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Original Research Article

A Study to Find Out the Incidence of Congenital Hypothyroidism in a Tertiary Care Centre, Eastern India

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Conflict of interest: Nil

Abstract

Background: Congenital hypothyroidism (CH) is regarded as the commonest cause of preventable mental retardation. With the introduction of newborn screening, early diagnosis and timely initiation of thyroxine replacement therapy have improved the outcomes of affected children. Study was conducted to find out the incidence of congenital hypothyroidism in term and preterm babies and to find out the epidemiological correlation of congenital hypothyroidism (incidence iodised salt and non-iodised salt consuming population.

Materials and Methods: Cord blood samples were collected with the help of a 5cc syringe from the cord stump of the babies satisfying the afore mentioned inclusion and exclusion criteria at the time of birth in the labour room or Operation Theatre in a clot vial and sent for analysing TSH levels within four hours of collection. The babies were re-evaluated on 4th day for term babies and 5th day for preterm babies by heel prick method. A short history and clinical examination about the babies were conducted. Babies with elevated TSH levels (>20mcU/L) this time also were re-evaluated at the age of one month with a venous sample for TSH levels. Those with persistently raised TSH levels (>20mcU/L) at the age of one month were considered to be suffering from congenital hypothyroidism. The data thus collected were analysed by statistical methods to find out the incidence of congenital hypothyroidism in the institution.

Results: rom the present study, we can see that of the 1640 babies 27.5% were from Kolkata, 14.2% from Murshidabad, 12.6% from Malda, 8.5% from North 24 parganas, 0.2% from Bankura, 2.7% from Birbhum,1.9% from Burdwan, 5.3% from Nadia, 4.8% from Paschim Midnapore,3.9% from Purba Midnapore, 5.9% from Howrah, 5.4% from Hoogly, 6.4%from South 24 parganas and 0.3% from Purulia. The study shows that 79.4% of the mothers had no complications, 15.2% had anaemia, 2.01%had hypertension, 1.58% had hypothyroidism, 0.9% had antepartum haemorrhage, 0.6% had gestational diabetes, 0.1% had fibroid uterus and increased maternal age respectively. In our study no mother was found to take antithyroid drug.

Conclusion: Congenital hypothyroidism has a high incidence in our country. Its inclusion in neonatal screening protocol has been rightly done. This can help us prevent an important cause of mental retardation. Transient hypothyroidism is a common entity. So treatment of hypothyroidism should not be started on the basis of Cord blood Thyroid Stimulating Hormone (CBTSH).

Keywords: Congenital hypothyroidism, Incidence, Thyroid Stimulating Hormone (TSH), Pregnancy, Vaginal Delivery, Caesarean Section.

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Introduction

Congenital hypothyroidism **(**CH) is inadequate thyroid hormone production in newborn infants. Thyroxin (thyroid hormone (T4)— 3,5,3',5'-tetraiodo-L-thyronine), an iodine containing

hormone which is produced and secreted by the thyroid gland, is an important regulator of metabolic rate in the body and plays a critical role in brain and bone growth in infancy and early childhood. Fetus starts secreting thyroid hormone by 12 weeks of gestation [1]. Untreated, CH has devastating effects on growth and development of infants. The biochemical defect in CH is a deficiency in circulating T4, and can result from absence of thyroid gland (aplasia) or structural abnormalities of the gland (dysplasia and hypoplasia), abnormal location of the gland (ectopic gland), or inability to synthesize thyroxin because of an inborn error of the metabolism of the thyroid gland (dyshormonogenesis) [2].

Percentages of specific aetiologies vary from country to country. The following ranges of aetiologies have been reported: ectopic thyroid, 35-42%; thyroid agenesis, 22-42%; and gland in place defects, 24-36%. Although a few cases of thyroid dysgenesis have been described resulting from gene mutations, there is no common link to explain the aetiological background in the majority of cases [3]. Congenital hypothyroidism (CH) occurs when a baby is born with an inadequate production of thyroid hormones. The primary causes are divided into developmental defects of the thyroid (thyroid dysgenesis), inborn errors of hormone production (dyshormonogenesis), and central or environmental issues.

