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Original Research Article

Clinical profile and early outcomes of neonates born to mothers with thyroid dysfunction at a tertiary care center in North-East India

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ABSTRACT

Background: The objectives of the study were to assess early neonatal outcomes among infants born to mothers with thyroid dysfunction and compare outcomes between subclinical and overt hypothyroidism.
Methods: This hospital-based cross-sectional study (May 2023-April 2025) included 72 neonates born to mothers with thyroid dysfunction. Comparative analysis was performed in neonates born to mothers with subclinical or overt hypothyroidism. Associations between neonatal morbidities and thyroid function were analysed using the Chi-square or Fisher's exact test, with odds ratios and 95% confidence intervals.
Results: Subclinical hypothyroidism (SCH) was the most common maternal disorder (63.9%). Neonatal hyperbilirubinemia was the predominant morbidity (50%). Prematurity was significantly higher in the SCH group than in the overt hypothyroidism group (41.3% versus 16.7%, p=0.037). Other morbidities showed no significant differences. Congenital hypothyroidism (CH) was detected in 5.6% of neonates.
Conclusions: Subclinical maternal hypothyroidism is associated with prematurity, and the high prevalence of CH emphasizes the need for targeted neonatal thyroid screening.

Keywords: Maternal thyroid dysfunction, Subclinical hypothyroidism, Neonatal outcomes, Congenital hypothyroidism, Newborn screening

INTRODUCTION

Thyroid disorders are the second most common endocrine condition among women of reproductive age and the most common congenital endocrine disorder worldwide. In India, thyroid dysfunction affects approximately 10-13% of pregnant women, with hypothyroidism being the predominant form.[1,2] Maternal hyperthyroidism is relatively uncommon, affecting approximately 0.7-2.8% of pregnancies worldwide.[3,4] Pregnancy is associated with substantial physiological and hormonal adaptations that impose significant demands on maternal thyroid function, including higher thyroxine (T4) requirements in early gestation and a relative decline in later trimesters, making the diagnosis and monitoring of thyroid dysfunction particularly challenging.[5] Maternal hypothyroidism during pregnancy is broadly classified into overt hypothyroidism, subclinical hypothyroidism, and isolated hypothyroxinaemia, each with distinct biochemical characteristics and clinical implications.[6-8] Timely detection and appropriate management are crucial to prevent adverse maternal and fetal outcomes.

Thyroid hormones are essential for fetal growth and development, particularly for neuronal differentiation, synaptogenesis, skeletal maturation, and protein synthesis. During the first trimester, the fetus is entirely dependent on transplacental transfer of maternal thyroid hormones, as the fetal thyroid gland becomes functional only by mid-

gestation. Inadequate maternal hormone levels during this critical period can result in long-term neurodevelopmental impairments, including deficits in cognition, motor function, and adaptive behaviour.[9,10] Thyroid hormones are also vital for normal skeletal and dental development, and congenital hypothyroidism (CH) remains a leading preventable cause of intellectual disability, highlighting the importance of early detection through newborn screening.[9] Maternal hypothyroidism has been associated with adverse neonatal outcomes such as prematurity, low birth weight (LBW), hyperbilirubinemia, respiratory distress, feeding difficulties, hypocalcemia, congenital anomalies, and neurodevelopmental sequelae.[11-13] Although timely levothyroxine therapy reduces these risks, physiological changes during pregnancy can cause fluctuations in thyroid hormone levels, complicating maintenance of euthyroidism and potentially impairing maternal-fetal thyroxine transfer, leading to neonatal thyroid dysfunction.[8,14,15]

Although the adverse effects of untreated hypothyroidism and the benefits of L-thyroxine therapy are well established, existing evidence largely pertains to overt hypothyroidism. SCH, which constitutes a substantial proportion of thyroid disorders in pregnancy and maternal hyperthyroidism remains relatively under-studied, particularly with respect to early neonatal outcomes.

Despite wider implementation of antenatal screening and treatment, data comparing immediate neonatal risks across different types of maternal thyroid dysfunction are limited and inconsistent, especially in Indian and resource-limited settings. This study addresses this gap by comparing early neonatal outcomes among infants born to mothers with SCH, overt hypothyroidism, and hyperthyroidism, with the aim of informing risk stratification, neonatal surveillance, and clinical decision-making.

