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Comparison of iron status of normoglycaemic pregnant women with gestational diabetes mellitus: An observational study

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Abstract
Objective: To evaluate/examine the influence of elevated serum ferritin and serum iron as a risk factor for Gestational Diabetes Mellitus.
Study Design: The study was designed as case control study.
Study Population: Study population includes pregnant females attending the OPD and IPD department of obstetrics and gynaecology in Maharaja Agrasen Hospital, New Delhi. Minimum of 60 women fulfilling the selection criteria were selected.
Sample Size and Sample Technique: The primary objective of the study is to find the association between serum ferritin, iron and gestational diabetes mellitus. With reference to previous study 84, thus a sample size of 21 was calculated based on a difference of 100 in mean serum iron between control and study group, with a SD of 100, at two-sided alpha of 0.05, and a power of 90%.
The formula for calculated sample size is given below.
n = (σ12 + σ22. [Z 1- α/2 + Z 1- β] 2
(M1 - M2)2
= (1002 + 1002) [1.96+1.282]2 / (100)2
= (20000) (10.51) / (10000)
= 21
But we will be taking 30 patients per group.
Where
M1 = Mean of serum iron in control group.
M2 = Mean of serum iron in study group.
σ1 = SD of serum iron in control group.
σ2 = SD of serum iron in study group.
Z 1- α/2 and Z 1- β are probability of two errors
So total 60 was taken sample size 30 as case and 30 as control.
Statistical Methods
Statistical testing will be conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables will be presented as mean {plus minus} SD or median if the data is unevenly distributed. Categorical variables will be expressed as frequencies and percentages. The comparison of continuous variables between the groups will be performed using Student's t test. Nominal categorical data between the groups will be compared using Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables will be compared using Mann Whitney U test. For all statistical tests, a p value less than 0.05 will be taken to indicate a significant difference
Main Outcome, Result and Conclusion: In our study level of serum ferritin was found elevated in case group with mean +SD of122.57 {plus minus} 17.92 and p value of <0.001 and serum iron values were higher in case group with mean+SD of 104.60 {plus minus} 16.88 and $p<$ 0.001.TIBC was found to be higher in non GDM group with mean+SD of 446.37+ 43.94 vs 278.73+16.89 in GDM group with p value of <0.001and MCHC, MCH and Transferrin saturation was found to be higher with Mean {plus minus} SD of 32.03 {plus minus} 2.30,29.21 {plus minus} 1.88 and 37.15 {plus minus} 4.88 respectively. Serum ferritin, an important indicator of iron status was found higher in women with GDM.

Keywords: iron status, normoglycaemic pregnant women, gestational diabetes mellitus

Introduction
The prevalence of gestational diabetes has been reported to range from 3.8% in Kashmir, [91] to 6.2% in Mysore [92], 9.5% in Western India [93] and 17.9% in Tamil Nadu [94]. In more recent studies, using different criteria, prevalence rates as high as 35% from Punjab [95] and 41% from Lucknow have been reported [96]. The geographical differences in prevalence have been attributed to differences in age and/or socioeconomic status of pregnant women in these regions.

It is estimated that about 4 million women are affected by GDM in India, at any given time point [97].

Elevated iron stores, reflected in elevated plasma ferritin levels, may induce baseline metabolic abnormalities that ultimately result in diabetes. Alternatively, elevated ferritin may be just one of several metabolic abnormalities related to the underlying process that ultimately results in diabetes, rather than a causal factor for diabetes [1].

The present study has been conducted with the objective of determining the findings of comparison of iron status of normoglycaemic women with women of gestational diabetes mellitus. According to selection criteria, cases and controls were selected and required investigations were done to compare iron status between them.

60 patients were registered for the study out of which 30 were taken as cases means those with GDM and 30 were taken as control.

Ferritin, the major iron storage protein, provides an indirect estimate of body iron stores, and is also a positive acute-phase reactant. Low ferritin is an accurate index of iron deficiency in pregnant women.

In our study, we demonstrated an association between elevated ferritin levels in the serum of pregnant women with an increased risk for GDM. In our study level of serum ferritin was found elevated in case group with mean +SD of122.57 ± 17.92 and p value of <0.001 which was similar with the results of the study conducted by V. Soubasi *et al* in which the group of mothers with high ferritin levels was associated with a significantly higher rate of GDM (5/24) compared with the other two groups taken together (1/39) (P =0.026, Fisher's exact test). Also, there was a 2.5-fold greater risk of GMD in mothers with elevated serum ferritin (95% CI: 1.4–4.1) [98].

In study conducted by XINHUA CHEN *et al* Women in the highest quintile of serum ferritin had a twofold increased risk of developing GDM adjusted for several known risk factors (adjusted odds ratio, 2.02 [95% CI 1.04–3.92], $P< 0.05$). Similar results were obtained with a nested case-control study, in which women in the highest centile of serum ferritin (2.35 [1.06–5.22], $P< 0.05$) or CRP (2.67 [1.16–6.17], $P< 0.001$) had a greater than twofold increased risk of GDM [17].

Dietary iron is of particular interest given that iron is a strong prooxidant, and high body iron levels can damage pancreatic β-cell function and impair glucose metabolism.

In our study serum iron values were higher in case group with mean+SD of 104.60 ± 16.88 and $p< 0.001$ and same association was found in study conducted by TT Lao in which GDM was diagnosed in 97 of the 401 women recruited. Compared with the 194 controls, there was no difference in the weight, body mass index, booking and third trimester haemoglobin, or third trimester red cell indices, but concentrations of serum ferritin, iron, transferrin saturation, and the post-natal haemoglobin were significantly higher. On multiple regression analysis, maternal BMI and the log-transformed ferritin concentration remained significant determinants of the OGTT 2-h glucose value. [100]

In our cases Hb levels came out to be higher as compared to control group which is similar with the study conducted by Lao *et al* in which the group in the highest hemoglobin quartile (more than 13 g/dL) had a significantly higher incidence of GDM (18.7% versus 10.9%, P =.007) [9].

TIBC was found to be higher in non GDM group with mean+SD of 446.37+ 43.94 vs 278.73+16.89 in GDM group with p value of <0.0001 in this study which is comparable with the study conducted by Mohammad Afkhami *et al* in which The mean TIBC was 383.09±30/55 µg/dl in the GDM group and was 457.79±58.20 µg/dl in the control group (according to P=.0001) [80].

Disclosure of interest

There is no financial, political, Personal and religious conflict of interest.

Contributions from authors

DR ANANDITA – This study is done by Dr Anandita in Maharaja Agrasen hospital in New Delhi after getting approval from the ethical and scientific committee of the institution.

DR. AMIT JAITLY– helped in the statistical work of this research work, all calculations, charts, graphs and other technical work.

Ethical approval

The ethical committee of the institute approved first the protocol of study in January 2015 and then after studied was done it was taken again approval from ethical committee in November 2016.

The ethical committee was the ethical committee of Maharaja Agrsen hospital. Reference Number IS ECR/745/Inst/DL/2015

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