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To Determine the Effect of Various Perinatal Factors on Cord Blood TSH Level of Newborn and To Correlate the Results with Neurodevelopmental Outcome Over Infancy

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ABSTRACT

Cord blood thyroid-stimulating hormone (CB-TSH) measurement is a standard component of newborn screening for congenital hypothyroidism (CH). However, CB-TSH levels may be influenced by maternal and perinatal factors, potentially leading to false-positive results and unnecessary interventions. To evaluate the impact of maternal and perinatal factors on CB-TSH levels and to correlate elevated levels with neurodevelopmental outcomes during infancy. This prospective observational study included 150 neonates delivered at the Integral Institute of Medical Sciences. Detailed maternal history, perinatal events, and antenatal drug exposures were recorded. CB-TSH levels were measured at birth and analyzed using clinical cut-offs and quartiles. Neurodevelopmental assessments were performed at 3, 6, 9, and 12 months using standard developmental milestone checklists. Associations were analyzed using chi-square and Fisher's exact tests. Elevated CB-TSH levels (≥6.6 mIU/L) were observed in 36.0% of neonates, although the screen-positive rate for CH (CB-TSH >20 mIU/L) was low at 1.3%. Significant associations were found between elevated CB-TSH and maternal hypothyroidism (25.0%), gestational diabetes mellitus (16.7%), and antenatal use of thyroxine or insulin ($p = 0.025–0.033$). Among perinatal factors, meconium-stained amniotic fluid (41.7%), birth asphyxia (12.5%), and NICU admission (22.9%) showed significant correlations with elevated CB-TSH. Mild delays in language and social domains were observed in infants with elevated TSH, although these did not reach statistical significance ($p > 0.05$). CB-TSH levels are significantly affected by maternal endocrine conditions and perinatal stressors. Despite a high prevalence of elevated TSH levels, the incidence of confirmed CH and neurodevelopmental delays was low. Careful interpretation of CB-TSH results is essential to avoid overdiagnosis and unnecessary clinical interventions.

Keywords: *Cord blood TSH, congenital hypothyroidism, maternal factors, perinatal complications, neurodevelopment, newborn screening.*

1. INTRODUCTION

The thyroid gland is a vital endocrine organ responsible for secreting hormones that regulate essential physiological functions, including growth, development, and metabolism. A deficiency in these hormones can lead to serious consequences such as cretinism, intellectual disability, short stature, and other developmental disorders. [1,2]

During pregnancy, maternal iodine requirements increase significantly due to enhanced thyroid hormone synthesis, increased renal iodine clearance, and the fetus's dependence on maternal iodine for normal thyroid function. In regions with mild to moderate iodine deficiency, maternal iodine stores may become progressively depleted as gestation advances. [3]

Congenital hypothyroidism (CH), defined by insufficient levels of triiodothyronine (T3) and/or thyroxine (T4) in neonates, is the most common and preventable cause of intellectual disability. Globally, CH affects approximately 1 in 3,000 to 1 in 4,000 live births, whereas in India, the incidence is higher—about 1 in 2,500 to 1 in 2,800. Clinical signs are often absent at birth, particularly in cases of thyroid agenesis, due to transplacental transfer of maternal thyroid hormones. This highlights the importance of universal newborn screening for early diagnosis and timely intervention to improve neurodevelopmental outcomes. [4,5]

Screening typically involves measuring thyroid-stimulating hormone (TSH) levels, either from cord blood at birth or from heel-prick samples collected between the third and fifth day of life. Cord blood TSH testing is widely used for its high sensitivity; however, it has a higher false-positive and recall rate due to postnatal TSH variability. [6] This variability is primarily attributed to the physiological TSH surge triggered by α-adrenergic stimulation in response to cold exposure immediately after birth.

