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Original Research Article

Transient neonatal hyperthyrotropinemia: prevalence and its associated materno-fetal factors: a hospital based prospective observational study

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ABSTRACT

Background: Transient neonatal hyperthyrotropinemia (TNH) should be interpreted with caution in newborns, to assess the risk of unnecessary treatment. There are very few studies reporting prevalence of TNH which ranges from 0.02 to 6.0%. Hence, this study was conducted to estimate the prevalence of TNH among neonates and factors associated with it.
Methods: A prospective observational study was conducted among neonates born for a period of one year. All neonates were subjected to thyroid hormones screening on day 3-5, and if TSH level was elevated (10-20 mIU/l), a repeat TSH and T4 after 2 weeks were done. Elevated TSH levels at 3-5 days with normal T4 levels, normalizing on re-examination at 2-4 weeks was diagnosed as TNH. Descriptive data were reported as frequencies. Chi square and unpaired 't' test was used to study association. Odd's ratio was calculated to study the strength of association using regression analysis.
Results: Out of 333 neonates studied, 17 (5.1%) had elevated TSH levels with normal fT4 on initial screening. Of 15 newborns who returned for follow up at 2 weeks, 14 (4.1%) neonates returned to normalcy, indicating the prevalence of TNH as 4.1%. Prevalence of TNH among neonates born to hypothyroid mothers (45) was 11.1%. Maternal hypothyroid status, birth weight, head circumference and gestational age were statistically significant with TNH.
Conclusions: Screening of all newborns for congenital hypothyroidism (CH) is useful, as they benefit from early initiation of treatment. However, interpretation of thyroid hormones must be done with utmost caution.

Keywords: Neonatal, Hyperthyrotropinemia, Transient, Prevalence, Hypothyroid

INTRODUCTION

Congenital hypothyroidism (CH) is the common endocrine disorder reported among neonates worldwide, characterized by an increase in serum thyroid stimulating hormone (TSH) and reduced thyroxine (T4). CH could be permanent due to abnormal development of the thyroid gland (dysgenesis) or from a failure in hormone production by the thyroid (dyshormonogenesis) and transient, defined as remission before introduction or after withdrawal of l-thyroxine, due to various factors like premature newborns, the transplacental passage of maternal TSH receptor blocking antibodies, maternal exposure to antithyroid drugs, iodine deficiency or excess.[1,2] Transient neonatal hyperthyrotropinemia (TNH) is defined as an abnormal transient elevation in neonatal TSH after 48 h of life, with normal thyroxine (T4) values, which reverts to normality at re-examination after 2 weeks.[3,4] As a form of neonatal thyroid abnormality, it can result from temporarily active causes, which include prenatal iodine deficiency, prenatal iodine excess, maternal TSH receptor (TSHR) blocking antibodies,

maternal antithyroid medication, mild gene mutations, perinatal iodine exposure, maternal hypothyroidism, prematurity, very low birth weight, dopamine, steroids, Sick-Euthyroid syndrome and hepatic hemangioma.[4]

As the developing brain has a critical dependence on thyroid hormone for the first 2 or 3 years of life, it is prudent to assure normal thyroid hormone levels during this period. TNH should be interpreted with caution in newborns, to assess the risk of unnecessary treatment, including: effects on brain development, hyperactivity, advancement in bone age, and craniosynostosis.[5] Effects of TNH on growth and development, and the risk of persistent hyperthyrotropinemia in children with TNH are being increasingly recognized in recent studies.[6-8] There are very few studies reporting prevalence of TNH which ranges from 0.02 to 6.0%.[9-11]

TSH elevation in infants with Down syndrome is also highly prevalent during the neonatal period.[12] The long-term implications of raised TSH in the neonatal period are not understood, but there is a suggestion of a relationship between TSH concentrations and poorer neurodevelopmental outcomes.[10,13] A proportion of affected individuals have also been found to have subclinical hypothyroidism in later childhood.[10] There is also controversy regarding the need for levothyroxine (L-T4) therapy in TNH.[12] Many practitioners elect to "play safe" and treat infants with TNH to prevent any possible adverse developmental effects.[14] There are very few studies to know the actual prevalence of TNH.

