Original Article

Impact Of Maternal Hypothyroidism In Women With Gestational Diabetes Mellitus And Its Adverse Pregnancy Outcomes In South-Indian Population- A Prospective Study

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Abstract

Introduction: The concurrent influence of Gestational diabetes mellitus (GDM) and hypothyroidism on the incidence of hypothyroidism in GDM is not yet clearly reported. Thyroid dysfunction has been associated with adverse obstetric outcomes. However, less is known regarding subclinical hypothyroidism and its relationship to pregnancy complications.

Methods: This prospective study was conducted with a total of 300 antenatal patients with GDM according to DIPSI criteria after 24 weeks and above were subjected to thyroid function tests. Patients with normal FT3, normal FT4 and S.TSH between 3.0mIU/L -10.0 mIU/L were diagnosed as Subclinical hypothyroidism and S.TSH more than 10.0mIU/L were diagnosed as Overt hypothyroidism. These patients were followed up and both maternal-fetal outcomes were observed in GDM patients with and without hypothyroidism.

Results: In the study, 14% of GDM women developed hypothyroidism, all of which were subclinical. When compared to GDM women, patients with combined endocrinopathy were more prone for Hypertensive Disorders (HD) in pregnancy. Other foetal outcomes, such as preterm delivery (P= 0.384), RDS (P= 0.465), sepsis (P= 0.366), and jaundice in newborns (P= 0.193), and maternal outcomes included anemia (P= 0.720), abruptio placenta (0%), mode of delivery (P= 0.9), and oligohydramnios were not statistically significant.

Conclusion: The incidence of hypothyroidism in GDM patients was only 14%. The incidence of HD in Pregnancy was more in combined endocrinopathy (26.19%) compared to GDM (13.57%) (P=0.035). This indicates the increased incidence of HD in Pregnancy, which emphasizes the importance of overseeing pregnancy as HD in Pregnancy may result in significant maternal- neonatal complications.

Keywords: gestational diabetes, hypothyroidism, hypertensive disorder, maternal outcome, neonatal outcome

INTRODUCTION:

The maternal biological system will undergo significant changes at the time of pregnancy in order to maintain a healthy milieu for the growth and development of the fetus. Pregnancy, a period of altered metabolic and hormonal physiology. Typically, several alterations in thyroid function occur throughout pregnancy (1). It is widely known that the demand for thyroid hormones rises during pregnancy. Hypothyroidism during pregnancy is characterised by an elevated serum TSH level. In addition, based on free T4 levels, it is classified as either overt (lower free T4 levels) or subclinical (normal free T4 levels) hypothyroidism (2). The prevalence of hypothyroidism is estimated as 11.07% in India (3). According to American Thyroid Association, Subclinical hypothyroidism is TSH value between 4.0-5.0 mIU/L in first trimester, 3.0 mIU/L-10.0 mIU/L in second and third trimesters with normal T3 and T4 values and Overt hypothyroidism is TSH more than 10.0 mIU/L with normal T3 and T4 values (2). Adverse effects of hypothyroidism during pregnancy are compromise in the neurodevelopment of the fetus, abortions, hypertensive disorders in pregnancy, abruptio placenta, preterm delivery, low birth weight, post-partum haemorrhage and still birth (4). Hypothyroidism can have substantial implications on glucose metabolism and insulin secretion. Thyroid hormones exhibit profound effects in the regulation of glucose homeostasis by lowering insulin secretion and its synthesis by pancreatic β cells, resulting in an increase in serum blood

glucose levels (5). Recent research has demonstrated an association between hypothyroidism and gestational diabetes. As a combined condition, hypothyroidism and Gestational Diabetes Mellitus have deleterious implications on both the mother and the fetus. Gestational diabetes is defined as "any degree of glucose intolerance with onset or first recognition during pregnancy." (6) Adverse maternal outcome in GDM include polyhydramnios, preterm delivery, PPROM, recurrent UTI, vulvovaginal candidiasis. Adverse fetal and neonatal outcome include macrosomia, sudden intrauterine death, shoulder dystocia, brachial plexus damage, clavicular fracture, neonatal hypoglycemia, birth trauma, hypomagnesemia, polycythemia of newborn, diabetic cardiomyopathy, sudden infant death syndrome (7). Due to the negative outcomes associated with combined endocrinopathy, Gestational Diabetes Mellitus patients should be examined for hypothyroidism. There are currently insufficient data addressing the prevalence of hypothyroidism among Indian women with gestational diabetes.