In addition to physiological changes, various maternal and perinatal factors can affect neonatal thyroid function, complicating the interpretation of cord TSH levels. [5] Both cord blood and heel-prick methods are effective; however, in low-resource settings—where early discharge and limited follow-up are common—cord blood sampling offers practical advantages. Some studies have reported lower recall rates with cord blood screening. [7] Accordingly, the Indian Academy of Pediatrics (IAP) recommends using cord blood TSH for CH screening. Despite this, normative data on cord TSH and T4 levels in Indian neonates remain limited, underscoring the need for region-specific research. [8]

When clinical signs of hypothyroidism are present, confirmatory testing with serum TSH and free T4 (FT4) is essential, even if initial screening results are normal. This is crucial, as maternal thyroid hormones can transiently mask symptoms of hypothyroidism in neonates. [9,10]

Although elevated cord TSH levels are commonly observed in preterm infants, the influence of maternal and perinatal factors is inconsistently reported. Maternal characteristics such as age, gestational diabetes, pregnancy-induced hypertension, and alcohol use have been associated with altered neonatal thyroid function. [6,11–13] Delivery-related factors including mode of delivery, fetal distress, gestational age, birth weight, and the need for neonatal resuscitation have also been linked to variations in cord TSH levels. [5] While not all associations are statistically significant, current evidence suggests that elevated cord TSH may serve as a marker of fetal or perinatal stress.

Therefore, this study aims to systematically evaluate the influence of maternal and perinatal factors on cord blood TSH levels in neonates and assess their potential association with early neurodevelopmental outcomes.

2. MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of Pediatrics at the Integral Institute of Medical Science and Research (IIMSR), Lucknow, from April 2023 to December 2024.

Study Population

A total of 150 term and late preterm neonates (both male and female), delivered either vaginally or via cesarean section at the study center, were enrolled.

Inclusion Criteria

- Term neonates (gestational age ≥37 weeks)
- Late preterm neonates (gestational age 33 weeks to 36 weeks + 6 days)

Exclusion Criteria

- Gestational age <33 weeks
- Hypoxic-ischemic encephalopathy (HIE) Grade III
- Major congenital anomalies
- Known chromosomal or genetic disorders
- Maternal TORCH infections
- Prolonged NICU stay (>7 days)
- Requirement for ventilator support
- Refusal of parental consent

Ethical Considerations

The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from the parents or legal guardians of all enrolled neonates prior to participation.

Sample Collection and Hormonal Assessment

At birth, 2 mL of cord blood was collected aseptically from the placental end of the umbilical cord and transferred into a plain tube for the estimation of serum TSH. Neonates with a cord blood TSH level >15 mIU/L underwent repeat venous sampling after 72 hours of life to confirm persistent elevation and rule out transient physiological TSH surge.

Developmental Assessment

Neurodevelopmental follow-up was conducted using the Developmental Screening Test (DST) [14], a standardized and validated tool for Indian children aged 0–15 years. The DST assesses motor, speech-language, and personal-social development through 88 semi-structured items.

Data Collection and Classification

Demographic and clinical data were recorded using a predesigned semi-structured proforma. Cord blood TSH levels were classified as follows:

- Normal: <15 mIU/L
- Mildly Elevated: 15–19.9 mIU/L
- Elevated (screen-positive): ≥20 mIU/L (suggestive of potential congenital hypothyroidism)

Neonates with TSH levels >15 mIU/L were retested at 72 hours for diagnostic confirmation.

Follow-up and Outcome Assessment

All neonates were followed up at 3, 6, 9, and 12 months of age. At each visit, developmental milestones were assessed using the DST.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 25.0. Cord blood TSH levels were evaluated in relation to developmental outcomes and perinatal factors. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. A p-value of <0.05 was considered statistically significant.

3. OBSERVATION & RESULTS

Baseline Characteristics of the Study Population

Out of 150 neonates, 116 (77.3%) were from urban areas and 34 (22.7%) from rural settings. The majority, 126 (84.0%), were delivered at term (>37 weeks), while 24 (16.0%) were preterm (33–37 weeks). LSCS was the mode of delivery in 114 (76.0%) cases, and NVD in 36 (24.0%).

The cohort included 77 (51.3%) male and 73 (48.7%) female neonates. Low birth weight (<2.5 kg) was noted in 32 (21.3%) cases. An Apgar score <7 at 1 minute was seen in 14 (9.3%) neonates, while none had Apgar <7 at 5 minutes. Resuscitation was required in 8 (5.3%) neonates.