METHODS

Study design and setting

This was a hospital-based cross-sectional observational study conducted over a period of two years, from May 2023 to April 2025, in the Department of Pediatrics at a tertiary care center in North East India. The study was designed to evaluate early outcomes in neonates born to mothers with thyroid dysfunction during pregnancy and to assess their association with neonatal morbidities.

Sample size estimation

The sample size was calculated based on a reported prevalence of thyroid dysfunction among pregnant women of 13.9%.[16] With a confidence level of 95% and an absolute allowable error of 8%, the minimum required sample size was calculated as 72 using the standard formula for estimating sample size for proportions.

$$n = (Z^2 \times p \times q)/d^2$$

Where, p=estimated prevalence, q=1-p, Z=standard normal deviate for the desired confidence level, and d=absolute allowable error.

Accordingly, a total of 72 neonates born to mothers with thyroid dysfunction were enrolled in the study.

Study population

Inclusion criteria

The study population comprised neonates (0-28 days) born to mothers diagnosed with thyroid dysfunction during pregnancy who presented to the Pediatrics outpatient department or were admitted to the Pediatrics ward or neonatal unit during the study period. Maternal thyroid dysfunction included overt hypothyroidism, SCH, and hyperthyroidism diagnosed during the antenatal period.

Exclusion criteria

Neonates born to mothers with a history of thyroid surgery or significant antenatal comorbidities such as gestational diabetes mellitus, pregnancy-induced hypertension, preeclampsia, eclampsia, rheumatic heart disease, collagen vascular disease, bronchial asthma, uncorrected anemia, or TORCH infections were excluded. Neonates with suspected/proven inborn errors of metabolism, or severe perinatal asphyxia requiring prolonged intensive care support were also excluded from the study.

Data collection

Data were collected using a predesigned and structured proforma. Maternal details included age, type of thyroid dysfunction, trimester of diagnosis, timing of initiation of treatment, treatment status during pregnancy, and presence of associated antenatal complications. Neonatal data included age at presentation, sex, gestational age, mode of delivery and birth weight. Clinical parameters such as presenting complaints, including hyperbilirubinemia, respiratory distress, or feeding difficulty were recorded.

Laboratory evaluation

Neonatal thyroid function tests including serum T3, T4, and TSH were performed after 72 hours of life using the chemiluminescence immunoassay method on the roche e411 analyzer in the department of biochemistry, of the participating tertiary care center. Complete blood count with peripheral smear examination was performed for all neonates. Additional investigations were carried out whenever clinically indicated.

Maternal thyroid reference ranges

Maternal thyroid function was interpreted according to the national guidelines for screening of thyroid dysfunction during pregnancy issued by the Ministry of Health and Family Welfare, Government of India.[17] Trimester-

specific reference ranges for TSH were 0.1-2.5 mIU/l in the first trimester, 0.2-3.0 mIU/l in the second trimester, and 0.3-3.0 mIU/l in the third trimester. In mothers with TSH levels below the trimester-specific reference range, thyroid hormone levels were assessed to differentiate overt hyperthyroidism from physiological changes of pregnancy, with free T4 being the primary parameter evaluated.[18] The normal reference ranges for free T4 and free T3 were 0.7-1.8 ng/ml and 1.7-4.2 ng/ml, respectively.

Neonatal thyroid screening protocol

Universal newborn screening for CH was carried out in accordance with the clinical practice guidelines of the Indian Society for Pediatric and adolescent endocrinology.[19,20] Screening was performed after 72 hours of life. Neonates with TSH levels >20 mIU/l on the initial screen, or >34 mIU/l if screened between 24 and 48 hours of life, underwent repeat testing. Neonates with TSH levels >40 mIU/l underwent immediate confirmatory venous testing for T4 or free T4 and TSH. Neonates with mildly elevated TSH levels underwent repeat testing between 7 and 10 days of life. Interpretation of thyroid function tests was based on the day of life at which the sample was collected. A diagnosis of primary congenital hypothyroidism was confirmed when venous TSH was >20 mIU/l before 2 weeks of age or >10 mIU/l after 2 weeks, in association with low total T4 levels <10 µg/dl or free T4 levels <1.17 ng/dl.