MATERIALS AND METHODS:

Ethics:

This prospective cohort study was performed in accordance with standard guidelines and regulations. The study was approved by the Scientific and Ethics committee of the department of Obstetrics and Gynaecology, SRM Medical college, Potheri, Tamil Nadu. Written informed consent was obtained from each subject before enrolment.

Patient enrolment:

The study group consisted of antenatal women who attended Obstetrics and Gynaecology Outpatient Department of SRM Hospital at or above 24 weeks of gestation and diagnosed as Gestational Diabetes Mellitus by Diabetes in Pregnancy Study Group of India (DIPSI) criteria, in which the plasma glucose levels was evaluated after 2hrs intake of 75g oral glucose load, it was diagnosed as GDM if 2hrs plasma glucose measured ≥140 mg/dL. The participants who were diagnosed as case of GDM were subjected to Thyroid function test (TFT), the inclusion criteria were: antenatal women diagnosed as GDM by DIPSI criteria at 24 weeks of gestation and above, no goitre, no use of medicines affecting the thyroid hormone levels and TSH levels. The exclusion criteria were: Pregestational Diabetes, Pregestational Thyroid disorders, Chronic Hypertension, Multiple Pregnancies, Recurrent Miscarriages, Infertility, Previous neck or head irradiation.

Analysis of Thyroid function:

The blood samples were collected from the eligible pregnant women who consented to enrol in the study upon their visit to antenatal clinic. Serum free T3, Serum freeT4, Serum TSH was measured by chemiluminescence immunoassay and blood sugars by Hexokinase method. Patients with normal FT3, normal FT4 and S.TSH between 3.0mIU/L -10.0 mIU/L were diagnosed as Subclinical hypothyroidism and S.TSH more than 10.0mIU/L were diagnosed as Overt hypothyroidism. GDM patients with hypothyroidism were categorized as Group A and GDM patients without hypothyroidism were categorized as Group B. This subgroup of patients was followed until delivery, and both maternal - fetal outcomes were evaluated, as well as screening for congenital hypothyroidism in the babies.

Statistical analysis:

All statistical analyses were performed using SPSS-22 software. Chi-square test and Mann Whitney- test were used to assess comparison of the maternal and fetal outcomes among both groups. p-values < 0.05 were considered statistically significant.

RESULTS:

This is a prospective cohort study, which includes a total of 300 subjects. Out of 300 antenatal women with GDM, 42 patients had hypothyroidism(14%), all were subclinical.

Group A patients were GDM with hypothyroidism and Group B patients were GDM without hypothyroidism. Majority of the patients in the study group were in the age group 26-30 years. In our study,100 patients were primigravida and 200 were multigravida.(Table.1)

Table 1: Participant Demographics

Demographic characteristics	**Group A (N=42) (14%)** (GDM with Hypothyroidism)	**Group B (N=256) (86%)** (GDM without Hypothyroidism)
AGE (years)		
<20	0 (0%)	5 (1.6%)
21-25	15 (5%)	84 (28%)
26-30	15 (5%)	112 (37.3%)
31-35	9 (3%)	47 (5.6%)
>35	3 (1%)	10 (3.3%)
GRAVIDA		
Primigravida	10 (3.33%)	90 (30%)
Multigravida	32 (10.6%)	168 (56%)

In GDM patients with hypothyroidism, the incidence of anemia is 11.9%, whereas it is 13.95% without hypothyroidism which is not statistically significant. The incidence of Preeclampsia is greater (26.19%) with hypothyroidism than without hypothyroidism (13.57%). The association of Hypertensive disorders in pregnancy with combined endocrinopathy was statistically significant. (P value-0.035). There was no oligohydramnios in the study group. There was no single case of Abruptio placenta in both groups. (Table.2)