In terms of birth order, 47 (31.3%) were first-born, 60 (40.0%) second-born, 37 (24.7%) third-born, and 6 (4.0%) fourth-born. Regarding maternal drug intake, 9 (6.0%) were on dietary control and 8 (5.3%) on insulin for GDM; 22 (14.7%) were on thyroxine, 4 (2.7%) on labetalol, and 107 (71.3%) reported no drug history.

Among maternal illnesses, 17 (11.3%) had GDM, 23 (15.3%) had hypothyroidism, 4 (2.7%) had PIH, while 106 (70.7%) had no reported illness during pregnancy.

Table 1: Frequency of Perinatal, Antenatal, Natal, and Post-natal Events.

Characteristics	Number	Percentage (%)
Perinatal Events		
Tachycardia/Bradycardia	0	0.0
Respiratory Distress	2	1.3
Weak Cry	2	1.3

Asphyxia	8	5.3
Meconium-Stained Amniotic Fluid	24	16.0
Moro Reflex Absent	0	0.0
Palmar Grasp Absent	0	0.0
Sucking Absent	0	0.0
Rooting Reflex Absent	0	0.0
NICU Admission (Perinatal)	16	10.7
Antenatal Events		
Any Antenatal Event	8	5.3
Leaking Per Vaginum (PV)	5	3.3
Preterm Premature Rupture of Membranes (PPROM)	3	2.0
Natal Events		
Any Natal Event	9	6.0
Cried After Tactile Stimulation	9	6.0
Post-natal Events		
Any Post-natal Event	10	6.7
Hypoglycemia	3	2.0
Transient Tachypnea of Newborn (TTNB)	2	1.3
NICU Admission (Post-natal)	5	3.3

The distribution of perinatal, antenatal, natal, and post-natal events among the 150 newborns revealed that meconium-stained amniotic fluid was the most frequent perinatal complication, observed in 24 (16.0%) cases. This was followed by asphyxia in 8 (5.3%) neonates and NICU admissions in 16 (10.7%). Respiratory distress and weak cry were each noted in 2 (1.3%) newborns. Notably, no cases of tachycardia/bradycardia, absent Moro reflex, palmar grasp, sucking, or rooting reflex were reported.

Among antenatal events, complications were recorded in 8 (5.3%) cases, including leaking per vaginum in 5 (3.3%) and PPROM in 3 (2.0%). For natal events, 9 (6.0%) babies cried only after tactile stimulation.

In the post-natal period, 10 (6.7%) newborns experienced adverse events. These included hypoglycemia in 3 (2.0%), transient tachypnea of the newborn (TTNB) in 2 (1.3%), and NICU admission in 5 (3.3%).

Table 2: Distribution according to Cord Blood TSH levels

SN	**Cord blood TSH levels**		**Number**	**Percentage**
	Quartile	**Range (mIU/L)**		
1-	First	<2.5725	37	24.7
2-	Second	2.5725-3.669	37	24.7
3-	Third	3.700-6.599	26	17.3
4-	Fourth (Raised TSH)	≥6.600	48	36.0
Categorical distribution				
1.	Normal (≤15 mIU/L)		143	95.3

2.	Mildly elevated (>15-20 mIU/L)	5	3.3
3.	Screen positive for CH (>20 mIU/L)	2	1.3
Mean Cord Blood TSH±SD (Range) mIU/L		5.38±4.52 (0.60-32.39)	

The distribution of cord blood TSH levels among 150 newborns revealed that 36% had raised TSH levels (≥6.600 mIU/L), placing them in the fourth quartile. The remaining infants were nearly evenly split across the lower three quartiles, each comprising roughly 17% to 25% of the total population. When categorized clinically, the majority (95.3%) had normal TSH levels (<15 mIU/L), while 3.3% showed mildly elevated values (>15–20 mIU/L), and 1.3% were screen-positive for congenital hypothyroidism (CH) with TSH levels exceeding 20 mIU/L. The overall mean cord blood TSH was 5.38 ± 4.52 mIU/L, with a wide range from 0.60 to 32.39 mIU/L, indicating substantial variability among the subjects.

