E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.02.584

Original Research Article

Fetomaternal Outcome in Mothers with Subclinical Hypothyroidism: A Comparative Analytical Cohort Study

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05-07-2026 Revised: 28-07-2026 Accepted: 14-09-2026 Published: 19-09-2026

ABSTRACT

Background: Thyroid dysfunction is the second most common endocrine disorder among women of reproductive age. SCH (Subclinical Hypothyroidism), characterized by elevated TSH (Thyroid-Stimulating Hormone) levels with normal FT4 (Free Thyroxine), has been associated with adverse maternal and fetal outcomes. Early identification and management during pregnancy may help improve pregnancy outcomes.

Methods: A comparative analytical cohort study was conducted in the Department of Obstetrics and Gynaecology, R.G. Kar Medical College and Hospital, from March 2023 to February 2024. Pregnant women diagnosed with subclinical hypothyroidism were compared with euthyroid pregnant women. Maternal outcomes, fetal outcomes, mode of delivery, thyroid function parameters, and neonatal outcomes were analyzed. Statistical analysis was performed to determine significant differences between the study and control groups.

Results: A total of 302 pregnant women were included in the study. Caesarean section was performed in 40.0% of SCH cases and 31.7% of controls. The mean TSH level was significantly higher in the SCH group (4.23±1.12 mIU/L) compared with controls (1.45±0.47 mIU/L; $p<0.0001$), whereas FT4 levels did not differ significantly. Gestational hypertension, premature rupture of membranes, and intrauterine growth restriction were significantly more common among mothers with SCH. The mean gestational age at delivery and mean birth weight were significantly lower in the SCH group than in controls.

Conclusion: Subclinical hypothyroidism during pregnancy is associated with an increased risk of adverse maternal and fetal outcomes, including gestational hypertension, PROM, IUGR, lower birth weight, and earlier delivery. Early screening, timely diagnosis, and appropriate management of SCH may reduce these complications and improve fetomaternal outcomes. Further large-scale prospective studies are recommended.

Keywords: Subclinical Hypothyroidism, Pregnancy, Fetomaternal Outcome, Thyroid Dysfunction, Gestational Hypertension, Intrauterine Growth Restriction, Premature Rupture of Membranes, Low Birth Weight.

INTRODUCTION

Thyroid hormones play a vital role in energy production, regulation of body temperature, and normal growth and development throughout life.[1-2] Hypothyroidism is one of the most common endocrine disorders

affecting women of reproductive age, making it a significant concern during pregnancy.[3] It can be classified as overt hypothyroidism or SCH (Subclinical Hypothyroidism). Overt hypothyroidism is characterized by elevated TSH (Thyroid-Stimulating Hormone) levels greater than 10 mIU/L with reduced FT4 (Free Thyroxine) levels, whereas SCH is defined by elevated TSH levels above the reference range despite normal FT4 levels.

Maternal thyroid function is particularly important during early pregnancy because the developing fetus depends almost entirely on maternal thyroid hormones until approximately 12–14 weeks of gestation. Adequate maternal thyroid hormone levels are essential for fetal brain and nervous system development. Deficiency during the first trimester has been associated with adverse neurodevelopmental outcomes, including reduced intelligence quotient (IQ), cognitive delay, and impaired psychomotor development in children.[4] Triiodothyronine also regulates key enzymes involved in nervous system maturation during later stages of fetal development.

Untreated maternal hypothyroidism has been linked to several adverse maternal and fetal outcomes, including miscarriage, pre-eclampsia, preterm birth, stillbirth, and placental complications.[5] Subclinical hypothyroidism, despite affecting approximately 2–3% of pregnancies, often remains undiagnosed because many affected women are asymptomatic. Previous studies have also associated SCH with GDM (Gestational Diabetes Mellitus), placental abruption, and an increased risk of stillbirth in subsequent pregnancies.[5]

Although the clinical significance of SCH during pregnancy is well recognized, there remains no universal consensus regarding routine thyroid function screening and treatment. Current recommendations from the American College of Obstetricians and Gynecologists and the Endocrine Society advocate targeted screening for women with symptoms or known risk factors for thyroid disease.

