should be given a 75 g oral glucose load and at 2 hrs, a venous blood sample should be collected for estimating plasma glucose (Grade A; EL 2).

Diagnostic criteria for GDM

Existing guidelines

The IADPSG suggested criteria for diagnosis of GDM based on the Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study. When fasting blood glucose (FPG) is ≥ 5.1 mmol/L (92 mg/dl) or 1-hour blood glucose is ≥ 10.0 mmol/L (180 mg/dl) or 2-hour blood glucose is ≥ 8.5 mmol/L (153 mg/dl) with 75 g OGTT then the patient is diagnosed with GDM. In the HAPO study, population from India, China, South Asian countries (except city of Bangkok, Hong Kong), Middle East and Sub Saharan countries were not included. Thus, essentially HAPO study was performed in Caucasian population. The IADPSG also suggests that FPG > 7.0 mmol/L (126 mg/dl)/HbA1c > 6.5% in the early weeks of pregnancy is diagnostic of overt diabetes. FPG > 5.1 mmol/L and < 7.0 mmol/L is diagnosed as GDM. The ACOG guideline does not endorse IADPSG recommendations. The World Health Organisation (WHO) recommends that “a standard OGTT should be performed after overnight fasting (8–14 hours) by giving 75 g anhydrous glucose in 250–300 ml water. Plasma glucose is measured of fasting and 2 hours after meal. Pregnant women who meet the WHO criteria for diabetes mellitus or IGT are classified as having GDM”. The WHO diagnostic criterion thus stands at a 2 hr. plasma glucose (PG) ≥ 140 mg/dl. The DIPI guideline diagnostic criteria, a modified version of the WHO criterion for GDM diagnosis, recommends testing in diabetic women, irrespective of meal time. The recommendation states “2 hr. PG ≥ 140 mg/dl with 75 g oral glucose administration in pregnant women in the fasting or non-fasting state, without regard to the time of the last meal is able to identify women with GDM.”

Evidence base

The DIPI recommendation has been shown to be cost effective and evidence-based and serves as a single step screening and diagnostic tool. The DIPI guideline further recommends the use of the term “decreased gestational glucose tolerance (DGGT)” for 2-hour PG ≥ 120 mg/dl but under 140 mg/dl. Women in this category have been shown to have worse postpartum outcomes (increased postpartum glycaemia, insulin resistance, and beta-cell dysfunction) than women with normal glucose tolerance. The use of 2-hour PG ≥ 140 mg/dl for diagnosis of GDM and subsequent treatment are known to be associated with decreased macrosomia rate and fewer emergency caesarean sections. Furthermore, the DIPI criterion avoids the use of FPG for screening as recommended by the IADPSG guideline, which would have led to only one- third of South Asian subjects with diabetes being diagnosed, if screening was limited to FPG measures. Even if the test is to be repeated in each trimester, the cost in performing the procedure is estimated to be 66% less than the cost of performing IADPSG recommended procedure. Table 1 summarizes the data from a randomized control trial showing that adherence to DIPI diagnostic and management criteria leads to improved outcomes.
A majority of existing guidelines do not recommend the use of OADs during pregnancy.

Evidence base

Recent studies have indicated that there may be beneficial effects associated with the use of metformin and glyburide during pregnancy.50-51 On the other hand significant concerns remain about the use of OADs during pregnancy, primarily due to safety issues.52-53 Currently, there is insufficient evidence to recommend the use of OADs in the management of GDM.

Recommendation for use of OADs for GDM

- The use of OADs is currently not recommended for glycaemic management during pregnancy (Grade A; EL 2).52,53

Insulin therapy

Existing guidelines

ADA, ACOG and NICE recommend the initiation of insulin therapy, if nutrition therapy fails to achieve blood glucose targets in women with GDM after assessing the response to a meal plan for 2 weeks if FPG > 90 mg/dL and 2-hour PG > 120 mg/dL.54 Insulin may be started at diagnosis along with a meal plan if FPG > 120 mg/dL and 2-hour PG > 200 mg/dL.54 The ACOG guideline recommends initiation of insulin in women with GDM with an ultrasound abdominal circumference greater than 75th percentile at 29-33 weeks of gestation.29 The ADA guideline on the initiation of insulin recommends initiation of insulin to achieve FPG ≤ 105 mg/dL (5.8 mmol/L) or 1-hour PG ≤ 155 mg/dL (8.6 mmol/L) or 2-hour PG ≤ 130 mg/dL (7.2 mmol/L).24