Table 3: Association of Raised Cord Blood TSH with Maternal/Obstetric Characteristics

Characteristics	**Total (N=150)**	**Normal CB-TSH (n=102)**		**Raised CB-TSH (n=48)**		**Statistical significance (Fisher/ c^2 test)**
		No.	**%**	**No.**	**%**	
Place of living						
Rural	34	22	21.6	12	25.0	'p'=0.678
Urban	116	80	78.4	36	75.0	
Gestational age						
33-37 wks	24	16	15.7	8	16.7	'p'=1.000
>37 wks	126	86	84.3	40	83.3	
Mode of delivery						
NVD	36	21	20.6	15	31.3	'p'=0.159
LSCS	114	81	79.4	33	68.8	
Gender of baby						
Male	77	47	46.1	26	54.2	'p'=0.385
Female	73	55	53.9	22	45.8	
Apgar <7 at 1m	14	6	5.9	8	16.7	'p'=0.066
Resuscitation	8	3	2.9	5	10.4	'p'=0.111
Low birth wt.	32	22	21.6	10	20.8	'p'=1.000
Birth order						
Birth order 1	47	37	36.3	10	20.8	c^2=4.818; p=0.186
Birth order 2	60	37	36.3	23	47.9	
Birth order 3	37	23	22.5	14	29.2	
Birth order 4	6	5	4.9	1	2.1	
Drug History						
Diet control (GDM)	9	5	4.9	4	8.3	c^2=10.482; p=0.033
Insulin (GDM)	8	4	3.9	4	8.3	
Labetelol	4	2	2.0	2	4.2	

Thyroxine	22	10	9.8	12	25.0	
No Drug history	107	81	79.4	26	54.2	
Maternal Illness						
GDM	17	9	8.8	8	16.7	c^2=9.388; p=0.025
Hypothyroid	23	11	10.8	12	25.0	
PIH	4	2	2.0	2	4.2	
No Illness	106	80	78.4	26	54.2	

Elevated cord blood TSH levels were notably linked to specific maternal and obstetric factors. Although variables like residence, gestational age, delivery mode, and birth weight showed no significant difference, maternal drug use and illnesses stood out. A higher proportion of mothers in the raised TSH group had taken thyroxine and insulin for GDM (p = 0.033), and conditions like hypothyroidism (25.0%) and GDM (16.7%) were significantly more common compared to the normal TSH group (p = 0.025). These results highlight a potential connection between maternal endocrine disorders and elevated neonatal TSH.

Table 4: Association of Raised Cord Blood TSH with Perinatal events

Characteristics	**Total (N=150)**	**Normal CB-TSH (n=102)**		**Raised CB-TSH (n=48)**		**Statistical significance (Fisher exact test)**
		No.	**%**	**No.**	**%**	
Respiratory distress	2	0	0.0	2	4.2	'p'=0.101
Weak cry	2	0	0.0	2	4.2	'p'=0.101
Asphyxia	8	2	2.0	6	12.5	'p'=0.014
Meconium-stained amniotic fluid	24	4	3.9	20	41.7	'p'<0.001
NICU Admission	16	5	4.9	11	22.9	'p'=0.002

Raised cord blood TSH levels were significantly associated with several adverse perinatal events. Asphyxia was more prevalent among neonates with elevated TSH (12.5%) compared to those with normal levels (2.0%) (p = 0.014). A strong association was observed with meconium-stained amniotic fluid (41.7% vs. 3.9%, p < 0.001) and NICU admissions (22.9% vs. 4.9%, p = 0.002). Although respiratory distress and weak cry were noted only in the raised TSH group (4.2% each), the differences were not statistically significant (p = 0.101). These findings suggest that elevated cord blood TSH may serve as a marker for increased risk of perinatal complications.

Table 5: Association of Raised Cord Blood TSH with Antenatal, Natal & Post-natal Events

SN	**Characteristics**	**Total (N=150)**	**Normal CB-TSH (n=102)**		**Raised CB-TSH (n=48)**		**Statistical significance (Fisher exact test)**
			No.	**%**	**No.**	**%**	
1-	Antenatal adverse events	8	1	1.0	7	14.6	'p'=0.002
2-	Natal adverse events	9	3	2.9	6	12.5	'p'=0.030
3-	Post-natal adverse events	10	4	3.9	6	12.5	'p'=0.075

Raised cord blood TSH levels were significantly associated with antenatal and natal adverse events. Among infants with raised TSH, 14.6% had antenatal complications compared to only 1.0% in the normal TSH group (p = 0.002). Similarly, natal complications were more common in the raised TSH group (12.5% vs. 2.9%, p = 0.030). Postnatal events were also higher (12.5% vs. 3.9%), though not statistically significant (p = 0.075). These findings suggest a notable link between elevated CB-TSH and adverse perinatal events.