Objectives

Objectives of the study were to estimate the prevalence of TNH among live births in a tertiary care setting, to estimate the proportion of neonates who have persistent neonatal hyperthyrotropinemia and to study maternal and foetal factors associated with TNH in tertiary care setting.

METHODS

Study design

It was a prospective observational study.

Study period

Study carried out for one year (from December 2023 to November 2024).

Study population

Neonates born in a tertiary care hospital were selected.

Inclusion criteria

All neonates born in a tertiary care hospital were included in the study after obtaining written informed consent from the mothers were included.

Exclusion criteria

Mothers with existing chronic illnesses like tuberculosis, HIV, malignancies, evidence of any foetal congenital malformations or any in utero abnormalities in the foetus were excluded from the study. Neonates requiring prolonged NICU stay due to sepsis, congenital heart disease and other surgical conditions in the neonate requiring surgical intervention were also excluded.

A pretested semi-structured questionnaire was used to collect basic demographic data including age, gender, address, educational qualification, occupation, socio-economic status (modified B. G. Prasad scale-2021) and past medical history. Also, antenatal records were reviewed to record blood investigation reports especially thyroid profile values, Ultrasound findings for foetal information and any other information related to pregnancy. Birth weight, sex, APGAR score, gestation, physical examination findings, and anthropometric data were recorded. All neonates were subjected to venous sampling on day 3 for thyroid function tests by chemiluminescence method. For those with elevated TSH levels between 10-20 mIU/l, a repeat TSH and T4 was done after 2 weeks of birth. Elevated TSH levels at 3-5 days with normal T4 levels, normalizing on re-examination at 2-4 weeks were diagnosed as TNH.[13] Those neonates with persisting high TSH level (10-20 mIU/l) with normal T4 were further evaluated for persistent hyperthyrotropinemia by thyroid ultrasound and thyroid scan as shown in Figure 1.

Sample size

Based on previous study expecting a prevalence of 0.06% with 3% absolute precision and 95% confidence level the sample size required was 241 using nMaster sample size calculator v2.[10] Expecting a 30% attrition for follow-up blood sample, a minimum of 313 expectant mothers must be studied. In the present study, about 333 mothers admitted to the hospital for safe confinement were enrolled for the study.

Ethical approval

The study was approved by the institute ethics committee [Faculty/1046/23 dated 01 December 2023].

Statistical analysis

The statistical analysis was performed by SPSS (Statistical package for the social sciences) 11.5 package program. Descriptive data including prevalence rates were expressed as frequencies and proportions. The variables are presented as mean±standard deviation. To study the association between groups, chi-square test was used for categorial variables and student's t-test for continuous variables. Odd's ratio was calculated to study the strength of association using regression analysis. A $p<0.05$ was considered for statistical significance.