Treatment and follow-up

Neonates diagnosed with CH were started on oral levothyroxine at a dose of 10-15 µg/kg/day. Follow-up plan for thyroid function assessment included estimation of free T4 at 2 weeks of age, both TSH and free T4 at 1 month, every 2 months until 6 months of age, every 3 months up to 3 years, and subsequently every 3-6 months.

Statistical analysis

Data were checked for completeness and consistency, entered into Microsoft Excel, and analyzed using statistical package for the social sciences (SPSS) version 26 (IBM corp., armonk, NY, USA). Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean and standard deviation or median with interquartile range. Associations between maternal thyroid dysfunction and neonatal outcomes were assessed using the chi-square test or Fisher's exact test, as appropriate. Odds ratios with 95% confidence intervals were calculated. A p value less than 0.05 was considered statistically significant.

Ethical considerations

Written informed consent was obtained from the parents or legally authorized representatives prior to enrolment of the neonates. Ethical approval for the study was obtained from the Research Ethics Board, of the participating tertiary care center. The privacy and confidentiality of all participants were strictly maintained. Data collection forms were securely stored within the department, and all personal identifiers were kept confidential and protected with password-secured access.

RESULTS

Study population

A total of 72 neonates born to mothers diagnosed with thyroid dysfunction during pregnancy were included in the study. Of the 72 mothers, 46 (63.9%) had SCH, 24 (33.3%) had overt hypothyroidism, and 2 (2.8%) had hyperthyroidism. The two cases of maternal hyperthyroidism were excluded from comparative statistical analyses due to the very small sample size, which precluded meaningful statistical inference, but were included in overall descriptive analyses. Accordingly, comparative analyses were performed on 70 neonates born to mothers with subclinical or overt hypothyroidism.

The mean age at presentation of the neonates was 5.99±6.03 days, with a median of 4 days (interquartile range: 2-7.75 days). Majority of the neonates, 54 (75%), presented during the early neonatal period (≤7 days). Female neonates predominated, accounting for 49 (68.1%) of the study population, while 23 (31.9%) were male. Baseline maternal and neonatal characteristics are summarized in Table 1.

Table 1: Baseline maternal and neonatal characteristics (n=72).

Variables	Value
Age at presentation, days (mean±SD)	5.99±6.03
Female sex, N (%)	49 (68.1)
Gestational age, weeks (mean±SD)	36.94±2.06
Term neonates, N (%)	49 (68.1)
Low birth weight, N (%)	28 (38.9)
Vaginal delivery, N (%)	37 (51.4)
Maternal age, years (mean±SD)	28.88±3.48

Maternal characteristics

The mean maternal age was 28.88±3.48 years (range: 22-41 years), with a median age of 29 years. Most mothers belonged to the 26-30 years age group (n=36, 50.0%). Among the study population with available maternal thyroid data (n=72), SCH was the most common maternal thyroid disorder (n=46, 65.7%), followed by overt hypothyroidism (n=24, 34.3%), while a small proportion had hyperthyroidism (n=2, 2.8%).

All mothers with subclinical or overt hypothyroidism were on levothyroxine replacement therapy during pregnancy, whereas those diagnosed with hyperthyroidism were receiving antithyroid treatment with propylthiouracil.

Neonatal baseline characteristics

The mean gestational age of the neonates was 36.94±2.06 weeks. Forty-nine neonates (68.1%) were born at term, while 23 (31.9%) were preterm. The mean birth weight was 2.59±0.54 kg. Normal birth weight was recorded in 44 neonates (61.1%), whereas 28 neonates (38.9%) were classified as having LBW (birth weight <2500 grams). Regarding the mode of delivery, 37 neonates (51.4%) were delivered by normal vaginal delivery, 22 (30.6%) by elective lower segment cesarean section, 10 (13.9%) by emergency cesarean section, and 3 (4.2%) by assisted vaginal delivery.

