Section: Pediatrics

Original Research Article

STUDY OF NEONATAL THYROID STIMULATING HORMONE LEVELS AND ASSOCIATED PERINATAL FACTORS IN A TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY

Vivekanandan.S[1], Solai Ganesh. S[2] Ganavi. Ramagopal[3], Madhumitha.S[4]

[1]Associate Professor, Department of Pediatrics, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur, India.
[23]Assistant Professor, Department of Pediatrics, Dhanalakshmi Srinivasan Medical College and Hospital. Perambalur, India.
[3]Professor and HOD, Department of Pediatrics, Dhanalakshmi Srinivasan Medical College and Hospital. Perambalur, India
[4]Junior resident, Department of Pediatrics, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur, India.

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Corresponding Author:
Dr. Ganavi. Ramagopal,
Email: ggganavi!0@mail.com

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ABSTRACT

Background: Congenital hypothyroidism (CH) is a major preventable cause for mental retardation in children. In newborns, several maternal and neonatal factors such as maternal age, maternal anemia, parity of themother, and fetus growth during the gestational period greatly influence TSH level. The primary screening test for the detection of CH is TSH measurement, which is the most sensitive test for detecting primary congenital hypothyroidism. **Aims and objectives:** To assess the TSH levels in neonates born at Tertiary Care Medical College hospital from January 2018 to September 2022 and To assess the effect of perinatal factors on neonatal TSH levels. Methodology : An Analytical cross-sectional study was conducted in a hospital setting. Both retrospective and prospective data was collected be collected using a preformed questionnarie as per the study duration period [January 2018 to September 2022].TSH level was considered as outcome variable and perinatal factors were considered as explanatory variables. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. **Results:** Both maternal and neonatal factors were analyzed extensively for their association with TSH levels. There were statistically significant association with Gestation (p =0.016), mode of delivery (p = 0.049), Maternal hypothyroid state (p=<0.001), placental abnormalities (p =0.042) and Cephalo pelvic disproportion (p =0.042).In univariate analysis, gestational age, gravida and maternal/fetal complication/s were found to be significantly associated with thyroid stimulating hormone. From multivariable analysis, neonates with mother having one or more maternal/fetal complication/s were 2 times (aOR=2.00; 95% CI: 1.27 to 3.14) more likely to have higher TSH level as compared to neonates with mother having no maternal/fetal complication (p<0.05). **Conclusions:** The cross-sectional study of neonatal TSH levels conducted at the tertiary care center found that there is significant percentage (high compared to global standards) neonates have increased TSH levels. They need to be followed up further to diagnose for Congenital hypothyroidism and manage adequately. Both maternal and neonatal factors were found to affect neonatal TSH levels which needed close monitoring and effective follow up.

INTRODUCTION

Congenital hypothyroidism (CH) is a major preventable cause for mental retardation in children.[1] Since the clinical signs of hypothyroidism are absent in newborns it goes undiagnosed and children will suffer from mental retardation later.[2] The overall incidence of CH globally ranges from 1:3000 to 1:4000 live births. The exact incidence of CH in India is relatively unknown, a considerably older study conducted in 1998reported the incidence to be 1:2640 of neonates amongIndian neonates. The first multi-centric study

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screening above 1 lakhs neonates born all over India was conducted by Indian Council of Medical Research (ICMR) National Task Force Team on New Born Screening (NBS) at AIIMS New Delhi (2007–2012) and the results showed a much higher incidence of CH all over India at 1 in 1172 live births, and the prevalence is relatively high in south Indian population (1 in 727).[3]

The cause for CH is multiple. Majority (80-85%) is caused due to non-genetic factors like thyroid embryogenesis leading to thyroidgland agenesis or dysgenesis. Fewer CH cases (10%) occur dueto genetic reasons or inborn errors which include impairedthyroxine (T4) synthesis. The mutations in the transcriptionfactors (PAX-8 and TTF-2) and in the genetic coding for sodium/iodide symporter, thyroid peroxidase, and thyroglobulin arealso responsible for causing CH.[4,5]

Early screening for CH is obligatory in many developed countries for timely diagnosis and treatment.[6] In India the routine Newborn Screening program (NBS) for metabolic disorders does not include CH. Addition of CH screening Early detection and treatment ofCH with the assistance of NBS program's may help improveoutcomes in children and neonates.[7] Screening of primary CH is recommended by measuringthyroid-stimulating hormone (TSH) in cord blood or bloodcollected after 24 h of age although the best "window" fortesting is 48–72 h of age after normal term delivery.[8] Further, reconfirmation isrequired in cases testing positive on first screening within1–2 weeks of birth to correct errors that might have occurred during screening procedure.[9] The primary screening test for the detection of CH is TSHmeasurement, which is the most sensitive test for detectingprimary CH.[6]

In newborns, several maternal and neonatal factorssuch as maternal age, maternal anemia, parity of themother, and fetus growth during the gestational period greatly influence TSH level.[10]

Hence this study was conducted to analyse the neonatal venous blood TSH levels and association of various perinatal factors with TSH level in neonates born at a Tertiary Care Medical College hospital.