Aetiology of congenital hypothyroidism

1. Permanent congenital hypothyroidism is a type of congenital hypothyroidism, a thyroid hormone deficiency present from birth [2] and may be due to primary or secondary (central) causes. Primary causes include defects of thyroid gland development, deficiencies in thyroid hormone production, and hypothyroidism resulting from defects of TSH binding or signal transduction. Peripheral hypothyroidism results from defects in thyroid hormone transport, metabolism, or resistance to thyroid hormone action. Secondary or central causes include defects of thyrotropin releasing hormone (TRH) formation or binding and TSH production [4-5].

2. Transient hypothyroidism is defined as transient abnormality in newborn which revert back to normal after varying period of time and are identified in neonatal screening tests. It may be caused by maternal or neonatal factors.

Maternal factors include antithyroid medications, trans placental thyrotropin receptor blocking antibodies and exposure to iodine deficiency or excess. Neonatal factors include, neonatal iodine deficiency or excess, congenital liver haemangioma and mutations in the genes encoding for DUOX and DUOXA2 [6, 7].

3. Overt hypothyroidism-Overt hypothyroidism is defined as a clinical syndrome of hypothyroidism associated with elevated TSH and decreased serum levels of T4 or T3 [8]

4. Subclinical Hypothyroidism- Subclinical hypothyroidism, also called mild thyroid failure, is diagnosed when peripheral thyroid hormone levels are within normal reference laboratory range but serum thyroid-stimulating hormone (TSH) levels are mildly elevated [9].

The critical points in the identification of CH, and its prevalence, are as follows:

- CH is due to a deficiency in circulating thyroxin.
- Untreated CH is a cause of severe mental retardation.
- Early detection and treatment that starts within the first month of life can prevent mental retardation due to CH.
- World data have shown that the birth prevalence of CH is approximately1:3000.

Aims and Objectives

Primary Objective

- To find out the incidence of congenital hypothyroidism in term and preterm babies in the institute.

Secondary objective

- To find out the correlation between congenital hypothyroidism and gestational maturity of the baby.
- To find out the epidemiological correlation of congenital hypothyroidism (incidence iodised salt and non-iodised salt consuming population)

Materials and Methods

Study Area: Babies born by vaginal delivery and Caesarean section in the Labour Room-Operation Theatre complex of Department of Obstetrics and Gynaecology in N.R.S. Medical College and Hospital

Study Population: 1000 term and preterm babies born in N.R.S. Medical College and Hospital by vaginal delivery or caesarean section.

Sample Size: 1000.

Study Period: 1 year.

Study Design: Prospective observational study

Inclusion Criteria: Term or preterm babies born by normal delivery or caesarean section.

Exclusion Criteria

1. Preterm babies of gestational age less than 28 weeks.

2. Term and preterm babies with congenital anomalies.
3. Either parent of the baby refusing to participate in the study.

Study Techniques: Cord blood samples were collected with the help of a 5cc syringe from the cord stump of the babies satisfying the afore mentioned inclusion and exclusion criteria at the time of birth in the labour room or Operation Theatre in a clot vial and sent for analysing TSH levels within four hours of collection. The babies were re-evaluated on 4th day for term babies and 5th day for preterm babies by heel prick method. A short history and clinical examination about the babies were conducted. Babies with elevated TSH levels (>20mcU/L) this time also were re-evaluated at the age of one month with a venous sample for TSH levels. Those with persistently raised TSH levels (>20mcU/L) at the age of one month were considered to be suffering from congenital hypothyroidism.

The data thus collected were analysed by statistical methods to find out the incidence of congenital hypothyroidism in the institution.