Table 6: Association of Raised Cord Blood TSH with Development at 3 months

Development milestones	Total (N=150)	Normal CB-TSH (n=102)		Raised CB-TSH (n=48)		Statistical significance (Fisher exact test)
		No.	%	No.	%	
Delayed Gross motor	3	2	2.0	1	2.1	'p'=1.000
Delayed Fine motor	3	2	2.0	1	2.1	'p'=1.000
Delayed Social & Adaptive	1	0	0.0	1	2.1	'p'=0.320
Delayed Language	4	1	1.0	3	6.3	'p'=0.097
Delayed Vision & Hearing	1	0	0.0	1	2.1	'p'=0.320

At 3 months, developmental delays were minimal and not significantly associated with raised cord blood TSH levels. Delays in gross motor and fine motor skills were seen in 2.0% of infants, equally distributed between groups (p = 1.000). One infant with raised CB-TSH had delays in social-adaptive and vision-hearing milestones (p = 0.320). Language delay was slightly higher in the raised TSH group (6.3% vs. 1.0%), but not statistically significant (p = 0.097). Overall, no meaningful link was found between raised CB-TSH and early developmental delays.

Table7: Association of Raised Cord Blood TSH with Developmental Milestones at 6, 9, and 12 Months (N = 150)

Development Milestones	Time Point	Total Delay	Normal CB-TSH (n=102)	Raised CB-TSH (n=48)	Statistical Significance (Fisher Exact Test)
Delayed Gross Motor	6 months	0	0 (0.0%)	0 (0.0%)	-
	9 months	0	0 (0.0%)	0 (0.0%)	
	12 months	0	0 (0.0%)	0 (0.0%)	
Delayed Fine Motor	6 months	0	0 (0.0%)	0 (0.0%)	-
	9 months	0	0 (0.0%)	0 (0.0%)	
	12 months	0	0 (0.0%)	0 (0.0%)	
Delayed Social & Adaptive	6 months	1	0 (0.0%)	1 (2.1%)	p = 0.320
	9 months	0	0 (0.0%)	0 (0.0%)	
	12 months	0	0 (0.0%)	0 (0.0%)	
Delayed Language	6 months	0	0 (0.0%)	0 (0.0%)	-
	9 months	0	0 (0.0%)	0 (0.0%)	
	12 months	0	0 (0.0%)	0 (0.0%)	
Delayed Vision & Hearing	6 months	0	0 (0.0%)	0 (0.0%)	–
	9 months	0	0 (0.0%)	0 (0.0%)	
	12 months	0	0 (0.0%)	0 (0.0%)	

There was no significant association observed between raised cord blood TSH levels and developmental delays in gross motor, fine motor, language, or vision & hearing domains at 6, 9, or 12 months of age. Only one case of delayed social & adaptive milestone was noted at 6 months in the raised TSH group (2.1%, p = 0.320), which was not statistically significant. Overall, developmental milestones were comparable between infants with normal and raised CB-TSH levels.

4. DISCUSSION

Neonatal thyroid function plays a pivotal role in early brain development, metabolic regulation, and overall growth. Among the available biomarkers, cord blood TSH serves as a reliable, non-invasive screening tool for the early detection of congenital hypothyroidism CH and potential neurodevelopmental risks. [1] This prospective observational study evaluated the influence of maternal and perinatal factors on cord blood TSH levels and explored their association with neurodevelopmental outcomes during the first year of life.

Of the 150 neonates enrolled, the majority were term births (84.0%) and from urban settings (77.3%), with a balanced gender distribution. Cesarean section was the predominant mode of delivery (76.0%), which aligns with institutional trends in urban India. Comparable cesarean rates were reported by Kale et al. (72.7%), while significantly lower rates (11.8%–36%) in other studies may reflect disparities in healthcare infrastructure, patient demographics, and institutional protocols.