Evidence base

Prospective trials have demonstrated that there is a reduced likelihood of macrosomic deliveries when insulin therapy is applied to all women with GDM.55-58 While conventionally only the use of human insulins was advised during GDM, recent data has demonstrated the benefits of insulin analogues during pregnancy. Insulin aspart and insulin lispro have been shown to be safe and effective for use during pregnancy.59,60 Insulin aspart is more effective than human insulin in decreasing postprandial glucose (PPG) concentrations (difference in PPG: -0.40%, P = 0.044) and is associated with lower hypoglycaemia (major hypoglycaemia, 1.4 vs. 2.1 episodes/year exposure).61 In a randomized, parallel-group, open-label, multinational trial, there were 137 and 131 live births and 14 and 21 foetal losses, perinatal mortality was 14 and 22 per 1000 births; number of congenital malformations were 6 and 9 and birth weight corrected for gestational age was 3438 g (± 71.5) and 3555 g (± 72.9; P = 0.091) for insulin aspart and human insulin respectively.62

Similarly, Balaji et al. showed that biphasic aspart 30 (BIAsp) was noninferior to biphasic human insulin 30 (BHI30) when administered during pregnancy.63 BIAsp30 and BHI showed similar degrees of FPG and PPG control in a randomized open-label controlled study (92.97 ± 14.44 vs. 95.43 ± 18.96 and 127.59 ± 28.99 vs. 126.98 ± 29.89 mg/dL, respectively; both P = ns). Neonatal macrosomia frequency was 6.3% in BHI group and 6.9% in BIAsp group; however, this difference was not statistically significant.63 By last visit, the required insulin dose was significantly lower for BIAsp 30 vs. BHI (19.83 ± 15.75 IU vs. 26.34 ± 23.15 IU, respectively; P = 0.006). BIAsp 30 may offer greater treat-to-target potential for pregnant women.64 This suggests that BIAsp 30 might offer greater scope for achieving blood glucose targets through dose titration.65 Among long-acting insulins, insulin detemir is the only long-acting analogue to be approved for use during pregnancy.66 Insulin detemir has...
been shown to result in lower FPG and noninferior HbA1c in late pregnancy compared with NPH insulin; the estimated HbA1c at 36 gestational weeks was 6.27% for insulin detemir and 6.33% for NPH, while FPG was lower for insulin detemir vs. NPH. (85.7 vs. 97.4 mg/dL, P = 0.017).  

**Recommendations for initiation and titration of insulin before delivery**

- After assessing the response to a meal plan for 2 weeks if FPG > 90 mg/dL and/or 2 hr PG > 120 mg/dL, then insulin initiation is recommended (Grade A; EL 2).  
- Insulin may be started at diagnosis along with a meal plan if FPG > 120 mg/dL and 2-hour PG > 200 mg/dL (Grade B; EL 4).  

**If only FPG is high, NPH should be started at bedtime (Grade A; EL 4).**  

- If postprandial PG is higher, insulin aspart should be added before that meal depending upon whether post breakfast or post lunch or post dinner value is elevated. Based on blood glucose monitoring BIAsp 30/70 may also be used before breakfast and before dinner (Grade A; EL 1).

- Single injection regimes consisting of single intermediate acting insulin either in the morning or evening with premixed insulin 30: 70 or 50: 50 (regular:isophane) should be initiated for GDM (Grade A; EL 4).  
- Depending on SMBG, multiple dose injection regimens are also recommended for achieving euglycaemia in pre-GDM (Grade A; EL 3).  
- Insulin aspart is recommended for bolus insulin need as it is more effective than human insulin in decreasing postprandial glucose concentrations (Grade A; EL 1).

- BIAsp 30 is recommended for use during pregnancy as it is non-inferior to BHI 30, producing comparable foetal outcomes, but requiring lower doses (Grade A; EL 1).

- Among long-acting insulins, insulin detemir is the only long-acting analogue to be approved for use during pregnancy and is thus recommended for basal insulin requirements (Grade B; EL 1).

- The following requirement of insulin for both GDM and pre-GDM falls.  

