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**Original Research Article**

# Comparing the fetal and maternal outcomes of dual endocrinopathy with that of isolated gestational diabetes mellitus and hypothyroidism in Indian pregnant women

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## ABSTRACT

**Background:** Both diabetes mellitus and hypothyroidism are known to cause adverse effects for mother and fetus, however, their combined effect has not been adequately studied in the Indian context. This study aimed to fill that gap.
**Methods:** A prospective cohort study was conducted with three groups. Group 1 consisted of mothers diagnosed with gestational diabetes mellitus only (n=61), group 2 consisted of hypothyroidism only (n=55) and group 3 consisted of pregnant patients diagnosed with both gestational diabetes mellitus and hypothyroidism (n=35). These three groups were followed up from the time of diagnosis, for up to one week following delivery. The maternal outcomes assessed include premature rupture of membranes, preterm labour and preeclampsia. Fetal outcomes include APGAR scores at 1 minute and 5 minutes, NICU admission and birth weight.
**Results:** Amongst the three groups, mothers with gestational diabetes mellitus had the highest birth weights of babies (2.99±0.61 kg), followed by dual endocrinopathy group (2.44±0.76 kg) , and lastly, by hypothyroidism group (2.22±0.71 kg). Other outcomes did not have any significant association with type of endocrinopathy.
**Conclusions:** Pregnant patients diagnosed with hypothyroidism alone have chances of having babies who are small for gestational age whereas the other two groups are likely to have large for gestational age babies. Further studies are required to confirm this finding.

**Keywords:** Dual endocrinopathy, Gestational diabetes mellitus, Hypothyroidism, Pregnancy outcome

## INTRODUCTION

In this study, the term dual endocrinopathy is used to refer to the simultaneous occurrence of gestational diabetes mellitus (GDM) and hypothyroidism in pregnant patients. Diabetes mellitus and hypothyroidism are common disorders found in pregnant patients in India. These conditions are especially aggravated when the affected patient is a pregnant woman. It may lead to several complications in pregnancy, in labour, and in postnatal period to the mother. It may also lead to several adverse fetal outcomes.[1]

Around 1-14% of all pregnancies in India are complicated by diabetes out of which 90% are GDM.[2] Around 11% of pregnancies in India are complicated by hypothyroidism.[3] Conditions like pre-eclampsia, anemia, intrauterine fetal death are common in hypothyroid mothers, whereas conditions like fetal macrosomia, birth injuries, preterm birth, polyhydramnios, genitourinary infections etc. are common in mothers with GDM.[1,2,4,5] Autoimmune diseases like insulin dependent diabetes and hypothyroidism are more common in pregnant patients, compared to the general population.[1] Review of literature suggests that occurrence of pre-eclampsia is significantly

higher in mothers with dual endocrinopathy, than in those with isolated gestational diabetes mellitus or hypothyroidism.[6]

Literature on the impact of dual endocrinopathy on fetal and maternal health is lacking in the Indian context in recent years. This study aimed to fill this gap.

By determining the outcomes of dual endocrinopathy in Indian pregnant patients, effective management procedures can be established to prevent adverse outcomes and mothers can be counselled regarding methods to alleviate such outcomes and their prevention in future pregnancies. Hence, determining the maternal and fetal outcomes of the combination of GDM and hypothyroidism is of utmost importance to ensure effective maternal and child healthcare.

## METHODS

### *Place*

OPD and IPD of the department of obstetrics and gynecology, Vani Vilas Hospital, BMCRI.

### *Study design*

It was a prospective cohort study.

### *Duration*

The study took place from October 2023 to August 2024.

### *Inclusion criteria*

Pregnant patients willing to provide informed consent. Age 19 to 40 years. Pregnant patients diagnosed with either gestational diabetes mellitus, hypothyroidism, or combination of the two, who are at least 24 weeks into gestation, in labour or who have delivered up to 1 week prior. Singleton pregnancies.

### *Exclusion criteria*

Pregnant patients who are either diagnosed with the following chronic diseases or those who have the following pre-existing conditions: gestational diabetes mellitus diagnosed in first trimester, chronic hypertension, chronic liver diseases, epilepsy, chronic renal diseases, chronic cardiac diseases. Pregnant patients diagnosed with hyperthyroidism. Pregnant patients with pre-existing diabetes mellitus before conception.