Table 2: Comparison Of Maternal Outcome Among Both Groups (N=300)

	Group A (N=42)		Group B (N=258)		Chi square	P-value
Parameter	Yes	No	Yes	No		
Anaemia	5 (11.9%)	37 (88.1%)	36 (13.95%)	222 (86.05%)	0.128	0.720
Preeclampsia	11 (26.19%)	31 (73.81%)	35 (13.57%)	223 (86.43%)	4.434	0.035
Oligohydramnios	0	42 (100%)	5 (1.94%)	253 (98.06%)		
Mode of delivery						
LSCS	28 (66.67%)		171 (66.28%)		0.014	0.905
Natural labour	14 (33.33%)		82 (31.78%)			
Ventouse	0		4 (1.55%)			
Outlet forceps	0		1 (0.39%)			

In GDM patients with Hypothyroidism,28 (66.67%) patients underwent LSCS, whereas in patients without hypothyroidism it was 171(66.28%). Patients who delivered vaginally were 14(33.3%) and 87(33.72%) in the hypothyroidism group and without hypothyroidism respectively. (Table.2). P value being 0.905 was not statistically significant.

Table. 3 Comparisons Of Fetal Outcome Among Both The Sub Groups.

Parameter	Group A(N=42)	Group B(N=258)	Chi Square	P Value
Term	37 (88.1%)	237 (91.86%)	0.647	0.384
Preterm	5 (11.9%)	21 (8.14%)		
Birth weight				
<1.5 kg	0	0	4.03	0.133
1.5 to 2.5 kg	11	23		
2.5 to 3.5kg	28	206		
>3.5 kg	3	29		
RDS	6 (14.29%)	49 (18.99%)	0.534	0.465
Jaundice	2 (4.76%)	32 (12.4%)	2.099	0.193
Sepsis	2 (4.76%)	7 (2.71%)	0.521	0.366

Fetal outcome measures like Preterm delivery, Low birth weight, Respiratory distress syndrome, Neonatal jaundice and sepsis in the study group were not statistically significant. (Table.3)

DISCUSSION:

In India, the incidence of hypothyroidism in pregnancy was much higher compared to western countries. The incidence of hypothyroidism in GDM patients in this current study was 14%. **Mahmoud Parham et al** (8) study showed that the prevalence of hypothyroidism in GDM patients was 27.5% which was higher when compared to our study. Hypothyroidism because of profound effect on glucose metabolism and insulin secretion, the resulting insulin resistance, glucose intolerance and dyslipidaemia were usually reversible when normal thyroid levels were restored.

The mean TSH value in our study was 2.57 ± 1.79. According to **Lakshman et al** (9), in GDM patients, mean TSH value was in the range of 0.10-26.0 with mean 5.34. **Parham et al** (8) study showed, mean TSH level of 3.43+/-2.06.

In this study, the incidence of anemia in Group A (GDM and Hypothyroidism) was 5 (11.9%) and in group B (GDM without hypothyroidism) was 36 (13.95%) (P value=0.720), (Table 1) the incidence of anemia in Group A was not statistically significant. In a study conducted by **Agarwal U et al** (10), incidence of anemia in hypothyroidism was 19.09%. It had been suggested that nutritional deficiencies were more common in hypothyroidism, the most recognised was iron deficiency.

In the present study, incidence of Hypertensive Disorders in Pregnancy in Group A was found to be 11 (26.19%) and in Group B, it was 35(13.57%) (p value 0.035). (Table 2) In **Amida Shukla et al** (11) study, incidence of HDP in GDM was 18%, whereas in **Ismail et al** (12) study, incidence of HDP in GDM was 2.6%. **Sreelatha S et al** (13) study showed the incidence of HDP in Hypothyroidism was 14.7%. These results may suggest that these two endocrinopathies, which modify an effect of one another, and were influenced by metabolic processes, might have an additive influence on the risk to develop hypertensive disorders during pregnancy. It was a well-known fact that the presence of hypothyroidism might enhance the risk for Hypertensive disorders of pregnancy. The same fact was reflected in our study as well.