**Recommendations for glycaemic management post delivery**

- Immediately after delivery during in-patient care, the requirement of insulin for both GDM and pre-GDM falls. The following algorithm should be followed after delivery based on blood glucose levels:
  - 60-90 mg/dL – 5% glucose (G)+normal saline (NS) @ 100 ml/hour  
  - 90-120 mg/dL – @ NS 100 ml/hour  
  - 120-140 mg/dL – @ NS 100 ml/hour plus 4 units of regular insulin added with IV fluid  
  - 140-180 mg/dL – @ NS 100 ml/hour plus 6 units of regular insulin added with IV fluid  
  - >180 mg/dL - @ NS 100 ml/hour plus 8 units of regular insulin added with IV fluid  

- Majority of GDM patients do not require any treatment for hyperglycaemia and if treatment is necessary the following considerations should be observed:
  - In lactating mothers, T1DM should be controlled with insulin only and T2DM preferably with insulin; Metformin can be used as an alternative for women who are reluctant to take insulin (Grade A; EL 4).

- In non-lactating mothers, T2DM should be managed using OADs or insulin according to the situation (Grade A; EL 4).

- Women with GDM require follow up: Glucose tolerance test with 75 g oral glucose is performed 6 weeks postpartum and if necessary repeated after 6 months. (Grade A; EL 4).

- Monitoring by 75 g oral glucose tolerance test every year is recommended to determine whether the glucose tolerance has returned to normal or progressed (Grade A; EL 4).

**Administration of insulin**

**Insulin pen**

**Existing guidelines**

A majority of existing guidelines do not address the specific clinical question of the use of insulin pen during pregnancy.

**Evidence base**

Insulin pens are novel devices which are relatively more user-friendly and comfortable mode of insulin administration. The ease of use of insulin pens and the flexibility of incorporating insulin injections into a busy lifestyle may improve diabetes control with much less effort, while maintaining the quality of life for the diabetic patients. Schuster et al. showed that patients find premixed insulin administered by the pen to be easier to use while there are no significant differences in glucose control or cost.

**Recommendations for insulin therapy using insulin pens**

- Insulin pens are recommended to make the injections accurate, discreet and painless with successful self-administration (Grade A; EL 2).
Continuous subcutaneous insulin infusion

Existing guidelines

A majority of existing guidelines do not address the specific clinical question of the use of continuous subcutaneous insulin infusion (CSII) during pregnancy. However, ADA and ACOG guidelines mention the use of CSII when necessary and note its benefits in providing glycaemic control.24,25

Evidence base

CSII is a safe and reliable method for satisfying basal insulin needs in pregnant women with GDM and pre-GDM. It needs to be combined with continuous glucose monitoring (CGM) for optimal glycaemic control in type 1 diabetes and can be used to effectively mimic physiologic insulin secretion. There is no significant difference in glycaemic control for pregnancy outcomes with CSII vs. multiple-dose insulin therapy and can help address daytime or nocturnal hypoglycaemia or a prominent dawn phenomenon.69,70 Insulin aspart and lispro are the standard of care for CSII. However, its complexity requires counselling and training, and is costly. Moreover, potential for insulin pump failure/user error or infusion site problems is greater with CSII.71