Parameters to be studied

The babies included in the study will be analysed in a methodical manner as follows-

1. Cord blood TSH: The cord blood collected were sent for analysis by chemiluminescence method. and evaluated by Beckman Coulter ACCESS machine

2. Heel prick sample for TSH on 4-5 day of life: The babies will be tested by heel prick method on day 4 for term neonates and day 5 for preterm neonates using a filter paper which will be sent to the laboratory for estimation of TSH by elution technique by the same machine

3. Short history and clinical examination: This will include a short maternal history including age, complications, address, type of delivery, paternal history, environmental history and examination of the baby including gestational age, birth weight, sex, post maturity, poor feeding, hypotonia, hoarse cry, macroglossia, size of posterior fontanelle, persistent jaundice, US:LS, head circumference etc.

4. Venous sample for TSH levels: The babies with raised TSH levels in heel prick method will be re-evaluated at one month of age for TSH levels in venous blood. Those found with raised TSH levels this time also will be considered to be suffering from hypothyroidism (overt hypothyroidism). The rest who was found to have TSH less than <20mIU/L were considered to have transient hypothyroidism.

Analysis of Data: Data of all the cases was entered into SPSS version 17 program and analyzed for statistical package. Socio-demographic data such as mother's age, weight, gestational age, was presented as mean and standard deviation. The qualitative data such as sex, history of any thyroid disease in mother, use of anti-thyroid drugs by mother during pregnancy and TSH results were presented as frequency tables. Chi-square test was applied to find out association of CH with mother's age, newborn's sex, weight and gestational age, history of any thyroid disease in mother and use of anti-thyroid drugs by mother during pregnancy.

Results

A total number of 1640 babies born in NRSMCH in the year Dec 2016-Sep 2017were screened for congenital hypothyroidism. the sociodemographic profile of the newborn is as follows:

Table 1: Sex distribution of the newborn screened

Sex	Number (%)
Boy	946 (57.6%)
Girl	694 (43.4%)

This shows that out of total 1640 newborn screened 946(57.6%) are boys and 694(43.4%) were girls [Table 1].

Table 2: Gestational age distribution in the population

Gestational Age	Number	Mean Gestational Age	Mean Birth Weight
Term (> 37 weeks)	1504 (81.7%)	38.5±3.4	2.87±0.87
Preterm (<37 weeks)	136 (8.3%)	33.3±9.6	1.7±0.7

Table 3: Distribution of preterm birth

Preterm	Number (%)	Mean GA	Mean Birth Weight
< 34 Weeks	69 (50.7%)	31.3±2.6	1.42±0.4
> 34 Weeks	67 (49.2%)	36.5±1.8	2.45±0.6

20The above tables show that out of 1640 babies 1504 (91.7%) were term babies with mean GA of 38.5±3.4 and mean birth weight of 2.87±0.87 and 136 (8.3%) were preterm (mean GA-33.3±9.6, mean B.W.- 1.7±0.7) of which 49.2% were of GA >34 wks (mean GA 36.5±1.8, mean B.W. 2.47±0.6) and 50.7% were of <34wks (mean GA 31.3±2.6, mean B.W. 1.4±0.4) [Table 2, 3].

Table 4: Religion distribution of the study sample

Religion	Number
Hindu	1138 (69.3%)
Muslim	497 (30.3%)
Christian	5 (0.3%)

The above tables show that of the 1640 babies 69.3% were Hindus, 30.3% were Muslims and 0.3% were Christians.

Table 5: Distribution of the newborns among different districts of West Bengal

District	Number
Bankura	4 (0.2%)
Birbhum	45 (2,7%)
Burdwan	32 (1.9%)
Kolkata	451 (27.5%)
Malda	207 (12.6%)
Murshidabad	233 (14.2%)
Nadia	88 (5.3%)
North 24 PGS	140 (8.5%)
Paschim Midnapore	79 (4.8%)
Purba Midnapore	64 (3.9%)
Howrah	97 (5.9%)
Hoogly	89 (5.4%)
South 24 PGS	105 (6.4%)
Purulia	6 (0.3%)

Thus, from the above data we can see that of the 1640 babies 27.5% were from Kolkata, 14.2% from Murshidabad, 12.6% from Malda, 8.5% from North 24 parganas, 0.2% from Bankura, 2.7% from Birbhum,1.9% from Burdwan, 5.3% from Nadia, 4.8% from Paschim Midnapore,3.9% from Purba Midnapore, 5.9% from Howrah, 5.4% from Hoogly, 6.4%from South 24 parganas and 0.3% from Purulia.