Aims and Objectives

Aim of the study: To study the Neonatal TSH levels and effects of perinatal factors on TSH levels

Objectives

Primary Objective: To assess the TSH levels in neonates born at Tertiary Care Medical College hospital from January 018 to September 2022.

Secondary Objective: To assess the effect of perinatal factors on neonatal TSH levels.

MATERIALS AND METHODS

Study site: Tertiary Care Medical College hospital

Study duration: January 2018 to September 2022

Study Population: All babies born and admitted in Tertiary Care Medical College hospital from January 2018 to September 2022.

Study Design: It is across sectional study. Both retrospective and prospective data was collected as per the study duration period.

Sample Size

Sample size was calculated assuming the proportion of neonates with abnormal TSH during the first screening test done at 72 hours - 5.57% as per the study by Chaudhary M et. Al.[16] The other parameters considered for sample size calculation were 1.5% absolute precision and 95% confidence level. The following formula was used for sample size as per the study by Daniel WW et al.[11]

where n = sample size,

Z= Z statistic for 95% level of confidence =1.96

P = expected prevalence/proportion of outcome = 0.0557

d= precision = 0.015

The required sample size as per the above-mentioned calculation was 898. To account for a non-participation rate of about 5%, another 45 subjects will be added to the sample size. Hence the final required sample size would be 943.

If the number of available samples during the study period is more than the calculated value, the higher sample size will be considered.

Inclusion Criteria: All babies born in tertiary care hospital from January 2018 to September 2022.

Exclusion Criteria: Neonates with major life-threatening malformations, those with antenatally detected central nervous system (CNS) malformations and neonates whose mothers were on any known anti-thyroid drugs will be excluded from the study.

Methodology

The retrospective data of neonates born in the hospital after considering inclusion and exclusion criteria was obtained from the medical records section of the hospital. The data of neonates born in the hospital during the study period was collected prospectively. Informed consent from the parents was obtained for data collected prospectively.

Determination of serum TSH is part of routine clinical care for neonates born in our hospital; they are tested for TSH levels at 72 hours of life during admission for observation. Venous samples of all the babies born werecollected and sent for TSH estimation. Blood samples (2 mL) were collected in a sterile container drawn from the peripheral vein of the baby with the help of a needle. The samples were analyzed within 4 h using electrochemiluminescence immunoassay on Snibe Megluim TMTSH (CLIA) analyzer. Normal value of TSH in neonates as per the kit is 0.28–6.80 μIU/mL. Values >6.080 and <0.28 μIU/mL were considered abnormal. All neonates who had TSH values in abnormal range were advised to repeat TSH assessment within 14 days of life.

As per guidelines, neonates with abnormal TSH levels (<0.28 or >6.80 μIU/mL) are started on

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supplemental levothyroxine of 10 µg/kg/day and TSH levels were recalled at 1st, 3rd, 6th, and 12th months after delivery, to confirm thyroid illness.[10] CH is diagnosed if the values 0f TSH >10 µIU/mL along with T4 <6.5 µg/dl and FT4 <0.8 ng/dl.

The data regarding the perinatal factors - parity of mother (birth order), maternal medical and obstetric conditions, mode of delivery, indication for caesarean section, birth weight, gestational age, gender, weight, requirement of resuscitation beyond initial steps, and the Apgar score was be collected using a preformed questionnarie

Ethical consideration and Confidentiality

The study was conducted after due Ethical clearance from the Institutional Ethics Committee. Informed consent from the parents was obtained for data collected prospectively. The confidentiality of the patient was maintained. Only the hospital Inpatient number and Medical records number were collected.

Statistical Analysis Plan

TSH level was considered as outcome variable and perinatal factors were considered as explanatory variables. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like pie diagram. For normally distributed Quantitative parameters the mean values were compared between study groups using ANOVA (more than 2 groups). For non-normally distributed Quantitative parameters, Medians and Interquartile range (IQR) were compared between study groups using Kruskal Wallis Test (P Value) (>2 groups). Categorical outcomes were compared between study groups using Chi square test. Both univariate and multivariable ordinal logistic regression was done to assess the factors associated with the outcome variable. P value < 0.05 was considered statistically significant. Data was analysed by using coGuide software.[12]

RESULTS

A total of 943 subjects were included in the final analysis.