In present study, the incidence of abruption was NIL in both the sub groups. This may be due to thyroxine supplementation given in the antenatal period. According to **Saraladevi et al** (14), the incidence of Abruptio placenta was 1.56% with hypothyroid mothers. The increase incidence of Abruption in hypothyroidism is mainly due to hypertensive disorders and defective placentation. There was no case of placental abruption in our study though we had 39.76% of hypertension cases.

In our study, there was no oligohydramnios in Group A, where as it was 5/258 (1.94%) in Group B. In **Sreelatha S et al** (13) study in hypothyroid mothers, oligohydramnios was 16.67%. Oligohydramnios in GDM is rare unless there was coexisting hypertensive disorder or vascular disorder. Oligohydramnios in Group B in our study was due to preeclampsia. Since HDP causes oligohydramnios, patients with GDM & hypothyroidism are prone for HDP and hence oligohydramnios.

Incidence of C-section in the current study in Group A was 66.67% and in Group B was 66.28%. In group A, 14 (33.33%) mothers had normal vaginal delivery. In group B, 87 (33.72%) patients delivered vaginally, out of which 4(1.55%) and 1(0.39%) required ventouse and forceps respectively. Therefore, it was not statistically significant. (P value 0.905)(Table 3). In study done by **Thiruvikrama et al** (15), in GDM mothers, 44% required cesarean section and 56% (74) delivered vaginally, of which 9% (7) required forceps assistance. **Ameya et al** (16) had shown that 52%of GDM mothers underwent LSCS,46% delivered vaginally and 2% was vacuum assisted delivery. In a study conducted by **Amidha shukla et al**(11)**,** caesarean section was 40% and vaginal delivery was 60 % in GDM mothers. According to **Sreelatha S et al** (13) study, in pregnant women with hypothyroid disorders, incidence of LSCS was 22.9%. In another study conducted by **George M et al** (17) it was 20% and in **Sangitha et al** (18) it was 16.6%. The increased incidence of caesarean section in GDM patients may be due to macrosomia caused by Gestational Diabetes.

In our study, incidence of preterm delivery in Group A was 11.9% (5/42 mothers) where as in Group B was 8.14% (21/258), statistically not significant. (P value-0.384) (Table 3) In a study conducted by **Thomas N et al** (19) at CMC Vellore in GDM mothers, the incidence of preterm deliveries was 15.8%. **Amida et al** (11) study on maternal and fetal outcome in GDM, preterm labor was seen in 12% of patients. In **SreeLatha S et al** (13) study, preterm labor in hypothyroidism was 3.1%, in **Sangitha et al** (18) it was 11.2%. GDM and Hypothyroidism are independent risk factors for preterm labour. As a combined endocrinopathy, the risk is even more. Preterm labour in GDM is due to infections, over distension secondary to polyhydramnios and macrosomia and iatrogenic preterm delivery due to HDP. Preterm labour in Hypothyroidism may be due to defective placentation and iatrogenic premature delivery due to Preeclampsia.

In our study, incidence of RDS in newborn was 49/258(18.99 %) in babies born to Group B mothers and 6/42 (14.29%) in Group A mothers (Table 3). It was not statistically significant (P value 0.465). The incidence of preterm babies in RDS in our study was 19 in babies of Group B and 2 in Group A. In the study **Thiruvikrama et al** (15) , RDS was seen in 11% of babies born to GDM mothers. In **Shukla et al** (11) study in GDM mothers, RDS was 1/50 (2%), In **Ameya et al** (16)**,** study in GDM mothers RDS was 12%, The RDS in babies born to the patients in our study group may be due to preterm babies delivered and also due to delayed lung maturity in babies born to GDM mothers.

