Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of various degrees that is first detected during pregnancy.[1] Hyperglycaemia in GDM results from an insulin supply that is inadequate to meet tissue demands for normal blood glucose regulation. Studies conducted during late pregnancy show that although the insulin requirements are higher, they differ only slightly between normal and gestational diabetic women. This signifies reduced insulin responses to nutrients in women with GDM.[8] There are various guidelines to diagnose GDM like O'Sulivan and Mahan, NDDG Carpenter and Coustan, International association of Diabetes & Pregnancy Group (IADPSG) and DIPSI. Settings and Design: It was cross sectional observational study, conducted at KGGMU, Lucknow, Uttar Pradesh between Aug 2016 and Sept 2017. 162 patients were enrolled after fulfilling the inclusion and exclusion criteria. Methods and Material: The study population was derived by screening pregnant females attending for their routine antenatal check up from 24 to 28 weeks of gestation. Plasma glucose levels was measured following 8hrs of overnight fasting. The pregnant females were given 82.5 glucose (equivalent to 75gm anhydrous glucose). Venous blood sample was collected for estimating plasma glucose at 0,1and 2hr. Results: In our study the prevalence of GDM among study population according to IADPSG criteria was 22.64%, as per Modified Carpenter & Coustan criteria was 17.61% while that as per DIPSI criteria was 13.21%. Conclusions: Considering IADPSG criteria as gold standard DIPSI is missing 66.6% of patients diagnosed as GDM by IADPSG. Considering Modified C&C criteria as gold standard over the years DIPSI is missing 64.2% of patients diagnosed as GDM by C&C.

Keywords: Diagnostic criteria, DIPSI, GDM, IADPSG, modified C and C
was to study the implications of implementing the DIPSI model in India when comparing to international standards like IADPSG and Modified C and C guidelines for screening and diagnosis of GDM. We wanted to evaluate the sensitivity and specificity of the DIPSI model as compared to the standard criteria, as it would help the clinicians in providing better care to the patients. We thus sought to evaluate the prevalence of GDM by three different diagnostic criteria considering C and C/IADPSG as the gold standard for diagnosis.

Material and Methods

This was a cross-sectional observational study, conducted at King George’s Medical University, Lucknow, Uttar Pradesh between Aug 2016 and Sept 2017. One hundred and eighty pregnant females between 24 and 28 weeks of gestation were included in the study and 159 fulfilled the inclusion criteria. We excluded the patients who were already diagnosed with type 1 or type 2 diabetes mellitus, patients with acute kidney injury (AKI) or chronic kidney disease (CKD) and patients on steroid therapy. The study population was derived by screening pregnant females attending for their routine antenatal check-up from 24 to 28 weeks of gestation. The plasma glucose levels were measured following 8 h of overnight fasting. The pregnant females were given 82.5 glucose (equivalent to 75 gm anhydrous glucose). Venous blood sample was collected for estimating plasma glucose at 0, 1 and 2 h, respectively.

Results

A total of 159 pregnant females were evaluated from Aug 2016 to Sep 2017. The incidence of GDM among the study population according to the IADPSG criteria was 22.64% while that as per the Modified C and C criteria was 17.61% and as per the DIPSI criteria was 13.21% [Table 1].

Out of the 36 patients who were under the domain of GDM as per the IADPSG criteria, the majority were diagnosed as GDM solely on the cut-off values of fasting blood sugar (64.29%) and all the other cut-offs—fasting blood sugar (FBS) + post prandial (PP) 1 h + PP 2 h were met in (13.89%) patients. Two (5.56%) patients each were diagnosed as GDM by FBP + PP 1 h, FBS + PP 2 h and PP 2 h. One patient each was diagnosed as GDM based on PP 1 h and PP 2 h cut-offs [Table 2].

Out of the 36 GDM diagnosed by the IADPSG criteria, 12 (33.33%) were confirmed to be GDM by DIPSI and of the 123 non-GDM cases excluded by the IADPSG criteria, 114 (92.68%) were also confirmed to be non-GDM. An agreement of 126 (12 + 114) cases out of 159 cases (79.25%) was observed. The level of agreement was found to be Fair ($\kappa =0.305$) and statistically significant ($P < 0.001$). The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy of DIPSI against IADPSG was 33.3, 92.7, 57.1, 82.6 and 79.2%, respectively [Table 3].