Table 1: Characteristics of the study population (N=943)

Variables		Frequency	Percentage
Gender	Male	474	50.27%
	Female	469	49.73%
Gestational age	<35 weeks	33	3.50%
	35-38 weeks	372	39.45%
	>38 weeks	538	57.05%
Obstetric code	Primigravida	557	59.07%
	Multigravida	386	40.93%
Birth weight	<2.5 kg	167	17.71%
	>=2.5 kg	776	82.29%
Mode of delivery	Normal Vaginal Delivery	776	82.29%
	Lower Segment Caesearean Section	167	17.71%

Out of 943 newborns analysed in the study 50.27% were Male and 49.73% were Females. Only 3.5 % were preterm delivery. Majority (39.4%) were Primigravida. 17.71 % of new born were low birth weight (<2.5Kg). Majority were Normal Vaginal delivery (82.29%). [Table 1]

Table 2: Comparison of TSH level according to several maternal/fetal complications in the study population (N=943)

Parameter	TSH levels (in mu/litre)			Chi square value	P value
	<6	6 to 13	>13		
DM					
Yes (N=34)	29 (85.29%)	4 (11.76%)	1 (2.94%)	0.456	0.796
No (N=909)	755 (83.06%)	137 (15.07%)	17 (1.87%)		
Liquor abnormalities					
Yes (N=31)	25 (80.65%)	4 (12.9%)	2 (6.45%)	3.579	0.167
No (N=912)	759 (83.22%)	137 (15.02%)	16 (1.75%)		
Previous LSCS					
Yes (N = 27)	20 (74.07%)	6 (22.22%)	1 (3.70%)	1.73	0.422
No (N = 916)	764 (83.41%)	135 (14.74%)	17 (1.86%)		
Hypothyroid					
Yes (N=22)	8 (36.36%)	10 (45.45%)	4 (18.18%)	51.194	**<0.001**
No (N=921)	776 (84.26%)	131 (14.22%)	14 (1.52%)		
Hypertension					
Yes (N=12)	8 (66.67%)	3 (25%)	1 (8.33%)	3.846	0.146
No (N=931)	776 (83.35%)	138 (14.82%)	17 (1.83%)		
Anemia					
Yes (N=10)	8 (80.00%)	2 (20.00%)	0 (0.00%)	0.377	1
No (N=933)	776 (83.17%)	139 (14.9%)	18 (1.93%)		

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RH negative					
Yes (N=8)	7 (87.50%)	1 (12.50%)	0 (0.00%)	0.205	1
No (N=935)	777 (83.10%)	140 (14.97%)	18 (1.93%)		
IUGR					
Yes (N = 4)	1 (25.00%)	3 (75.00%)	0 (0.00%)	11.397	0.077
No (N = 939)	783 (83.39%)	138 (14.70%)	18 (1.92%)		
Infective cause					
Yes (N=4)	3 (75.00%)	0 (0.00%)	1 (25.00%)	11.854	0.072
No (N=939)	781 (83.17%)	141 (15.02%)	17 (1.81%)		
MAS					
Yes (N = 3)	3 (100.00%)	0 (0.00%)	0 (0.00%)	0.61	1
No (N = 940)	781 (83.09%)	141 (15.00%)	18 (1.91%)		
PROM					
Yes (N = 2)	1 (50.00%)	1 (50.00%)	0 (0.00%)	1.9495	0.29
No (N = 941)	783 (83.21%)	140 (14.88%)	18 (1.91%)		
Placental abnormalities					
Yes (N = 2)	1 (50.00%)	0 (0.00%)	1 (50.00%)	24.849	**0.042**
No (N = 941)	783 (83.21%)	141 (14.98%)	17 (1.81%)		
CPD					
Yes (N = 2)	1 (50.00%)	0 (0.00%)	1 (50.00%)	24.849	**0.042**
No (N = 941)	783 (83.21%)	141 (14.98%)	17 (1.81%)		
Miscellaneous					
Yes (N=17)	14 (82.35%)	2 (11.76%)	1 (5.88%)	1.551	0.46
No (N=926)	770 (83.15%)	139 (15.01%)	17 (1.84%)		

Association of TSH were analysed with various maternal and fetal characteristics. There were statistically significant association with Gestation (p =0.016), mode of delivery (p = 0.049), Maternal hypothyroid state (p=<0.001), placental abnormalities (p =0.042) and Cephalo pelvic disproportion (p =0.042). [Table 2]

Table 3: Comparison of TSH level according to maternal/fetal complication/s in the study population (N=943)