Aims and Objectives

The study aimed to evaluate the effects of subclinical hypothyroidism on maternal and perinatal outcomes during pregnancy. The study also aims to estimate the prevalence of gestational hypertension and pre-eclampsia among pregnant women with subclinical hypothyroidism, assess the role of thyroid function testing in improving maternal and perinatal outcomes through early detection and management, and evaluate the potential role of thyroxine supplementation in influencing pregnancy outcomes among women diagnosed with subclinical hypothyroidism.

MATERIALS AND METHODS

Study Design

This hospital-based comparative analytical cohort study was conducted at R.G. Kar Medical College and Hospital over a period of one year, from March 2023 to February 2024.

Inclusion and Exclusion Criteria

The study included pregnant women aged more than 18 years who attended the OPD (Out-Patient Department) during the first trimester of pregnancy, were subsequently delivered in the same hospital, and fulfilled the study eligibility criteria. Women were excluded if they had overt thyroid disorder, a previous or current history of treatment with thyroxine or anti-thyroid drugs, any other autoimmune disease, congenital heart disease, or elevated serum transaminase or creatinine levels beyond the reference ranges (glutamic-pyruvic transaminase: 0–55 IU/L, glutamic oxalacetic transaminase: 6–60 IU/L, and serum creatinine: 40–106 µmol/L).

Sample Size Calculation

In this study unit during a single antenatal OPD, the number of patients in their first trimester visiting for the first time was 15. So during the 6-month data collection period, 360 patients got enrolled, among whom 58 patients were excluded according to exclusion criteria (overt hypothyroidism = 2.74%, autoimmune disease 0.9%, congenital heart disease 4.3%, elevated creatinine or transaminase level 3%, and lost to follow-up in 5% cases). Then we have considered (360-58) 302 patients for our study. Among these 302 patients, the patients whose serum TSH level (> 2.5 mIU/ml and < 10 mIU/ml) which means the patients who meet the criteria of subclinical hypothyroidism, were considered as cases. The same number of patients among these 302 were considered as controls.

Data Collection Procedure

Data were collected prospectively from eligible pregnant women during their first-trimester visit to the OPD using a predesigned case

proforma. Information regarding maternal age, educational status, parity, blood pressure, blood sugar levels, general and obstetrical examination findings, and pregnancy-related details was obtained through detailed history taking, clinical examination, and review of case records. Participants were followed until delivery, and data on gestational age at delivery, mode of delivery, neonatal birth weight, admission to the SNCU (Special Newborn Care Unit), and neonatal morbidity and mortality were recorded. Laboratory investigations, including serum TSH, FT3, FT4, complete haemogram, fasting and postprandial blood sugar, ultrasonography (TVS/TAS), and other clinically indicated tests, were performed as required.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using SPSS version 27.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequency and percentage. Statistical tests, including the paired t-test, Chi-square test, and Fisher's exact test, were used for comparison of variables as applicable. A p-value of ≤0.05 was considered statistically significant.

RESULTS

Variable	Category	Frequency (n)	Percent (%)
Group	Case	15	5.0
	Control	287	95.0
	Total	**302**	**100.0**
Age (in years)	≤ 20	30	9.9
	21–30	210	69.5
	31–40	62	20.5
	Total	**302**	**100.0**
Educational Level	College	120	39.7
	Middle School	115	38.1
	Primary School	67	22.2
	Total	**302**	**100.0**
Parity	P0+0	187	61.9
	P0+1	15	5.0
	P0+3	2	0.7
	P0+4	3	1.0
	P1+0	43	14.2
	P1+1	15	5.0
	P1+2	1	0.3
	P2+0	14	4.6
	P3+0	10	3.3
	P3+2	6	2.0
	P4+0	6	2.0
	Total	**302**	**100.0**
Mode of Delivery	Caesarean Section	97	32.1
	Vaginal Delivery	205	67.9
	Total	**302**	**100.0**

Table 1. Baseline Demographic and Obstetric Characteristics of the Study Population (N = 302)

Table 1 illustrates the baseline demographic and obstetric profile of the 302 women enrolled in the study, of whom 15 (5.0%) formed the case group (subclinical hypothyroidism) and 287 (95.0%) formed the Control group. Most participants (69.5%) were aged 21–30 years, and the majority were college (39.7%) or middle school (38.1%) educated. Nulliparity (P0+0, 61.9%) was the commonest parity category, and vaginal delivery (67.9%) occurred more often than Caesarean section (32.1%) in the cohort overall.