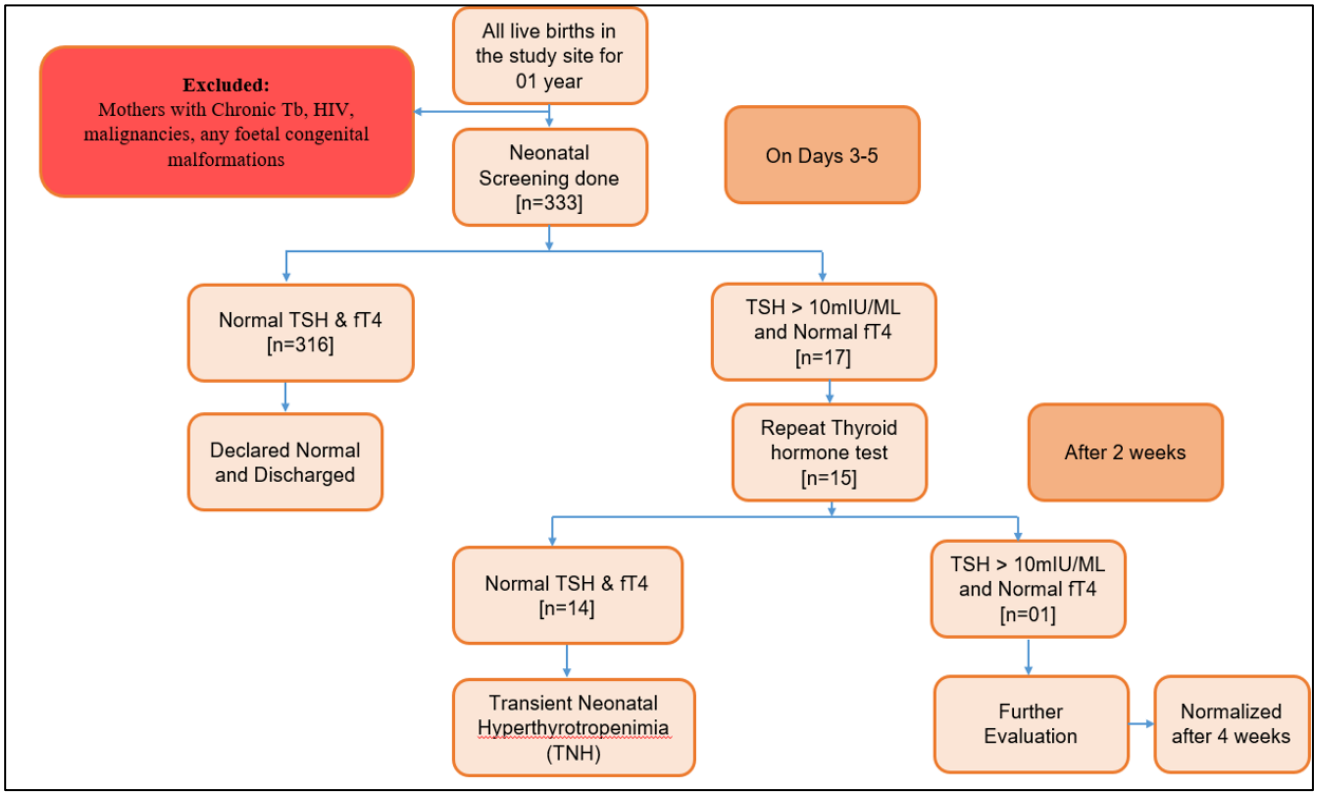

Figure 1: Study plan.

RESULTS

Details of expectant mothers

Sociodemographic characteristics

We collected data of 333 mothers admitted for safe confinement over a period of 1 year. Majority of mothers were in the age group of 21-25 years (51.7%, n=172) followed by 26-30 years (31.5%, n=105), 19-20 years (7.5%, n=25), >31 years (6%, n=20) and <18 years (3.3%, n=11). Mean age was 24.74±3.40 years. About 45% of mothers had primary level education and 51.4% were educated up to secondary level. Based on occupation, 44.4% mothers were homemakers, 33.6% were semi-skilled workers. Majority (48.9%) of the mothers belonged to middle socioeconomic class followed by lower middle class (40.2%).

Past medical and obstetric history

The mean age at menarche was 12.26±1.0 years, with a range from 10 to 16 years. Out of 333 patients, 99.7% (n=332) had regular menstrual cycles, and 99.4% (n=331) reported normal cycle flow. Clots during menstruation were observed in 12.9% (n=43) of patients, and 14.1% (n=47) reported abdominal pain. Mean maternal free thyroxine (fT4) and TSH levels in the first trimester were 9.15±4.09 ng/dL and 2.77±1.78 mIU/l, respectively. Among the study subjects, 12 (3.6%) mothers were hypothyroid before pregnancy and all received levothyroxine at recommended doses. There were 288 mothers who were euthyroid during their antenatal period whereas 45 were in hypothyroid state. Other comorbidities include bronchial asthma, ASD, epilepsy, PCOS, pulmonary TB (treated 13yrs back), and RHD, were also observed in one patient each (0.3%).