### *Methodology*

After obtaining approval and clearance from the institutional ethics committee of Bangalore Medical College and Research Institute, the patients fulfilling the inclusion criteria were enrolled for the study after obtaining informed consent. Candidates were chosen if they were in any of the following stages of gestation/labour: more than 24 weeks into gestation, in labour, Up to 1 week postnatal period.

They were selected if they were diagnosed with any of the following conditions at anytime during their gestation, based on the given criteria:

Gestational diabetes mellitus (as per DIPSI guidelines). 75 gm glucose was given orally in 300 ml water, irrespective of fasting state, and random blood sugar was estimated after 2 hours of ingestion of this liquid. Value above 140 mg/dl were considered as diagnostic of gestational diabetes mellitus.[7]

Hypothyroidism (as per ATA guidelines):[8] Normal- I) 1$^{st}$ trimester: 0.1-2.5 mIU/l, II) 2$^{nd}$ trimester: 0.2-3 mIU/l, III) 3$^{rd}$ trimester: 0.3-3 mIU/l. Hypothyroidism: TSH>2.5-3 mIU/l with low FT4 (OR) TSH>10 mIU/l irrespective of FT4).[9] A combination of the above two.

The subjects selected based on the above criteria were divided into 3 groups: Group 1 (n=61): pregnant patients diagnosed with only gestational diabetes mellitus. Group 2 (n=55): pregnant patients diagnosed with only hypothyroidism. Group 3 (n=35): pregnant patients diagnosed with dual endocrinopathy, a combination of gestational diabetes mellitus and hypothyroidism.

These 3 groups were followed upto 1 week after delivery, from the time of diagnosis and their corresponding maternal and fetal outcomes were observed. Any subject who did not deliver at Vani Vilas Hospital was excluded from the study.

### *Outcome measures*

Maternal outcomes: premature rupture of membranes (PROM), preterm labour, pre-eclampsia. Fetal outcomes: APGAR score at 1 minute and 5 minutes, birth weight, NICU admission.

## RESULTS

Out of 151 patients who were included in the study, group 1 included 61 patients (40.4%) diagnosed with gestational diabetes mellitus alone. Group 2 included 55 patients (36.4%) with hypothyroidism alone and group 3 included 35 patients (23.2%) with both gestational diabetes mellitus and hypothyroidism.

Of the outcome measures studied, birth weight was found to be significantly different between the three groups ($p<0.001$). Babies born to mothers with gestational diabetes mellitus (GDM) have higher birth weights on average compared to those born to mothers with dual endocrinopathy or hypothyroidism.

**Table 1: Maternal characteristics.**

| | Group 1 (gestational diabetes mellitus) | Group 2 (hypothyroidism) | Group 3 (dual endocrinopathy) |
|---|---|---|---|
| **Age of mother in years (mean±SD)** | 27.6±4.8 | 26.1±4.3 | 27.3±3.9 |
| **>3 Pregnancies** | 40.9% | 30.9% | 31.4% |
| **History of spontaneous abortions** | 27.9% | 36.4% | 37.1% |

**Table 2: Outcome measures observed.**

| | Gestational diabetes mellitus n=61 | Hypothyroidism n=55 | Dual endocrinopathy n=35 | |
|---|---|---|---|---|
| **PROM** | 17.3% (10/61) | 13.33% (7/55) | 5.7% (2/35) | p>0.05 |
| **Preterm birth** | 34.6% (21/61) | 39.1% (21/55) | 47.8% (17/35) | p>0.05 |
| **Preeclampsia** | 21.1% (13/61) | 36.96% (20/55) | 26.09% (9/35) | p>0.05 |
| **Intrauterine fetal demise** | 9.8% (6/61) | 4.44% (2/55) | 17.39% (6/35) | p>0.05 |
| **APGAR score at 1 min** | 7 | 7 | 7 | p>0.05 |
| **APGAR score at 5 min** | 8 | 8 | 8 | p>0.05 |
| **Mean Birth weight** | 2.99 kg | 2.44 kg | 2.22 kg | p<0.001 |
| **NICU admission** | 43.13% (26/61) | 51.1% (28/55) | 50% (17/35) | p>0.05 |

Group 1 had the highest mean birth weight of (2.99±0.61) kg, followed by group 3, with (2.44±0.76) kg and group 2 had the least birth weight of (2.22±0.71) kg.