Neonatal clinical profile

Morbidities were classified based on the predominant clinical presentation. Neonatal hyperbilirubinemia was the most common morbidity, observed in 36 neonates (50.0%). Respiratory distress was present in 19 neonates (26.4%), while feeding difficulty was noted in 4 neonates (5.6%). 12 neonates (16.7%) had no apparent morbidity at presentation. Universal newborn screening identified CH in 4 neonates (5.6%), while 68 neonates (94.4%) had normal thyroid function. None of the neonates born to mothers with hyperthyroidism in the present cohort were diagnosed with CH, and thyroid function tests were within normal limits in both cases.

Association between maternal thyroid dysfunction and neonatal outcomes

Comparative analysis of neonatal outcomes was restricted to neonates born to mothers with SCH and overt hypothyroidism, excluding the two cases of maternal hyperthyroidism due to insufficient numbers for statistical comparison. Notably, both cases of maternal hyperthyroidism were associated with neonatal hyperbilirubinemia. Categorical variables were analyzed using the Chi-square test or Fisher's exact test, as appropriate. Odds ratios with 95% confidence intervals were calculated to assess the strength of association. Comparative outcomes are detailed in Table 2.

Neonatal hyperbilirubinemia was observed in 23 of 46 neonates (50.0%) born to mothers with SCH and in 11 of 24 neonates (45.8%) born to mothers with overt hypothyroidism. There was no statistically significant association between maternal thyroid status and neonatal hyperbilirubinemia (OR 1.18; 95% CI 0.44-3.18; p=0.741).

Respiratory distress was present in 13 neonates (28.3%) in the SCH group and in 6 neonates (25.0%) in the overt hypothyroidism group. The association between maternal thyroid dysfunction and respiratory distress was not statistically significant (OR 0.85; 95% CI 0.28-2.61; p=0.771).

Feeding difficulty was observed in 2 neonates (4.3%) born to mothers with SCH and in 2 neonates (8.3%) born to mothers with overt hypothyroidism. This difference was not statistically significant (OR 2.00; 95% CI 0.26-15.16; p=0.495).

LBW was noted in 19 neonates (41.3%) in the SCH group and in 9 neonates (37.5%) in the overt hypothyroidism group. No statistically significant association was found between maternal thyroid dysfunction and LBW (OR 0.85; 95% CI 0.31-2.35; p=0.758).

Preterm birth occurred in 19 neonates (41.3%) born to mothers with SCH compared to 4 neonates (16.7%) born to mothers with overt hypothyroidism, and this difference was statistically significant (OR 0.28; 95% CI 0.08-0.97; p=0.037), indicating a higher likelihood of prematurity among neonates born to mothers with SCH. CH was diagnosed in 3 neonates (6.5%) in the SCH group and in 1 neonate (4.2%) in the overt hypothyroidism group. The association between maternal thyroid dysfunction and CH was not statistically significant (OR 0.62; 95% CI 0.06-6.34; p=0.687).

Table 2: Neonatal outcomes according to maternal thyroid status (n=70).

Neonatal outcome	Subclinical hypothyroidism n/N (%)	Overt hypothyroidism n/N (%)	Odds ratio (95% CI)	P value
Neonatal hyperbilirubinemia	23/46 (50.0)	11/24 (45.8)	1.18 (0.44-3.18)	0.741
Respiratory distress	13/46 (28.3)	6/24 (25.0)	0.85 (0.28-2.61)	0.771
Feeding difficulty	2/46 (4.3)	2/24 (8.3)	2.00 (0.26-15.16)	0.495
Low birth weight	19/46 (41.3)	9/24 (37.5)	0.85 (0.31-2.35)	0.758
Prematurity	19/46 (41.3)	4/24 (16.7)	0.28 (0.08-0.97)	0.037
Congenital hypothyroidism	3/46 (6.5)	1/24 (4.2)	0.62 (0.06-6.34)	0.687

DISCUSSION

In this study of 72 neonates born to mothers with thyroid dysfunction, SCH predominated (63.9%), followed by overt hypothyroidism (33.3%), and hyperthyroidism (2.8%). Neonatal hyperbilirubinemia was the most common morbidity (36/72, 50%), consistent with prior large cohorts linking maternal thyroid disease to increased NICU admissions and respiratory complications.[21]