Variable	Category	Case n (%)	Control n (%)	χ^2 (df), p-value / OR (95% CI)
Age Group	≤ 20	2 (13.3)	28 (9.8)	χ^2=0.6145, df=2 p=0.7355
	21–30	11 (73.3)	199 (69.3)	
	31–40	2 (13.3)	60 (20.9)	
Educational Level	College	7 (46.7)	113 (39.4)	χ^2=0.7636, df=2 p=0.6826
	Middle School	6 (40.0)	109 (38.0)	
	Primary School	2 (13.3)	65 (22.6)	
Parity	P0+0	8 (53.3)	179 (62.3)	χ^2=17.6039, df=11 p=0.0912
	P0+1 – P1+2 (combined)	4 (26.7)	72 (25.1)	
	P2+0 – P4+0 (combined)	0 (0.0)	36 (12.5)	
Mode of Delivery	Caesarean Section	6 (40.0)	91 (31.7)	χ^2=0.4496, df=1 p=0.5025 OR=1.4359 (0.4962–4.1549)
	Vaginal Delivery	9 (60.0)	196 (68.3)	

Table 2. Association of Baseline Characteristics with Study Group (Case vs. Control)

Table 2 compares the baseline demographic and obstetric characteristics between the case and control groups. No statistically significant differences were found in age distribution (p = 0.7355), educational level (p = 0.6826), parity (p = 0.0912), or mode of delivery (p = 0.5025) between women with subclinical hypothyroidism and euthyroid controls, indicating that the two groups were comparable at baseline with respect to these variables.

Maternal Complication	Category	Frequency (n)	Percent (%)
Gestational Hypertension (GH)	No	294	97.4
	Yes	8	2.6
Gestational Diabetes Mellitus (GDM)	No	291	96.4
	Yes	11	3.6
Placenta Previa	No	301	99.7
	Yes	1	0.3
Placental Abruption	No	301	99.7
	Yes	1	0.3
Premature Rupture of Membranes (PROM)	No	285	94.4
	Yes	17	5.6
Premature Delivery	No	287	95.0
	Yes	15	5.0

Table 3. Distribution of Maternal Complications in the Study Population (N = 302)

Table 3 shows the frequency of major maternal complications recorded in the total study population. PROM (5.6%) and premature delivery (5.0%) were the most frequently observed complications, followed by GDM (3.6%) and GH (2.6%), while placenta previa and placental abruption were rare, each occurring in only 1 patient (0.3%).

Maternal Complication (Yes)	Case n (%) (of 15)	Control n (%) (of 287)	χ^2, p-value / OR (95% CI)
Gestational Hypertension (GH)	2 (13.3)	6 (2.1)	χ^2=6.9869, p=0.0082* OR=0.1388 (0.0255–0.7553)
Gestational Diabetes Mellitus (GDM)	1 (6.7)	10 (3.5)	χ^2=0.4113, p=0.5212 OR=0.5054 (0.0604–4.2302)
Placenta Previa	0 (0.0)	1 (0.3)	χ^2=0.0524, p=0.8188
Placental Abruption	0 (0.0)	1 (0.3)	χ^2=0.0524, p=0.8188
PROM	3 (20.0)	14 (4.9)	χ^2=6.1362, p=0.0132* OR=0.2051 (0.0519–0.8109)
Premature Delivery	3 (20.0)	12 (4.2)	χ^2=7.5571, p=0.0811 OR=0.1745 (0.0434–0.7014)

Table 4. Association of Maternal Complications with Study Group (Case vs. Control)

Table 4 presents the association between maternal complications and study group, restricted to women who experienced each complication ("Yes" category). GH was significantly more frequent in the case group (13.3% vs. 2.1%, p = 0.0082), as was PROM (20.0% vs. 4.9%, p = 0.0132); both had odds ratios below 1, indicating higher odds of these complications among women with subclinical hypothyroidism. GDM, placenta previa, placental abruption, and premature delivery did not differ significantly between groups (all p > 0.05), although premature delivery showed a numerically higher rate in the case group (20.0% vs 4.2%).