On comparing dual endocrinopathy and GDM, it was noted that there was a mean difference of −0.553 kg (p<0.001). This means that the birth weight in the dual endocrinopathy group was, on average, 0.553 kg lower than that in the gestational DM group. In other words, gestational DM has a higher mean birth weight.

On comparing GDM and hypothyroidism a mean difference of 0.771 kg is found (p<0.001). This indicates that the gestational DM group has a mean birth weight that was 0.771 kg higher than that of the hypothyroidism group.

On comparing dual endocrinopathy and hypothyroidism, a mean difference of 0.218 (p=0.323) was found. Here, the dual endocrinopathy group appears slightly higher than the hypothyroidism group, but the difference was not statistically significant.

Group 1 demonstrated an intrauterine fetal demise rate of 9.8% (6/61), while group 2 had a lower incidence at 4.44% (2/55). In contrast, group 3 showed the highest rate of IUFD, with 17.39% (6/35) of cases resulting in fetal demise. This observation had a borderline statistical significance with a p value of 0.06, slightly above the conventional threshold.

In this study, newborns born to mothers with both GDM and hypothyroidism had APGAR scores at both the one-minute and five-minute marks that were comparable to those of infants whose mothers had only one of these conditions.

Additionally, the rate of premature rupture of membranes (PROM) was highest in the gestational diabetes mellitus group (17.3%), but did not show a statistically significant association with type of endocrinopathy. Preterm labor was highest in dual endocrinopathy (47.8%) but did not significantly differ among the groups, implying that the dual diagnosis did not contribute to a higher risk of these obstetric complications.

Similarly, the incidence of pre-eclampsia remained consistent across all study populations, with no meaningful variation linked to the presence of both conditions together. Finally, newborn admission to the neonatal intensive care unit (NICU) was found to occur at similar rates regardless of whether the mother had both GDM and hypothyroidism or just one of these conditions.

## DISCUSSION

This study found that babies born to patients diagnosed with dual endocrinopathy or isolated hypothyroidism have a low mean birth weight, thus predisposing them to complications such as hypothermia, hypoglycemia, birth asphyxia, etc all of which contribute to an elevated perinatal and neonatal mortality, while, those patients diagnosed with gestational diabetes mellitus gave birth to babies of higher mean birth weights, leading to complications such as shoulder dystocia, perineal trauma, obstetric brachial plexus injury, etc.[9,10]

The findings of Tirosh et al suggest smaller differences in the mean birth weights between the three groups, but agree with gestational diabetes mellitus being the group with the highest birth weights, followed by dual endocrinopathy and lastly, hypothyroidism.[1] Amudha et al reported a similar rate of fetal macrosomia in gestational diabetes mellitus and dual endocrinopathy groups.[11]

This study found a correlation of borderline significance in the difference between rates of intrauterine fetal demise amongst the three groups, with dual endocrinopathy being the highest. Sahu et al and Haddow et al found a significant association between hypothyroidism and intrauterine fetal demise, while the findings of Tirosh et al suggest no significant association between the three groups.[1,12,13]

Here, the influence of hypothyroidism in adding to the risk of intrauterine fetal demise is not very certain as patients diagnosed with hypothyroidism have well controlled disease and most patients suffer from subclinical hypothyroidism.[14]

These inconsistent findings suggest the requirement of further studies with large sample sizes and accounting for various possible confounding factors such as maternal age, existence of other comorbidities, access to healthcare, socioeconomic status etc. in order to arrive at a reliable conclusion regarding the effect of endocrinopathy on intrauterine fetal demise.