Table 6: Mode of delivery of the mother

Type of Delivery	Number (%)
Vaginal Delivery	827 (50.5%)
Caesarean Section	813(49.5%)

The above table shows that of the 1640 mothers, 50.4% had vaginal delivery and 49.5% had caesarian section.

Table 7: Maternal age distribution

Maternal Age	Number (%)
<25	1422 (86.7%)
>25	218 (13.3%)

The above table shows that out of total 1640 mothers 86.7% were <25yrs old and 13.3% were more than 25 yrs old.

Table 8: Salt consumed by mother

Type of salt consumed	Number
Iodised	1612 (98.2%)
Non-iodised	28 (1.7%)

The above table shows that 98.2% mothers consumed iodised salt and 1.7% consumed non-iodised salt.

Table 9: Maternal history

Maternal History	Number (%)
Anaemia	250 (15.2%)
Antepartum haemoorage	16 (0.9%)
Gestational Diabetes	10 (0.6%)
Hypertension	33 (2.01%)
Hypothyroidism	25 (1.58%)
Fibroid Uterus	2 (0.1%)
Increased Age	2 (0.1%)
NAD	1304 (79.4%)
Anti-Thyroid Drug Consumption	0

The above table shows that 79.4% of the mothers had no complications, 15.2% had anaemia, 2.01%had hypertension, 1.58% had hypothyroidism, 0.9% had antepartum haemorrhage, 0.6% had gestational diabetes, 0.1% had fibroid uterus and increased maternal age respectively. In our study no mother was found to take antithyroid drug.

Table 10: Conditions and their incidences

Condition	Incidences
Overall	1:820
Male	1:946
Female	1:694
Term	0:1594
Preterm <30 wks 30-34 wks 34-36 wks	1:68 0:8 1:31.5 0:66
Muslim	1:248.5
Hindu	1: 1138
Chirstian	0:5
Vaginal Delivery	1:827
Caesarean Section	1:813
Maternal Age ≤ 25 yrs ≥ 25 yrs	 1:1422 1:218
Types of Salt Consumed Iodized Non-iodized	 1:1612 1:28
Complications Hypotonia Prolonged jaundice Difficulty in oral feeding Constipation	 1:3 1:3 1:3 1:6

Discussion

Congenital hypothyroidism (CH) is regarded as the commonest cause of preventable mental retardation. With the introduction of newborn screening, early diagnosis and timely initiation of thyroxine replacement therapy have improved the outcomes of affected children. Congenital hypothyroidism fulfils all the criteria provided by Wilson and Jungner for a condition requiring a screening test. It is easy to screen, has a lag time before symptoms manifest, has a definitive diagnostic test, is inexpensive to treat, and the affected children have excellent outcomes when timely treatment is initiated [10].