In our study Jaundice was seen in 32/258 (12.4 %) babies born to Group B, and 2/42 (4.76 %) in Group A (Table 3), which was not statistically significant (P value 0.193). In a study done by **SreeLatha S et al** (13) et al, babies of Hypothyroid mothers showed jaundice in 9.4%, whereas in **George M et al** (17) it was 8%, In babies born to GDM mothers, Neonatal jaundice in **Ameya et al** (16) study was 10%. Hyperbilirubinemia in GDM is due to hypoxemia, which

results in polycythemia. Lysis of these RBCs leads to neonatal hyperbilirubinemia. Hypothyroidism causes decreased rate of bilirubin conjugation, slows gut motility and impairs feeding, all contributing to jaundice.

In our study, neonatal sepsis was 7/258 (2.71 %) in Group B and 2/42 (4.76%) in Group A. (Table 3). It was not statistically significant. Only one preterm baby had sepsis in Group B. There was none in Group A. In a study done by **Ameya et al** (16) in GDM mothers showed sepsis in 4% babies. In Elahe Mesdhaghinia et al, study, incidence of sepsis was 3.5%. According to **Ajmani et al** (20) incidence of neonatal sepsis was 2.7% in hypothyroid mothers. Sepsis in newborns of GDM mothers may be due to PROM and Preterm deliveries.

Present study showed no babies with neonatal hypothyroidism in both the sub groups. A study conducted by **SreeLatha S et al** (13) showed in hypothyroid mothers also showed no neonatal hypothyroidism. This may be due to adequate replacement in antenatal mothers and all the patients in the study had only subclinical hypothyroidism.

In our study, 7 % babies born to Group A and 11.2% of babies born to Group B were more than 3. 5kgs.Incidence of VLBW (<1.5 kg) was nil in both the groups. Low birth weight (1.5kg -2.5 kg) in Group A was 26% whereas in group B was 8.91% (Table 3). In **Makhwana et al** (21) study, incidence of LBW was 7.89%. In a study conducted by **SreeLatha S et al** (13) in hypothyroid mothers, LBW was 21.9%. **Hareesh MV et al** (22) was 16.32%, **Sangitha A et al** (18) was 25%. In study by **Ameya et al** (16) more than 3.5kg was 40%, less than 2.5 kg was 20% and in **Amidah et al** (11) study, less than 2.5 kg was 18%, macrosomia was 14 %. There was increased incidence of LBW in combined disorder in our study. LBW in GDM is rare unless there is coexistent HDP & vasculopathy. Hypothyroidism can cause LBW due to Hypertensive disorders and uteroplacental insufficiency secondary to defective placental implantation.

Limitations and strength of the study:

GDM patients in the study group were screened at 24 weeks of gestation and above. Early screening of Hypothyroidism in the first trimester was not done.

The incidence of hypothyroidism in GDM patients was only 14%. This may be due to smaller sample size. So, further large cohort studies are required. Most of the adverse maternal and perinatal outcomes have not surfaced as the patients were on thyroxine supplementation. Early screening and supplementation with thyroxine would have prevented the complication like Hypertensive Disorder of Pregnancy caused by defective implantation. In spite of these limitations, the strength of this study was its homogeneity as it was a single hospital study.

CONCLUSION:

In this study, the incidence of hypothyroidism in GDM patients was only 14% which was less when compared to other past studies. This may be due to smaller sample size. So, further large cohort studies are required to prove the association between the two endocrinopathies. The incidence of Hypertensive Disorder in Pregnancy was more in combined endocrinopathy (26.19%) when compared to GDM alone (13.57%) (P=0.035). This indicates the increased incidence of Hypertension Disorder in Pregnancy, which emphasizes the importance of managing the pregnancy with extra care as Hypertensive disorders in Pregnancy may result in significant maternal and neonatal complications. According to this study, the incidence of preterm delivery was high in combined endocrinopathy, though not statistically significant (P=0.384).

The incidence of anemia (P-0.720), abruption, oligohydramnios, mode of delivery (P-0.905) and newborn complications like preterm birth (P-0.384), respiratory distress syndrome (P-0.465), jaundice (P-0.193), sepsis (0.366) and birth weight (P-0.133) were not statistically significant in the study group.

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ABBREVIATION:

GDM Gestational diabetes mellitus
HD Hypertensive Disorders
FT4 free T4 levels
TSH Thyroid stimulating hormone
TFT Thyroid function test