Cord blood TSH levels in this cohort ranged from 0.60 to 32.39 mIU/L. Elevated TSH levels (≥6.600 mIU/L) were identified in 36.0% of neonates; however, most values remained below the diagnostic threshold for CH (<15 mIU/L). The screen-positive rate for CH was 1.3%, consistent with findings from Raichurkar AV, et al. (2021) [15] (1.7%), Karthik RN, et al. (2023) [16] (3.1%), Pawar AV, et al., (2023) [17] (2.3%), and Rathod S, et al., (2024) [18] who reported a mean TSH level of 6.14 mIU/L. [15, 16]

A statistically significant association ($p < 0.05$) was observed between elevated cord TSH levels and maternal comorbidities such as hypothyroidism and gestational diabetes mellitus (GDM), particularly among mothers receiving thyroxine or insulin therapy. These findings support existing evidence that maternal endocrine dysfunction may disrupt fetal thyroid regulation. Similar trends were observed in studies by Raichurkar AV, et al. (2021) [15] (1/1357 confirmed CH), Jillela MR, et al. (2021) [19] (1/263), and Venugopalan L, et al., (2021) [20] (10.2 per 1000 births using a lower cutoff). Kale R, et al., (2022) [21] reported a screen-positive rate of 1/300 using a 10 mIU/L threshold, further highlighting variability based on cutoffs used.

Neonates with elevated TSH also had a significantly higher incidence of perinatal complications, including meconium-stained amniotic fluid, birth asphyxia, and NICU admissions. These findings suggest that perinatal stress may transiently activate the hypothalamic-pituitary-thyroid (HPT) axis, potentially mediated by hypoxia or inflammatory insults. Raguvaran R, et al., (2023) [5] similarly observed elevated TSH in neonates experiencing acute intrapartum stress, such as vacuum-assisted deliveries or first-born status.

Antenatal and intrapartum complications showed a stronger correlation with elevated cord TSH levels than postnatal events, indicating that thyroid dysregulation likely begins in utero or during labor. This is supported by Sree NN et al., (2025) [1] who linked high cord TSH levels (>20 µIU/mL) with factors such as low APGAR scores, birth asphyxia, and maternal diabetes.

Serial neurodevelopmental assessments conducted at 3, 6, 9, and 12 months revealed no statistically significant delays in gross motor, fine motor, language, social-adaptive, or sensory domains among neonates with elevated TSH levels. Although a mild trend toward early language delay was noted at the 3-month evaluation, it did not reach statistical significance ($p > 0.05$). These findings suggest that transient TSH elevations in the neonatal period may not adversely affect short-term neurodevelopment. Nevertheless, the possibility of subtle or delayed cognitive effects cannot be excluded, underscoring the need for long-term follow-up.

Strengths and Limitations

A key strength of this study is the comprehensive evaluation of maternal, perinatal, and neonatal factors influencing cord blood TSH levels, paired with structured, longitudinal neurodevelopmental assessments across multiple functional domains. The inclusion of both clinical and biochemical parameters enhances the study's validity.

However, certain limitations must be acknowledged. The relatively small number of neonates with markedly elevated TSH or confirmed CH limited the statistical power for subgroup analyses. Additionally, the 12-month follow-up period may be insufficient to capture late-emerging cognitive or behavioral issues that may manifest beyond infancy.

5. CONCLUSION

The findings from this study indicate that CB-TSH levels are significantly influenced by maternal and perinatal factors. Elevated CB-TSH levels (≥6.6 mIU/L) were observed in 36.0% of neonates, though the screen-positive rate for congenital hypothyroidism was low (1.3%). Higher TSH levels were significantly associated with maternal conditions such as

gestational diabetes, hypothyroidism, and treatment with thyroxine or insulin, as well as perinatal complications including meconium-stained amniotic fluid, birth asphyxia, and NICU admissions. Notably, no statistically significant neurodevelopmental delays were identified up to 12 months of age. These findings highlight the importance of interpreting elevated CB-TSH values in the context of maternal and perinatal history to prevent unnecessary interventions. Further large-scale, long-term studies are recommended to assess developmental outcomes more thoroughly.

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