There was no significant difference in the rates of NICU admission among the three groups in this study, which aligns with findings from previous research by Amudha et al.[11] This suggests that NICU admission rates may not be strongly influenced by these variables. These findings contribute to the growing body of literature indicating that NICU admissions may be more dependent on broader clinical, patient-related and hospital care related factors, and in several cases, cannot be attributed to a specific set of causes or interventions, as substantiated by Kathryn et al.[15]

Our study showed no statistically significant difference in the occurrence of PROM across the three groups. Tirosh et al found higher rates of PROM in the hypothyroidism group.[1] This is corroborated by Zhuo et al, who found increased rates of preterm premature rupture of membranes in isolated maternal hypothyroxinemia, while Wakwoya found increased rates of PROM in women with gestational diabetes mellitus, which was not seen in the study conducted by Tirosh et al.[1,16,17] This may be attributed to the fact that PROM is influenced by a far wider range of socio-cultural and clinical factors including socio-economic status, cervical manipulation, urogenital infections, malpresentation, coitus in late pregnancy, polyhydramnios, smoking, etc. as concluded by Choudary et al.[18] Further large scale studies which account for such confounding factors are necessary in order to firmly establish the risk, or the lack thereof, of PROM in dual endocrinopathies.

Both Tirosh et al and Amudha et al documented a significantly higher risk of preterm delivery in the dual endocrinopathy group, which was not observed in the current study.[1,11] Furthermore, the rates of preterm birth in all the 3 groups was found to be much higher in this study, compared to those of Tirosh et al and Amudha et al.[1,11] This can be attributed to the high prevalence of anemia in women both during pregnancy and prior to conception and relatively low adherence to prophylactic anti-anemic therapy during pregnancy which independently increase the risk of preterm delivery in all three groups.[2,19-21] Thus, studies with longer duration of follow up, preferably accounting for pre-pregnancy anemic status in the Indian context are essential to clarify the effect of dual endocrinopathies on preterm delivery.

In the current study, recruitment was done both in pregnancy, labour and in postnatal period. Restricting the recruitment of participants to only pregnant women may throw light on this matter.

Thyroid function tests suggestive of hypothyroidism are significantly associated with increased rates of preeclampsia, similarly, pregnant women diagnosed with gestational diabetes mellitus also have a higher chance of diagnosed with preeclampsia compared to the general population.[22,23] Both Tirosh et al and Amudha et al conclude that pregnant women diagnosed with dual endocrinopathy have higher rates of preeclampsia than isolated gestational diabetes mellitus and hypothyroidism.[1,11]

However, this study found that there was no statistically significant association between type of endocrinopathy and occurrence of preeclampsia, although all three groups were generally at a higher risk compared to the general population. This is most likely a result of the fact that several socio-economic risk factors such as age, residence, family history of diabetes mellitus, the past history of diabetes mellitus in the participant, history of ANC follow up during previous pregnancy and parity were significantly associated with preeclampsia.[24] Therefore, more meticulous studies which stratify patients based on these factors must be conducted in order to firmly establish the association between preeclampsia and type of endocrinopathy.

Yeagle et al found no statistically significant difference between AGPAR scores at 1 minute and 5 minutes between mothers with gestational diabetes mellitus and those without any comorbidity.[25] Hamm et al found no risk of poor APGAR score in neonates born to mothers with isolated hypothyroxinemia, while Tirosh et al found higher rates of poor APGAR scores at 5 minutes(<7) in healthy women, compared to dual endocrinopathy.[1,26] This illustrates the fact that APGAR scores are not associated with type of endocrinopathy, a finding noted in this study. Hence, they cannot be used for reliably assessing neonatal well-being in mothers diagnosed with either gestational diabetes mellitus or hypothyroidism or both.

There is a need for further research in order to improve understanding of this topic, especially in the Indian context. Prospects of this study include data collection of a larger scale across multiple centers and larger sample size. The major drawbacks of this study include the relatively short duration of follow up and a lack of

comparison between treated and untreated patients, between subclinical and overt hypothyroidism, and between various treatment modalities. The fact that gestational diabetes mellitus predisposes to higher birth weight is well known. In our patients, hypothyroidism was well controlled, hence the influence of uncontrolled hypothyroidism is not clear. Comparison with normal women also has not been made.

## CONCLUSION

In conclusion, this study highlighted the need for early diagnosis, adoption of screening measures and prompt management of endocrinopathies in pregnancy in order to ensure adequate fetal and maternal health.

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