Fetal / Neonatal Outcome	Category	Frequency (n)	Percent (%)
Intrauterine Growth Restriction (IUGR)	No	294	97.4
	Yes	8	2.6
Fetal Distress	No	289	95.7
	Yes	13	4.3
Stillbirth	No	299	99.0
	Yes	3	1.0
Congenital Malformation	No	297	98.3
	Yes	5	1.7
SNCU Admission	No	251	83.1
	Yes	51	16.9

Table 5. Distribution of Fetal and Neonatal Outcomes in the Study Population (N = 302)

Table 5 presents the distribution of fetal and neonatal outcomes in the overall study population. SNCU admission was the most common adverse neonatal outcome (16.9%), followed by Fetal distress (4.3%), IUGR (2.6%), Congenital malformation (1.7%), and Stillbirth (1.0%).

Fetal/Neonatal Outcome (Yes)	Case n (%) (of 15)	Control n (%) (of 287)	χ^2, p-value / OR (95% CI)
IUGR	3 (20.0)	5 (1.7)	χ^2=18.4264, p<0.0001* OR=0.0709 (0.0152–0.3320)
Fetal Distress	1 (6.7)	12 (4.2)	χ^2=0.2138, p=0.6438 OR=0.6109 (0.0741–5.0365)
Stillbirth	0 (0.0)	3 (1.0)	χ^2=0.1584, p=0.6906
Congenital Malformation	1 (6.7)	4 (1.4)	χ^2=2.4342, p=0.1187 OR=0.1979 (0.0207–1.8889)
SNCU Admission	5 (33.3)	46 (16.0)	χ^2=3.0416, p=0.0811 OR=0.3817 (0.1247–1.1687)

Table 6. Association of Fetal and Neonatal Outcomes with Study Group (Case vs. Control)

Table 6 demonstrates that IUGR was significantly more common in the case group than the control group (20.0% vs. 1.7%, p < 0.0001), with an odds ratio well below 1, indicating markedly higher odds of IUGR in babies born to mothers with subclinical hypothyroidism. Fetal distress, stillbirth, and congenital malformation showed no statistically significant association with group (all p > 0.05). SNCU admission was numerically higher in the case group (33.3% vs 16.0%) but did not reach conventional statistical significance (p = 0.0811).

Parameter	Group	Mean	SD	p-value	t-statistic
Age (years)	Case	25.6667	4.4024	0.3069	1.0234
	Control	27.1463	5.5052		
Gestational age at delivery (weeks)	Case	36.4667	3.5024	0.0032*	2.9736
	Control	38.1429	2.0374		
Birth weight (grams)	Case	2450.9333	819.9261	0.0002*	3.8036
	Control	2862.5610	377.1155		
TSH level (mIU/L)	Case	4.2347	1.1176	<0.0001*	20.2365

	Control	1.4529	0.4705		
FT4 (ng/dL)	Case	7.7267	1.0074	0.7152	0.3652
	Control	7.8192	0.9538		

Table 7. Comparison of Mean Maternal and Neonatal Parameters Between Case and Control Groups

Table 7 compares continuous maternal and neonatal parameters (mean ± SD) between the case and control groups using the independent t-test. As expected, TSH level was markedly and significantly higher in the case group (4.2347 ± 1.1176 mIU/L) than the control group (1.4529 ± 0.4705 mIU/L, $p < 0.0001$), confirming the diagnostic separation between groups. Women with subclinical hypothyroidism also delivered at a significantly lower mean gestational age (36.4667 ± 3.5024 vs 38.1429 ± 2.0374 weeks, $p = 0.0032$) and had significantly lower mean birth weight babies (2450.9333 ± 819.9261 vs 2862.5610 ± 377.1155 grams, $p = 0.0002$). Maternal age ($p = 0.3069$) and FT4 level ($p = 0.7152$) did not differ significantly between the two groups.

