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Original Research Article

Congenital hypothyroidism screening by umbilical cord blood thyroid stimulating hormone: a cross sectional study

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ABSTRACT

Background: Congenital hypothyroidism is one of the most important and common preventable cause of intellectual disability. The objective of the study is to determine the proportion of congenital hypothyroidism among newborn babies delivered at ESIC-MC and PGIMSR Hospital, Bangalore.
Methods: Present study was a cross sectional study conducted in the Department of Paediatrics, ESICMC and PGIMSR over a period of 18 months from march 2021 to august 2022. All babies wherein the cord blood TSH was found to be over 20 mIU/l will be intimated within 24 hrs of the test. The babies were advised to give fresh samples TSH on day 3.
Results: In the present study, of the 1900 deliveries, cord blood was available for 1669 newborns. Of the 1669 newborns, 3.1% (N=51) newborns had cord blood TSH more than 20 mIU/l and remaining 96.9%(n=1618) had cord blood TSH levels of less than 20 mIU/l. Out of 51 newborn who were screened positive for congenital hypothyroidism were subjected to futher testing by serum TSH on day 3. Serum TSH on day 3 levels was high (>20 mIU/l) 11.7% (N=6) neonates and serum TSH (<20 mIU/l) 88.2% (N=46) neonates. In this study, the proportion of congenital hypothyroidism was 0.4% (N=6) which was 1 in 278 babies delivered.
Conclusions: The present study adds emphasis on the need for continuing screening for congenital hypothyroidisn, one of the preventable cause for intellectual disability. In developing countries, incidence is very high, the need for screening programs is the need of the hour.

Keywords: Hypothyroidism, Thyroid stimulating harmone, Intellectual disability

INTRODUCTION

Congenital hypothyroidism is one of the most common and important preventable cause for intellectual disability.[1] Incidence being 1in 1172 to as high as 1in 727 in some southern states.[2] If congenital hypothyroidism is not detected early it may lead to serious neurodevelopmental damage in the newborn.[3] Most of the babies with congenital hypothyroidism can be detected by new born screening program in first few weeks after birth, before any clinical symptoms and signs develop. It is the responsibility of each individual Pediatrician and Obstetrician, to take an initiative and start screening all the babies born under their care, one baby at a time.[4] Newborn screening for congenital hypothyroidism (NSCH) has been universally accepted as an essential part of screening for various metabolic disorders.[5] Ideally screening for congenital hypothyroidism should be done after the TSH surge is over i.e., at 72 hours of life but in our country many babies are discharged early and it is difficult to follow up all babies once discharged hence cord blood TSH is an available alternative.[6] Various studies done to test different types of screening methods to evaluate congenital hypothyroidism , concluded that cord blood

TSH as an initial screening test with higher specificity and sensitivity.[7] The present study adds emphasis on the need for continuing screening for congenital hypothyroidisn, one of the preventable cause for intellectual disability. In developing countries, incidence is very high, the need for screening programs is the need of the hour.

METHODS

Source of data

ESIC-MC and PGIMSR Hospital, Bangalore. Clinical data was obtained from the inpatient case files of the patient. The laboratory data of the subject‘s samples will be obtained from hospital laboratory records.

Study design, duration and location

Cross sectional study conducted from prospectively 1.5 years (from March 2021 to August 2022) conducted at ESIC-MC PGIMSR and Model hospital, Bangalore.

Inclusion and exclusion criteria

All inborn babies were included. Mothers on thyroid medications and Preterm newborns (<30 weeks of gestation) were excluded.

Procedure

Umbilical cord blood samples was collected in a sterile container drawn from placental side of the umbilical cord incised while severing it at the time of birth of the baby. At birth, the babies weight, sex, time to first cry, congenital abnormalities, APGAR scores were noted. TSH was estimated within 24hrs by electrochemiluminescence immunoassay. All babies wherein the cord TSH was found to be over 20 mIU/l will be intimated within 24 hrs of the test. The babies were advised to give fresh samples for T4 and TSH on day 3 of life.