Among 333 patients, 45.6% (n=152) were gravida 1, 45.3% (n=151) were gravida 2, and 8.7% (n=30) had three or more pregnancies. Most patients (99.1%, n=330) had no history of infant death, and 83.8% (n=279) had not experienced an abortion, while 16.2% (n=54) had one or more. Regarding pregnancy complications, 4.2% (n=14) had pregnancy-induced hypertension (PIH), 9.0% (n=30) had gestational diabetes mellitus (GDM), and 13.5% (n=45) had hypothyroidism diagnosed during pregnancy and received adequate treatment.

Newborn details

Neonatal characteristics

Out of 333 neonates studied, 183 (55%) were females and 150 (45%) were males. The mean birth weight for term neonates (n=273) was 2878.51±371.53 grams. Preterm neonates (n=59) had a lower mean birth weight of 2561.27±434.17 grams. The only post term infant (n=1) had a birth weight of 2950 grams. Overall, the mean birth weight for all neonates (n=333) was 2822.52±400.97 grams. Out of 333 deliveries, 50.5% were normal vaginal deliveries and 49.5% were made by lower segment

cesarean section (LSCS). The indications for LSCS among 333 patients were as follows: 81 (24.3%) had a previous LSCS, 37 (11.1%) had fetal distress, and 19 (5.7%) had non-progression of labor. Other indications included cephalon-pelvic disproportion (CPD) (3.9%), breech (2.1%), and preeclampsia (1.5%), with smaller percentages for deep transverse arrest, twins, meconium-stained liquor, oligohydramnios, mother with history of rheumatic heart disease, elective LSCS, and elderly mother. The anthropometric details of the newborn are illustrated in Table 1.

Table 1: Anthropometric details of newborns (n=333).

Variables	N	Percentage (%)
Weight of infant (percentile)		
<3rd	02	0.6
3-10th	29	8.7
10-50th	255	76.6
50-90th	44	13.2
90-97th	03	0.9
Length of infant (percentile)		
<3rd	01	0.3
3-10th	16	4.8
10-50th	308	92.5
50-90th	08	2.4
HC of infant (percentile)		
<3rd	02	0.6
3-10th	17	5.1
10-50th	308	92.5
50-90th	06	1.8

At one minute, seven neonates (2.1%) had an APGAR score of 5, 29 neonates (8.7%) scored 6, 285 neonates (85.6%) scored 7, and 12 neonates (3.6%) scored 8. At five minutes, one infant (0.3%) scored 0, four neonates (1.2%) scored 7, nine neonates (2.7%) scored 8, 314 neonates (94.3%) scored 9, and five neonates (1.5%) scored 10. Regarding breastfeeding initiation, for 302 neonates (90.7%) breastfeeding was initiated within one hour of birth whereas for 31 neonates (9.3%) breastfeeding initiation was delayed due to various factors. 03 neonates (0.9%) were initiated on artificial feeding. About 65 neonates (19.5%) were admitted to NICU, the indications being respiratory distress, which was the most common in 31 neonates (47.7%), followed by hyperbilirubinemia in 26 neonates (40.0%), preterm birth in five neonates (7.7%), while IDM (Infant of diabetic mothers) in 04 neonates (6.2%). IUGR (intrauterine growth restriction) and LBW (low birth weight) were observed in 01 neonate each.

Thyroid status of neonates

Upon screening all 333 neonates recruited for the study for thyroid hormones on day 3-5 days, about 94.9% (316 neonates) had TSH <10 mIU/l whereas 5.1% (17 neonates) had elevated TSH (10-20 mIU/l). Out of 15 neonates with high TSH levels who had turned up for follow-up after 2 weeks, the TSH levels returned to <10 mIU/l in 14 neonates except one, which was normalized at 4 weeks follow up. Thus, the prevalence of TNH among the neonates was found to be 4.2% (14/333) and there was no case of persistent neonatal hyperthyrotropinemia detected in the present study. Out of which, 08 were females and 06 were male neonates. Also, there was an increase in the mean TSH level at 2 weeks compared to 3-5 days, while the mean fT4 level decreased slightly as shown in Table 2. Based on the thyroid status of the mothers, the mean TSH (4.10±4.15 mIU/l) was higher and mean fT4 (8.22±4.80 ng/dL) were lower among neonates born to hypothyroid mothers compared to mean TSH (3.35±3.22 mIU/l) and mean fT4 (9.16±4.22 ng/dL) levels among neonates born to euthyroid mothers. But this difference was not statistically significant (p=0.165, 0.173) using unpaired 't' test. Similar non statistical difference was observed after 2 week follow up among 15 neonates born between euthyroid and hypothyroid mothers as shown in Table 3.