Maternal/Fetal complication/s	TSH levels(in mu/litre)			Chi square value	P value
	<6	6 to 13	>13		
Present (N=133)	97 (72.93%)	25 (18.80%)	11 (8.27%)	36.302	**<0.001**
Absent (N=810)	687 (84.81%)	116 (14.32%)	7 (0.86%)		

There was significant association with maternal/fetal complications with neonatal TSH levels. There was increased percentage (8.27%) of values >13 mu/Litre when there was one or more maternal complications. [Table 3]

Table 4: Univariate and multivariable ordinal logistic regression to assess the perinatal factors associated with thyroid stimulating hormone

Parameters	Univariate analysis		Multivariable analysis	
	cOR (95% CI)	P-value	aOR (95% CI)	P-value
Gestational Age	0.89(0.81-0.98)	**0.020**	0.95(0.85-1.08)	0.446
Birth weight	0.90(0.59-1.36)	0.612	0.96(0.63-1.46)	0.845
APGAR score 5 minute	0.85(0.56-1.28)	0.436	0.93(0.6-1.46)	0.762
Gender: Female	0.92(0.65-1.29)	0.622	0.94(0.66-1.32)	0.712
Gravida: Multigravida	1.64(1.15-2.28)	**0.006**	1.41(0.97-2.06)	0.075
Maternal/fetal complication/s: Present	2.24(1.47-3.41)	**<0.001**	2.00(1.27-3.14)	**0.003**
Mode of delivery: LSCS	1.37(0.90-2.08)	0.143	0.95(0.59-1.53)	0.830

Note: Gestational age, birth weight and APGAR score 5 minutes are numerical variables; Male, primigravida, absence of maternal/fetal complication/s and normal delivery were taken as reference for gender, gravida, maternal/fetal complication/s and mode of delivery respectively; cOR=crude Odds ratio; aOR=adjusted Odds ratio.

In univariate analysis, gestational age, gravida and maternal/fetal complication/s were found to be significantly associated with thyroid stimulating hormone. Neonates with lower gestational age, neonates with multigravida mothers and neonates with mother having one or more maternal/fetal complication/s had higher probability of higher TSH level according to univariate analysis.

In multivariable analysis, only maternal/fetal complication/s was found to be significantly associated with thyroid stimulating hormone. From multivariable analysis, neonates with mother having one or more maternal/fetal complication/s were 2 times (aOR=2.00; 95% CI: 1.27 to 3.14) more likely to have higher TSH level as compared to neonates with mother having no maternal/fetal complication (p<0.05). [Table 4]

DISCUSSION

The primary objective of the study to detect the TSH levels in newborns. Our study showed that Majority that is 83.14% had TSH <6 mu/litre. 14.95% had TSH levels 6 to 13 mu/litre.[12] (1.91%) of newborns

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had TSH levels >13 mu/litre. The findings are similar to study by Gopalakrishnan et.al which shows using fixed TSH cut off of 20 mIU/L yielded high TSH levels of 1.39%.[13] Our study shows no association of gender, prematurity and birth weight of the baby for high TSH levels. This is similar to study findings of Lee SY et.al which shows the TSH level between birth weight and gestational age did not show any significant variation (p-value 0.685).[14] This study showed significant high TSH in Primigravida (p =0.016). This is comparable to two studies by Lakshminarayan SG et.al and Gupta Aet.al which concluded similar high TSH levels in first pregnancy.[15,16] Herbstman et alassumed this pattern to be related probably to environmental exposure where some persistent chemicals are present at higher levels in firstborn neonates.[17]

The logistic regression analysis showed positive correlation between LSCS mode of delivery and maternal and fetal complications. The study by Verma NR et.al showed that maternal and fetal complications like low birth weight, lower maternal haemoglobin levels and prematurity have high TSH levels.[14]

CONCLUSION

The cross-sectional study of neonatal TSH levels conducted at the tertiary care center found that there is significant percentage (high compared to global standards) neonates have increased TSH levels. They need to be followed up further to diagnose for Congenital hypothyroidism and manage adequately. Both maternal and neonatal factors were analyzed extensively for their association with TSH levels. There were statistically significant association with Gestation (p =0.016), mode of delivery (p = 0.049), Maternal hypothyroid state (p=<0.001), placental abnormalities (p =0.042) and Cephalo pelvic disproportion (p =0.042). In univariate analysis, gestational age, gravida and maternal/fetal complication/s were found to be significantly associated with thyroid stimulating hormone. From multivariable analysis, neonates with mother having one or more maternal/fetal complication/s were 2 times (aOR=2.00; 95% CI: 1.27 to 3.14) more likely to have higher TSH level as compared to neonates with mother having no maternal/fetal complication (p<0.05).

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