Similarly, out of the 28 patients who were under the domain of GDM as per the Modified C and C criteria, the majority were diagnosed as GDM solely on the cut-off values of the fasting blood sugar (64.29%) and all the other cut-offs—fasting blood sugar (FBS) + PP 1 h + PP 2 h were met in (14.29%) patients. Two (7.14%) patients each were diagnosed as GDM by PP 1 h and PP 1 h + PP 2 h. One (3.57%) patient each was diagnosed as GDM based on Fasting + PP 1 h and Fasting + PP 2 h. None of the females were diagnosed as GDM solely on PP 2 h cut-off values [Table 4].

Out of 28 GDM diagnosed by the Modified C and C criteria, only 10 (35.71%) were confirmed to be GDM by DIPSI and of the 131 non-GDM cases excluded by the Modified C and C criteria, 120 (91.60%) were also confirmed to be non-GDM by DIPSI. An agreement of 130 (10 + 120) cases out of 159 cases (81.76%) was observed. The level of agreement was found to be Fair ($\kappa =0.303$) and statistically significant [Table 5].

A significant point to note was that
- 9 cases were diagnosed as GDM by DIPSI but not by IADPSG
- 11 cases were diagnosed as GDM by DIPSI but not by Modified C and C.

This also points to the discordance in the 2 h PP glucose values as these patients had a 2-h PP value between 140 and 153 or 155 mg/dL, respectively.

Discussion

The diagnosis of GDM is still debated as there are various guidelines present. The Modified C and C is the most widely used criteria all over the world. With the recent release of the IADPSG criteria, and followed all over the world, a lot of controversy has been generated about the medicalisation of pregnancy. In our study, we tried to analyse three criteria namely, IADPSG, MODIFIED C and C and DIPSI for the diagnosis of the GDM.
Table 3: Distribution of GDM patients by Modified C&C (n=28)

| Criteria                          | No. of patients | Percentage |
|-----------------------------------|-----------------|------------|
| Only by Fasting                   | 18              | 64.29      |
| Only by PP 1 h                    | 2               | 7.14       |
| Only by PP 2 h                    | 0               | 0.00       |
| Both Fasting + PP 1 h             | 1               | 3.57       |
| Both Fasting + PP 2 h             | 1               | 3.57       |
| Both PP 1 h + PP 2 h              | 2               | 7.14       |
| Fasting + PP 1 h + PP 2 h         | 4               | 14.29      |

Table 4: Comparison of DIISI with IADPSG criteria for the diagnosis of GDM

| DIISI Criteria | Total GDM (n=36) | Non-GDM (n=123) |
|----------------|------------------|-----------------|
|                | No. | %   | No. | %   |
| GDM            | 21  | 12/36| 33.33| 9/123| 7.32 |
| Non-GDM        | 138 | 24/36| 66.67| 114/123| 92.68 |

Table 5: Comparison of C&C criteria with IADPSG criteria for diagnosis of GDM

| Modified C&C Criteria | Total GDM (n=36) | Non-GDM (n=123) |
|-----------------------|------------------|-----------------|
|                        | No. | %   | No. | %   |
| GDM                   | 28  | 28/36| 77.78| 0/123| 0.00 |
| Non-GDM               | 131 | 8/36| 22.22| 123/123| 100.0 |

We considered two scenarios:
1. Taking IADPSG as the gold standard, we compared patients using the Modified C and C and DIISI criteria.
2. Taking the Modified C and C as the gold standard, we compared patients using the IADPSG and DIISI criteria.