A statistically significant association was observed between maternal SCH and prematurity when compared

with overt hypothyroidism (odds ratio of 0.28, 95% CI 0.08-0.97; p=0.037), suggesting that even mild or fluctuating thyroid hormone insufficiency may impair placental function, increase inflammatory mediators, and alter fetal hypothalamic-pituitary-thyroid axis regulation, contributing to preterm labor. This aligns with systematic reviews and prospective cohorts, which reported that SCH is associated with a modestly increased risk of preterm delivery relative to euthyroid pregnancies.[22,23]

Although SCH in pregnancy is recommended for treatment by guidelines such as the 2017 American Thyroid Association, existing evidence remains inconclusive, with observational data suggesting mixed maternal outcomes and randomized trials showing no clear benefit of levothyroxine therapy on obstetric, neonatal, or neurodevelopmental outcomes.[24,25]

In this study, no significant association was observed between the type of maternal hypothyroidism and other common neonatal morbidities, indicating that biochemical severity of hypothyroidism alone does not substantially influence most early neonatal outcomes.

Many neonatal morbidities such as hyperbilirubinemia, respiratory distress, and feeding difficulty are multifactorial and influenced by gestational age, perinatal events, and postnatal adaptation rather than maternal thyroid status alone.

The role of levothyroxine in mitigating adverse neonatal outcomes in SCH remains an area of ongoing investigation. Although recent meta-analyses have suggested potential maternal benefits, evidence for neonatal benefits remains inconclusive. Both observational and randomized studies have not consistently demonstrated improvements in obstetric, neonatal, or neurodevelopmental outcomes following treatment.[24,26]

CH was detected in 5.6% of neonates, with no statistically significant difference between neonates born to mothers with subclinical versus overt hypothyroidism. This prevalence is substantially higher than global estimates (0.025-0.05%) based on population-based newborn screening data, and large screening programs reporting a prevalence of approximately 0.043% (4.25 per 10,000 live births).[27-29] In India, the prevalence of CH is higher, estimated at approximately 1 in 1,000 live births.[30,31] Meta-analytic data demonstrated a markedly increased prevalence of CH among infants born to mothers with thyroid disorders, with reported rates approaching 5% and a 3.5-fold higher risk compared with the general population among neonates.[30,32]

Our findings are consistent with these observations suggesting that maternal hypothyroidism, despite treatment, may be associated with an increased risk of CH, supporting the need for targeted neonatal surveillance in this high-risk group.

None of the neonates born to mothers with hyperthyroidism developed CH, consistent with evidence that neonatal thyroid dysfunction in the context of maternal hyperthyroidism-particularly Graves' disease-is uncommon and manifests as transient abnormalities rather than permanent CH.[33,34]

Overall, these findings in our study indicate that maternal hypothyroidism-particularly SCH-is associated with prematurity and an increased risk of CH, even in the context of treatment. Larger prospective studies are needed to clarify the optimal screening, monitoring, and treatment strategies to improve both obstetric and neonatal outcomes in this high-risk population.

Strengths and limitations

This study provides region-specific insight into neonatal outcomes of maternal thyroid dysfunction in North East India, using standardized diagnostic criteria and uniform laboratory methods. It underscores the underrecognized impact of SCH.

However, the small sample size and cross-sectional design limit generalizability and causal inference. Planned longitudinal follow-up of neonates with CH post-discharge could not be completed, preventing distinction between permanent and transient cases. Exclusion of mothers with common comorbidities reduces broader applicability, and reliance on medical records and maternal recall introduces the potential for information bias.

CONCLUSION

This study demonstrates significant neonatal morbidity associated with maternal thyroid dysfunction, with SCH being the most prevalent condition and significantly associated with prematurity. Neonatal hyperbilirubinemia was the most common morbidity, indicating that adverse outcomes may occur despite maternal treatment. While most morbidities were similar across subclinical and overt hypothyroidism, the higher prevalence of CH supports targeted neonatal thyroid screening. These findings emphasize the need for vigilant antenatal surveillance, perinatal planning, and postnatal monitoring, highlighting the need for larger prospective studies with long-term follow-up to refine screening strategies and differentiate between transient and permanent CH.

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