DISCUSSION

This comparative analytical cohort study was conducted in the Department of Obstetrics and Gynaecology, R G Kar Medical College and Hospital, from March 2023 to February 2024 and included a total of 302 patients.

Demographic Profile

Most patients (210, 69.5%) were aged 21–30 years, though this was not statistically significant (p=0.7355). Mean age was higher in the control group (27.1463±5.5052) than the case group (25.6667±4.4024), also not statistically significant (p=0.3069). This contrasts with Kunwar R et al.,[6] (2022), who reported that thyroid abnormalities are the predominant endocrine disorders in pregnancy, accounting for 10% of subclinical hypothyroidism cases, with a mean maternal age above 30 years (53.3%). Kiran Z et al.,[7] (2019) similarly noted ongoing international disagreement regarding screening, therapy, and outcomes of hypothyroidism in pregnancy, in a cohort of women diagnosed either pre-conception or antenatally.

Educational Status

A higher proportion of case group patients had completed college education [7 (46.7%)] compared to controls [113 (39.4%)], though not statistically significant (p=0.6826). Chidanandaiah SK et al.,[8] (2019) used a revised TSH threshold (>3 mIU/L) to define hypothyroidism, comparing a study group (TSH 3.1–6 mIU/L) with an age- and parity-matched control group (TSH 0.4–3 mIU/L), and similarly found no significant differences in fetal outcomes between groups (p>0.05), along with comparable rates of vaginal delivery and caesarean section.

Mode of Delivery

Vaginal delivery was less frequent in the case group [9 (60.0%)] than in controls [196 (68.3%)], not statistically significant (p=0.5025). This aligns with observations by Chen LM et al[9] (2014), who found that overt maternal hypothyroidism was strongly associated with adverse maternal and neonatal outcomes, while SCH remained more debated. Their study reported higher rates of gestational hypertension (1.819% vs 3.504%, p=0.020, OR 2.243, 95% CI 1.251–4.024), preterm PROM (4.973% vs 8.625%, p=0.002, adjusted OR 6.014, 95% CI 3.975–9.099), IUGR (1.008% vs 2.965%, p<0.001, adjusted OR 3.336, 95% CI 1.745–6.377), and low birth weight (1.885% vs 4.582%, p<0.001, adjusted OR 2.919, 95% CI 1.650–5.163) among SCH patients compared to euthyroid women.

Gestational Hypertension (GH)

GH was significantly more common in the case group [2 (13.0%)] than in controls [6 (2.1%)] (p=0.0082). Sreelatha S et al.,[10] (2017) similarly identified thyroid dysfunction as a major endocrine complication in pregnancy-second only to diabetes mellitus-reporting associated complications including abortion (2.1%), anemia (4.20%), PIH (14.7%), GDM (4.2%), preterm labor (3.1%), oligohydramnios (16.67%), LSCS (22.9%), PPH (6.3%), LBW (21.9%), hyperbilirubinemia (9.4%), and NICU admission (14.6%); hyperthyroid cases in their cohort, as in ours, were too few for meaningful outcome analysis.

GDM and Placental Complications

GDM occurred in 1 (6.7%) case patient versus 10 (3.5%) controls (p=0.5212, not significant). Placenta previa and placental

abruption each occurred in only 1 (0.3%) control patient (p=0.8188, not significant).

PROM and Preterm Delivery

PROM was significantly higher in the case group [3 (20.0%)] than in the controls [14 (4.9%)] (p=0.0132). Chen LM et al.,[9] (2014) also assessed maternal outcomes including gestational hypertension, GDM, placenta previa, placental abruption, PROM, and preterm delivery, alongside perinatal outcomes such as IUGR, fetal distress, LBW, stillbirth, and malformation; in their cohort, premature delivery was less frequent among controls (4.9%) than cases (20.0%), though not statistically significant (p=0.0811).