Table 2: Thyroid screening among the study subjects.

Parameters	3–5 days, (n=333)	2 weeks, (n=15)
TSH (mIU/l), mean±SD	3.45±3.36	7.37±2.45
fT4 (ng/dl), mean±SD	9.04±4.31	8.48±3.57
TSH >10-20 mIU/l	17 (5.1%)	1 (6.7%)
TSH <10 mIU/l	316 (94.9%)	14 (93.3)

Though the association between thyroid status of mothers and mean TSH and fT4 were not significant, categorical analysis between thyroid status of mothers and TNH status were found to be statistically significant (p=0.049) using chi square test as shown in Table 4. Thus, the prevalence of TNH among neonates born to hypothyroid mothers was 11.1% in the present study.

Table 3: Association between thyroid status of mothers and neonatal thyroid status.

Time	Mother thyroid status	TSH (mIU/l) mean±SD	P value	fT4 (ng/dL) mean±SD	P value
3-5 days, (n=333)	Euthyroid, (n=288)	3.35±3.22	0.165	9.16±4.22	0.173
	Hypothyroid, (n=45)	4.10±4.15		8.22±4.80	
2 weeks, (n=15)	Euthyroid, (n=12)	7.49±2.61	0.727	8.32±3.72	0.747
	Hypothyroid, (n=3)	6.91±2.01		9.11±3.50	

Table 4: Association between thyroid status of mothers and TNH, (n=333).

TNH status	Hypothyroid mothers, N (%)	Euthyroid mothers, N (%)	Total, N (%)
TNH	5 (11.1)	12 (4.2)	17 (5.1)
No TNH	40 (88.9)	276 (95.8)	316 (94.9)
Total	45	288	333
Pearson chi-square value=3.87, p=0.049*			

*Statistically significant

Table 5: Association between baseline variables and TNH.

Baseline variables	TSH <10 mIU/l-Normal group, (n=316)	TSH 10-20 mIU/l-TNH group. (n=17)	P value
Mean maternal TSH level (mIU/l)	2.75±1.79	3.20±1.57	0.311
Birth weight (kg)	2834.14±392.75	2606.47±497.11	0.023*
Length at 3-5 days (cm)	48.5±1.57	48.05±2.92	0.286
Head circumference at 3-5 days (cm)	34.56±1.10	33.58±1.44	0.001*
Mode of delivery			
Normal vaginal delivery	161 (95.8)	07 (4.2)	0.432
Caesarean section	155 (93.9)	10 (6.1)	
Gender			
Male	143 (95.3)	07 (4.7)	0.345
Female	173 (94.6)	10 (5.4)	
Gestational age (in weeks)			
Preterm	52 (88.1)	07 (11.9)	0.009*
Term	263 (96.3)	10 (3.7)	

*Statistically significant.

Studying the effect of various factors on TNH, it was found that the mean birth weight, head circumference of TNH neonates were lesser compared to normal thyroid status group, which was found to be statistically significant (p=0.023, 0.001) using chi square test. The mean birth weight for the TSH <10 mIU/l group was 2834.14±392.75 g, compared to 2666.00±497.11 g for the elevated TSH (10-20 mIU/l) group. The p=0.023 suggests a statistically significant difference, with neonates in the TSH<10 mIU/l group having a higher mean birth weight. The TSH<10 mIU/l group had a mean head circumference of 34.56±1.10 cm, while the elevated TSH (10-20 mIU/l) group had a mean of 33.58±1.44 cm. The p=0.001 shows statistically significant difference. The odds of preterm delivery are 3.56 times higher in individuals with TNH compared to those without TNH (No TNH) [OR=1/0.281(Exp(B)]=3.56] using nominal regression analysis.