Statistical analysis

Based on a previous study conducted by ZionGE et al concluded that the proportion of congenital hypothyroidism among new-born babies ranges from 0.1% to 4%.[2] We calculated the sample size using the formula:

$$(n) = [DEFF * Np(1-p)]/[d2/Z21-A/2 * (N1) + p * (1-p)]$$

With a 4% proportion of congenital hypothyroidism among new-born babies, at 95% Confidence interval, and absolute allowable error of 1%. The sample size was estimated to be 1476.Considering the attrition rate of 13% the sample size for the study would be 1667.Accordingly, 1669 new-born babies were included in the study. All the data collected were entered into a Microsoft Excel worksheet and analyzed using the statistical software SPSS version 20.0

All variables such as TSH levels, maternal age, gestational age, gender, etc analysed using mean, percentage, range, standard deviation, frequency. The mean TSH was compared between various factors like gender, gestational age, birth weight. The Qualitative characteristics were expressed in frequency with proportions and Quantitative characteristics of birth weight and TSH were expressed in Mean±SD. To compare the cord blood TSH among the groups, Mann Whitney u test is applied since the does not follow normality.

RESULTS

Gestational age in the study population

In the study majority were term babies 92% (N=1536) and preterm babies were 8.0% (N=133).

Table 1: Gestational age in the study population.

Gestational age	N	%
Term	1536	92.0
Pre-term	133	8.0
Total	1669	100.0

Birth weight of the new born in the study population

Among 1669 normal birth weight were 72.6% (N=1212), low birth weight 27.1% (N=452) and large for gestational age 0.3% (N=5). The average birth weight was 2.66 kgs.

Table 2: Birth weight of the new born in the study population.

Parameters	N	%
Birth weight (kg)		
Normal (2.5-4.0)	1212	72.6
Low birth Weight (<2.5)	452	27.1
Large for gestational age (>4.0)	5	0.3
Total	1669	100.0
Descriptive statistics		
Min-Max	**Mean±SD**	**Median (Q1-Q3)**
0.80-4.58	2.66±0.47	2.69 (2.41-2.96)

Table 3: Cord blood TSH levels of the new born in the study population.

Variables	N	%
Cord blood TSH		
Positive (>20 mIU/l)	51	3.1
Negative (<20 mIU/l)	1618	96.9
Total	1669	100.0
Descriptive statistics		
Min-Max	**Mean±SD**	**Median (Q1-Q3)**
0.34-263.4	8.36±9.54	6.87 (5.01-9.4)

Table 4: Serum TSH on day 3 of the newborns with positive screening in the study.

Parameters	N	%
TSH on day 3		
Positive	6	0.4
Negative	45	2.7
Not subjected for test	1618	96.9
Total	1669	100.0
Descriptive Statistics (n=51)		
Min-Max	**Mean±SD**	**Median (Q1-Q3)**
0.9-53.0	8.48±11.56	5.2 (2.6-7.3)

Table 5: Cord blood TSH levels of neonates based on gestational age.

Gestational age	N	Mean±SD	Median (Q1-Q3)	Mann-Whitney U test	P value
Pre-term	133	9.1±4.2	8.5 (6.68-12.5)	77370	0.000003 (<0.05)
Term	1536	8.3±9.9	6.7 (4.9-9.31)		

Table 6: Cord blood TSH levels of neonates based on gender.

Gender	N	Mean±SD	Median (Q1-Q3)	Mann-Whitney U test	P value
Male	925	8.0±5.4	6.82 (4.9-9.31)	334138	0.3087 (>0.05)
Female	744	8.8±13.0	6.91 (5.12-9.40)		

Cord blood TSH levels of the new born in the study population

In the study, among 1669 newborns it was found that at Cordblood TSH was between 0.34-263.4 with mean of 8.36±9.54 standard deviation.

Majority of newborns had normal cord blood TSH 96.9% (1618) and 3.1% (51) were Positive for screening (ie.,cordblood TSH >20 mIU/l)

Serum TSH on day 3 of the newborns with positive screening in the study

The 51 samples which were screen positive in cord blood samples were subjected to TSH evaluation on day 3. The Day 3 TSH was between 0.9-53.0 with mean of 8.48±11.56 standard deviation of which 88.2% (45) negative and 11.8% (6) were positive.

The proportion of Congenital hypothyroidism in the study is 0.4% (N=6).