Screening for congenital hypothyroidism (CH) is widespread for the last two decades. We have not been able to implement it in India because of several factors, like cost, lack of reliable laboratories on a large scale, and nonavailability of baseline data in our population. Use of cord blood TSH as a screening tool is an attractive preposition because of its simplicity and accessibility. Fuse, et al.[11] had shown that mixed cord blood is a good sampling technique for screening for CH. Walfish [12]concluded that cord TSH had a better specificity and sensitivity as compared to cord or filter paper T4 at 3-5 days of age. The present study population consisted of 1640 babies of which 946 (57.6%) were male and 694(43.4%) were females, 1504 (91.7%) babies were term and 136(8.3%) were preterm, 1138(69.3%) were Hindus, 497(30.3%) were Muslims, and 5(0.3%) were Christians. Similar demographic statistics were found in studied conducted by Manglik et al [13] and Anand et al [14]. Our study shows that 5.12% (84) babies had a cord blood TSH more than 10mIU/L. This is comparable to figures from Ethiopia. Our mean value was 4.19±6.8mIU/L while Feleke, et al.[15] observed value of 9.6 ± 7.8 mIU/L in 4206 newborns. Thus, our values are much lower compared to other studies. Our 97th percentile is 11.09mIU/L and Kung, et al.[16] have quoted a 95th percentile of 16 mIU/L. However, our TSH values were somewhat lower than found by Khadilkar, et al.[17] who, in a study of 203 neonates found a mean cord blood TSH value of 12.3 ± 4.9 mIU/L. Thus, we have found a lower TSH baseline values compared to that found in other studies worldwide. but our normative data is comparable to other Indian studies. We had two babies with CH out of a cohort of 1640 establishing an incidence of 1:820 which is much higher than the world figure of 1 in 4000 [18], but other Indian

data too have quoted higher incidences as 1 in 248 [19] and 1 in 1700 [20] and study done by Manglik et al [13] also shows an incidence of 1:600. A recent Iranian study found an incidence of 1 in 914 [21]. Probably geographic and ethnic differences are responsible and of course, this cohort of 1640 samples are too small to assess incidence. In our study there is no statistical correlation between sex of the baby and congenital hypothyroidism (p value- 0.8). But the incidence of congenital hypothyroidism has been found to be higher in females (1:694) than males (1:946). These results are in accordance to Nelson textbook of paediatrics [18] which states that the incidence of congenital hypothyroidism is much higher in females (ratio is 2:1). Rastogi et al [3] also found higher incidence in females. The study done by Anjum et al [22] however found a male: female ratio is1.1:1. This could be due to higher number of males in the population.

The correlation of type of delivery and congenital hypothyroidism has been found to be statistically insignificant (p value-0.9). However Miyamoto et al [23] in his study found significant corelation between vaginal delivery and congenital hypothyroidism. This might be due to his smaller population size. Seth et al [24] conducted a study in which 130 neonates were screened. Her population size was smaller but she also found results similar to our study. This difference might be due to different ethnic background. There is no literature available to show the possible cause of this correlation between vaginal delivery and congenital hypothyroidism. which is also consistent with our results.

Present study has certain limitations. We could not perform T4 level along with TSH for neonatal screening. This would not detect central hypothyroidism. This would not precisely able to differentiate between true or physiological rise in TSH. However, since Neonatal screening for CH is recommended by the 5th day of the child's life at the latest we have screened the babies on 1st and 4th day of life, the rise in TSH in the present study might be true We were unable to do maternal TSH levels, maternal anti-TSH receptor antibody and urinary iodine levels which would have been useful for determination of etiology in cases of transient CH. The prevalence of CH was estimated separately for neonates in endemic and non-endemic regions, neonates born to mothers with thyroid disease and preterm neonates. Meta-analysis of 54 studies that included term neonates from non-endemic regions (55 datasets, and 819 559 neonates), gave a pooled prevalence of 0·97 per 1 000 neonates (95% confidence interval/CI: 0·9 to 1·04), which is about 1 in 1 031 neonates [10].

Conclusion

Congenital hypothyroidism has a high incidence in our country. Its inclusion in neonatal screening protocol has been rightly done. This can help us prevent an important cause of mental retardation. Transient hypothyroidism is a common entity. So treatment of hypothyroidism should not be started on the basis of Cord blood Thyroid Stimulating Hormone (CBTSH). 4-5th heel prick TSH and 28 day venous TSH should be done before diagnosing a case of congenital hypothyroidism. The children with CH grow generally in a normal tempo but the disappearance of bone age retardation is individual and may be protracted until 10 years of age. The incidence of hypothyroidism in India is different in different studies. Larger and multicentric studies are required to correctly document the actual incidence.

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