In our study, the prevalence of GDM among the study population according to the IADPSG criteria was 22.64%, as per the Modified C and C criteria was 17.61% while that as per the DIISI criteria was 15.21%. The previous studies conducted in India show that the incidence of GDM varies from region to region. The reported prevalence rate includes 3.8% in Punjab (WHO criteria), 6.2% in Mysore (ADA criteria), 9.5% in Western India (DIPSI criteria) and 17.9% in Tamil Nadu (WHO criteria). In more recent studies, using different criteria, prevalence rates as high as 35% from Punjab (WHO criteria) and 41% from Lucknow (IADPSG criteria) have been reported. The differences in the prevalence of the incidence in GDM is due to the various demographic profiles of the patients and also the usage of different criteria applied for the diagnosis. Out of the 36 GDM patients diagnosed by the IADPSG criteria, 12 were picked up by DIISI. And according to the DIISI criteria, 21 patients were diagnosed as GDM, out of which 9 were diagnosed as GDM only by the DIISI criteria. So it is seen that DIISI is missing 66.6% of the patients diagnosed as GDM by the IADPSG criteria and over-diagnosing 42% of the patients. This suggests that DIISI misses a substantial amount of the GDM patients, and on the other hand, also diagnoses a few non-GDM patients as GDM. This result is in concordance with the studies like Pulkit Vij et al.[9] which showed that the diagnosis of GDM by the DIISI criteria leaves 22.36% undiagnosed which may easily be detected through IADPSG. Out of the 36 patients who fall under the domain of GDM as per the IADPSG criteria, the majority were diagnosed as GDM solely on the cut-off values of the fasting blood sugar (63.89%) followed by all the three cut-offs—FBS + PP 1 h + PP 2 h (13.89%). This suggests that the deranged fasting blood sugar is an important criterion to diagnose the GDM, which is not used in DIISI, which only utilises the 2 h PP criteria. A study by Shrestha B et al.[10] showed that the sensitivity of DIISI was 73.68% and the specificity was 98.52%. The agreement between both the studies was 60–80%. So, they concluded that it could be used as it is less expensive and easily adopted in their institute. A study by Mitra Sujoy et al.[11] concludes that the DIISI criteria have a low diagnostic rate as compared to the IADPSG criteria because it ignores the fasting blood glucose (FBG) levels. The patients diagnosed as GDM by fasting value have a similar severity of GDM as those diagnosed by the non-fasting values. Out of the 36 GDM diagnosed by the IADPSG criteria, 28 (77.78%) were confirmed to be GDM by the Modified C and C criteria also and all the (n = 123; 100.0%) non-GDM cases diagnosed by the IADPSG were confirmed to be non-GDM by the Modified C and C criteria. So, IADPSG is over-diagnosing 22% of the patients as GDM, which is beneficial in the long-term pregnancy outcomes. A study by Katrien Benhalima et al.[12] suggested that using the IADPSG criteria, more women are identified as having GDM, and these women carry an increased risk for adverse gestational outcomes compared to the women without GDM. But more needs to be done to evaluate its long-term pregnancy and perinatal outcomes. Out of the 28 GDM diagnosed by the Modified C and C criteria, only 10 were picked up by the DIISI criteria. And according to the DIISI criteria, 21 patients were diagnosed as GDM, out of it, 11 patients were diagnosed as GDM only by DIISI. So, it can be said that DIISI is missing 64.2% of the GDM diagnosed by Modified C and C and over-diagnosing 52.3% as GDM. Considering the Modified C and C criteria as the gold standard over the years, DIISI is missing 64.2% of the patients diagnosed as GDM by Modified C and C criteria also and all the (n = 123; 100.0%) non-GDM cases diagnosed by the IADPSG were confirmed to be non-GDM by the Modified C and C criteria. So, IADPSG is over-diagnosing 22% of the patients as GDM, which is beneficial in the long-term pregnancy outcomes. A study by Katrien Benhalima et al.[12] suggested that using the IADPSG criteria, more women are identified as having GDM, and these women carry an increased risk for adverse gestational outcomes compared to the women without GDM. But more needs to be done to evaluate its long-term pregnancy and perinatal outcomes. Out of the 28 GDM diagnosed by the Modified C and C criteria, only 10 were picked up by the DIISI criteria. And according to the DIISI criteria, 21 patients were diagnosed as GDM, out of it, 11 patients were diagnosed as GDM only by DIISI. So, it can be said that DIISI is missing 64.2% of the patients diagnosed as GDM by IADPSG. Most patients are diagnosed as GDM by fasting sugar alone (23/36 in IADPSG and 18/28 by C and C), so fasting blood sugar should be used for diagnosing GDM, which is not included in DIISI. So, DIISI should not be the preferred method for diagnosing GDM. Thus, it can be said that DIISI is simpler to use, however, it is missing a number of patients, so in the centre of excellence, IADPSG or Modified C and C should be used as the gold standard. DIISI can
be used in rural areas as it is simpler, economical and convenient. Whether to use the Modified C and C or IADPSG, more studies are needed to access the perinatal and maternal outcomes, based on the diagnosis.

**Compliance with ethical standards**

Ethical approval for the study was obtained from the Institutional Ethics Committee of King George’s Medical University, Lucknow (UP). Prior to entering the study, all the participants were given a verbal presentation of information on the study, together with a written document (in Hindi and English) describing the purpose and procedures of the study.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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