Cord blood TSH levels of neonates based on gestational age

Mean±SD cord blood TSH in pre-term neonates was 9.1±4.2, as opposed to Mean±SD cord blood in term neonates which was 8.3±9.9. The cord blood TSH valuesare statistically significant between pre-term and term with the Mann-Whitney U test value of 7737.0 and p value 0.000003<0.05 as seen in the (Table 5).

Cord blood TSH levels of neonates based on gender

The Mean±SD cord blood TSH in male babies and female babies were 8.0±5.4and 8.8 ± 13.0 respectively. The cord blood TSH values arenot statistically significant between male and female babies with the Mann-Whitney U test value of 334138.0 and p value 0.3087>0.05 as shown the (Table 6).

DISCUSSION

Present study was a single cantered, cross-sectional study conducted at ESICMC and PGIMSR Bengaluru, with an

objective to determine the proportion of congenital hypothyroidism among newborn babies delivered at our institution. Congenital hypothyroidism is one of the most common preventable causes of intellectual disability. [1]Incidence being 1 in 1172 to as high as 1in 727 in some southern states.[2] If congenital hypothyroidism is not detected early it may lead to serious neuro developmental damage in the newborn.[3] Ideally screening for congenital hypothyroidism should be done after the TSH surge is over i.e., at 72 hours of life but in our country many babies are discharged early and it is difficult to follow up all babies once discharged hence cord blood TSH is an available alternative.[6] Various studies done to test different types of screening methods to evaluate congenital hypothyroidism , concluded that cord blood TSH as an initial screening test with higher sensitivity.[7] Indian Academy of Paediatrics recommends the use of cord blood samples for screening of congenital hypothyroidism.[8]

During the study period total 1669 newborns were screened for congenital hypothyroidism using cord blood TSH and 51 babies (term babies-48, preterm babies-03) had positive screen and were subjected to day 3 TSH, 6 babies out of 51 had elevated TSH and were diagnosed to have congenital hypothyroidism. In the present study the cord blood TSH values among preterm babies were higher (mean-9.1±4.2) when compared toterm babies (Term-8.3±9.9) which was statistically significant (p value <0.05) as compared with study done by Zion et al in which term babies had higher TSH values.[13] In the present study the cord blood TSH had wide range of 0.34-263.4mIU/L ,however in the studies conducted by Bhatia et al, Manglik et al, Sunil et al had a lower range of cord blood TSH and even lower range was found in study done by Zion et al.[11-14] In the present study percentage of newborns screened positive for congenital hypothyroidism was 3.1% (N=51) and the study done by Bhatia et al had similar results with our study 2.4% (N=88) and lowest by Manglik et al 1.80% (N=22) and highest by Zion et al 10% (N=7).[11,13,14] In the present study the Proportion of congenital hypothyroidism was found to be 0.4% which was similar with study done by Sunil et al which had 0.6%.[12] Lower proportion was found in studies done Bhatia et al and Manglik et al.[11,14] In the present study the proportion of congenital hypothyroidism was found to be 1 in 278 which was high when compared to other studies done by Manglik et al, 2 in 1200 , Rasul et al, 1.5 in 1000, UrviSanghvi et al, 1 in 1000, Ordookhani et al, with 1 in 914, Bhatia et al, 1 in 1458.[11,14-17]

Limitations

Limitations were; the present study was a single centered study and day 3 serum TSH was only done for babies with positive screen in cord blood TSH, hence sensitivity and specificity analysis could not be calculated.

CONCLUSION

The present study adds emphasis on the need for continued screening for congenital hypothyroidism which is one of the important preventable cause for intellectual disability. In developing countries, incidence is very high, the need for screening programs is need of the hour. The study includes umbilical cord blood TSH done at ESICMC and PGIMSR, which is a tertiary care hospital. Out of total 1900 deliveries, 1669 babies cord blood TSH was screened for congenital hypothyroidism of which 3.1% (N=51) babies had screen positive, these babies were subjected to day 3 serum TSH of which 0.4% (N=6) babies were diagnosed to have congenital hypothyroidism. The initiative prospects of my study to do the screening of congenital hypothyroidism by cord blood TSH have helped in identifying cases of congenital hypothyroidism and start treatment in the first two weeks of life.

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