Table 3: Comparison of current guidelines with existing guidelines for management of gestational diabetes mellitus (GDM)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Current guidelines</th>
<th>DIPSI</th>
<th>ADA</th>
<th>ACOG</th>
<th>NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Universal vs. selective screening</strong></td>
<td>Universal, one-step screening</td>
<td>Selective screening</td>
<td>Universal preferred, two-step method</td>
<td>Selective screening</td>
<td>First at 16-18 weeks; repeated at 24-28 weeks</td>
</tr>
<tr>
<td><strong>Time and periodicity of screening</strong></td>
<td>First at 16 weeks; repeated at 24-28 weeks and after 32-34 weeks</td>
<td>First at 16-18 weeks; repeated at 24-28 weeks</td>
<td>50 g GCT followed by 100 g OGGT</td>
<td>First at 16-18 weeks; repeated at 24-28 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Method of screening</strong></td>
<td>75 g OGTT</td>
<td>75 gm OGTT</td>
<td>100 g OGTT</td>
<td>100 g OGTT</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnostic criteria</strong>*</td>
<td>2-hr PG ≥140 mg/dl-GDM and ≥ 120 mg/dl-DGGT</td>
<td>Any 2 of the following: Fasting &gt; 120 mg/dl; 1-hr &gt; 180.0 mg/dl; 2-hr&gt; 200mg/dl (only if 75 g glucose used); 3-hr&gt; 140.4 mg/dl</td>
<td>Any 2 of the following: Fasting &gt; 95.4 mg/dl; 1-hr &gt; 180.0 mg/dl; 2-hr&gt; 154.8 mg/dl; 3-hr&gt;140.4 mg/dl</td>
<td>Any of the following: Fasting &gt; 25.6 mg/dl; 2-hr 140.4 mg/dl</td>
<td></td>
</tr>
<tr>
<td><strong>Blood glucose targets</strong></td>
<td>FPG and post prandial peak levels around 90 mg/dl and 120 mg/dl.</td>
<td>Fasting 95.4 mg/dl; 1-hr 140.4 mg/dl; 2-hr 120.6 mg/dl</td>
<td>Fasting 95.4 mg/dl; 1-hr 129.6 mg/dl</td>
<td>Fasting 63.0–106.2 mg/dl; 1-hr 140.4 mg/dl</td>
<td></td>
</tr>
<tr>
<td><strong>OADs</strong></td>
<td>Not recommended; benefits of OADs noted</td>
<td>Not recommended; both benefits and contraindications of OADs noted</td>
<td>Not recommended; benefits of analogues noted</td>
<td>Not recommended; Metformin may be used as an adjunct</td>
<td></td>
</tr>
</tbody>
</table>
| **Insulin therapy**                   | Initiated after 2 weeks of MNT, if FPG > 90 mg/dl and/or 2-hr PG > 120 mg/dl; At diagnosis FPG > 120 mg/dl and 2-h PG > 200 mg/dl. | Initiated after 2 weeks of MNT, if FPG > 90 mg/dl and/or 2-h PG > 120 mg/dl; At diagnosis FPG > 120 mg/dl | Initiated after MNT, if FPG > 105 mg/dl and/or 1 hr PG > 155mg/dl or 2 hr PG > 130 mg/dl; If ultrasound abdominal circumference in the 75th percentile in the third trimester | Initiated after MNT, if FPG > 106 mg/dl. 

**Insulin analogues**

Insulin aspart for bolus and detemir for basal needs recommended BIAsp for basal/bolus is also recommended. Benefits of analogues noted.

**Insulin pen**

Insulin pens which use 32G needles are recommended. Not mentioned.

**CSII**

Cautious, appropriate use recommended. Not mentioned.

*Converted mmol/L value to mg/dL; Abbreviation: DIPSI: Diabetes in Pregnancy Study group India; ADA: American Diabetes Association; ACOG: American College of Obstetricians and Gynecologists; NICE: National Institute of Health and Clinical Excellence; OGTT: Oral glucose tolerance test; GCT: Glucose challenge test; PG: Plasma glucose; FPG: Fasting plasma glucose; MNT: Medical nutrition therapy; CSII: Continuous subcutaneous insulin infusion; OADs: Oral antidiabetic drug

Recommendations for insulin therapy using insulin pumps

- CSII is recommended in patients with GDM and pre-GDM for achieving euglycaemia when warranted. However, it is not recommended as a part of routine practice (Grade A; EL 2).69

Summary

GDM with its trans-generational risk of diabetes represents a unique risk as well as an opportunity, in the context of diabetes management. As it represents current as well as future risk of diabetes, its proper management and control can be expected to help in addressing the problem of a burgeoning population of people living with diabetes. In light of the availability and approval of insulin analogues for use during pregnancy, their use is ideal given their association with better outcome. The recent approval of insulin detemir for use during pregnancy raises hopes of its use for improving antenatal outcomes. Thus, it is of paramount importance in the Indian clinical scenario, that there are clear and updated guidelines for the management of GDM, with a strong evidentiary foundation (Table 3). The current guideline is an attempt to present an updated view of the role of insulin therapy in the management of GDM, in light...
of new evidence about the potential role of insulin analogues in managing hyperglycaemia during pregnancy.

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References


64. Levemir Package Insert, updated: 5/2013