Other factors like gender, mode of delivery, length, maternal TSH levels were not significant. The mean maternal TSH level for the TSH<10 mIU/l group was 2.75±1.79 mIU/l, while for the elevated TSH (10-20 mIU/l) group, it was 3.20±1.57 mIU/l. The p=0.311 indicates that there is no significant difference in maternal TSH levels between the two groups. The mean length was 48.5±1.57 cm for the TSH <10 mIU/l group and 48.05±2.92 cm for the elevated TSH (10-20 mIU/l) group. The p=0.286 indicates that there was no significant difference in the length of the neonates between the two groups as shown in Table 5.

DISCUSSION

CH is regarded as the commonest cause of preventable mental retardation.[15] A recent meta-analysis reported an overall CH prevalence of 0.97 per thousand (1:1031) that ranged from <1:4057 to 1:23.[16] Hypothyroidism remains asymptomatic in many neonates and requires a screening test to diagnose. Screening should be done for every newborn using cord blood, or postnatal blood, ideally at 48 to 72 h of age, as per the Indian society for pediatric and adolescent endocrinology (ISPAE) guidelines.[17] In the present study, initial screening for all neonates were done at 3-5 days.

Transient CH, defined as remission before introduction or after withdrawal of l-thyroxine, is more common in premature newborns and is mostly caused by the transplacental passage of maternal TSH receptor blocking antibodies, maternal exposure to antithyroid drugs, iodine deficiency or excess.[18] All newborns experience a state of TSH elevation after birth due to different stimuli, either exposure to cold in the ambient atmosphere or perinatal stress that may reach some very high levels during the first 36 h of life, and this physiological state should be well differentiated from TNH.[19] TNH should be differentiated from a false-positive screening test, defined

as an abnormal screening test value, with normal results of serum tests taken immediately afterward. TNH is defined as a transient elevation of TSH levels (10-20 mIU/l) after 48 h of life with normal free thyroxine (fT4) levels, reverting to normal levels after 2 weeks of life.[10,20] Similar definition was used in the present study. It has been also demonstrated that the concentration of neonatal TSH decreases with age until it stabilizes at between 11 and 15 days of life.[21] In the present study also, the follow up evaluation was done after 2 weeks of initial evaluation.

In a large longitudinal study by Cuestas et al where 5040 normal term newborns were studied, 301 newborns had TNH which translated to a prevalence of 6.0%.[10] In a systemic review study done in 2021 reported an overall TNH prevalence of 6%.[14] The present study estimated TNH prevalence of 4.1%, which may be due to loss to follow up of 02 neonates who had high TSH at initial screening. In a study conducted by Garg et al in India, the prevalence of TNH was found to be 1:47, and two neonates with TNH were found to have low development quotient score as well as deranged thyroid profile at 3 months of age.[9] But no newborn was found to have persistent neonatal hyperthyrotropinemia in the present study as the one subject with elevated TSH at 2 weeks also returned to normalcy at 4 weeks.

In a study in India done among 50 newborns born of hypothyroid mothers found a prevalence of 6%.[11] Maternal autoimmunity, maternal thyroid dysfunction, and female sex were significantly associated with TNH in that study. The present study estimated the prevalence of TNH among 45 neonates born to hypothyroid mothers as 11.1%, which is higher. In addition, the present study also found statistical significance (p=0.04) between thyroid status of mothers and TNH status of neonates. The incidence of TNH varies widely based on ethnicity, population genetics, and the variability of screening method used.[22] Pathogenesis of TNH is multifactorial, caused by extrauterine stressors such as prematurity, low birth weight and perinatal goitrogen exposure, or intrauterine factors like maternal hypothyroidism.[23] Preterm delivery, birth weight and head circumference had statistically significant association with TNH in the present study.

CONCLUSION

As thyroid hormones are pivotal in overall growth and development of children, especially up to first 2-3 years of life, ensuring an euthyroid state during this period is essential. Hence, early screening of mothers for hypothyroidism in pregnancy and screening of all newborns for CH as they benefit most from early initiation of treatment. However, interpretation of thyroid hormones in neonatal period must be done with utmost caution. The long term effects of TNH on these infants must be studied to understand its impact.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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