IUGR

IUGR was significantly higher in the case group [3 (20.0%)] versus controls [5 (1.7%)] (p<0.0001). Kunwar R et al.,[6] (2022) similarly reported that overt hypothyroidism was linked to adverse fetal outcomes including low APGAR score (<6 at 5 minutes), IUGR, NICU admission, neonatal respiratory distress syndrome, IUFD, and congenital anomalies.

Fetal Distress

Fetal distress was noted in 1 (6.7%) case patient versus 12 (4.2%) controls, not statistically significant (p=0.6438). Singh G et al.,[11] (2016) similarly examined maternal outcomes (miscarriage, GH, preeclampsia, placenta previa, placental abruption, preterm labor, PROM, caesarean rate, PPH) and fetal outcomes (prematurity, LBW, fetal distress, fetal mortality, congenital malformation) in the context of the physiological strain pregnancy imposes on mother and fetus.

Stillbirth and Malformation

Stillbirth occurred in only 3 (1.0%) control patients (p=0.6906, not significant). Malformation was less frequent in controls [4 (1.4%)] than cases [1 (6.7%)], not statistically significant (p=0.1187). Kiran Z et al.,[7] (2019) similarly documented pregnancy loss (miscarriage, stillbirth/IUD, MTP, ectopic pregnancy), gestational hypertension, pre-eclampsia, PPH, placental abruption, and delivery mode as key maternal outcomes.

SNCU Admission

SNCU admission was more frequent in the case group [5 (33.3%)] than controls [46 (16.0%)], though not statistically significant (p=0.0811).

Gestational Age and Birth Weight

Mean gestational age at delivery was significantly higher in controls (38.1429±2.0374) than cases (36.4667±3.5024) (p=0.0032), consistent with Tudela CM et al.,[12] (2012), who examined the association between subclinical thyroid dysfunction and gestational diabetes using normal TSH reference limits of 0.03–4.13 mIU/L (2.5th–97.5th percentile) and normal free T4 of 0.9–2.0 ng/dL. Mean birth weight was also significantly higher in controls (2862.5610±377.1155 g) than cases (2450.9333±819.9261 g) (p=0.0002), in line with the fetal outcome findings of Singh G et al[11] (2016).

TSH and FT4 Levels

Mean TSH was significantly higher in the case group (4.2347±1.1176) than in controls (1.4529±0.4705) (p<0.0001), consistent with the revised screening criteria (TSH cut-off >3 mIU/L) applied by Chidanandaiah SK et al.,[8] (2019). Mean FT4 was marginally higher in controls (7.8192±0.9538) than in cases (7.7267±1.0074), but this difference was not statistically significant (p=0.7152).

Limitations

The relatively small sample size of 302 participants may limit the generalizability of the results. As the study was conducted at a single tertiary care center, the findings may not be representative of the broader population, and hospital-based selection bias cannot be excluded. Additionally, the study did not evaluate the effect of thyroxine supplementation on maternal and fetal outcomes, limiting the assessment of treatment-related benefits in women with subclinical hypothyroidism.

CONCLUSION

Our comparative analytical cohort study suggests that subclinical hypothyroidism during pregnancy is associated with adverse maternal and fetal outcomes. Women with subclinical hypothyroidism had significantly higher rates of gestational hypertension, premature rupture of membranes (PROM), intrauterine growth restriction (IUGR), higher maternal TSH levels, lower gestational age at delivery, and lower birth weight compared with women with normal thyroid function. Although outcomes such as preterm delivery, gestational diabetes mellitus, fetal distress, stillbirth, congenital malformations, and SNCU admission were more frequent in the case

group, these differences were not statistically significant. These findings highlight the importance of early screening, timely diagnosis, and appropriate management of subclinical hypothyroidism during pregnancy to improve maternal and neonatal outcomes, while larger prospective studies are needed to further validate these observations.

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