INTRODUCTION

Congenital Hypothyroidism is the one of the most common preventable cause of mental retardation all over the world as well as in India and with an incidence of 1:2500 to 1:2800 live births in India.[1,2] Clinical diagnosis is difficult at birth and the time of initiation of therapy is a critical determinant of outcome. In view of paramount importance of early diagnosis and treatment, various screening programs were initiated. According to American Academy of paediatrics, more than 95% of newborn infants with congenital hypothyroidism have few clinical manifestations.[3,4] Though the Screening for congenital hypothyroidism will decrease the burden of mentally retarded children in the society but the method of screening is not uniform. Some countries use T4 while others prefer TSH as the tool since maternal diseases affecting placental dynamics influence T4 levels.[5,6] Few others use both T4 and TSH. Technically, using both T4 and TSH will be superior but would increase the cost of screening. Most of the countries have accepted TSH either through heel prick or through cord-blood as the screening method for congenital hypothyroidism. Cord blood collection of sample is preferred for its...
ease of collection of sample, more practical for mothers with short hospital stay following delivery and its utility as an indicator of the prevalence of iodine deficiency disorders.[7,8]

Cord blood TSH (CBTSH) estimation has the advantages of having low rates of follow up loss as the results would be available before the mother leaves the hospital, enabling repeat sampling if needed at the earliest, which is critical for early institution of treatment if necessary. Changes in TSH levels in response to T3 and T4 levels forms the basis of screening using CBTSH.[9]

In most of the countries, blood samples are collected after 24 hours of life to evaluate CH but, the ideal timing of collection is between days 3 and 5 of life because a surge in neonatal TSH, and also fT4, occurs just after the birth and then subsides to baseline over the next 24–72 hours.[10,11,12] So, another screening is advisable if the specimen was collected just after the birth for reducing the number of false positives. But, in India, mothers and their neonates are often get discharged from the hospital after 1 day of delivery, so second screening is not only difficult but also impossible due to different socioeconomic reasons. Therefore the first screening of cord blood TSH is used to detect CH for early intervention.

**MATERIALS AND METHODS**

This Institution based cross sectional observational study was held from January, 2019 to June, 2020 for the duration of 6 months over total 500 neonates in the department of Biochemistry, COMSDH, Kamarhati. The study was approved by the institutional ethical committee. Written consent was obtained from all participants.

Samples were collected from apparently healthy mother without any complications during delivery.

**Inclusion Criteria**

All healthy neonates irrespective of gender.

**Exclusion Criteria**

1. Infants having congenital abnormalities.
2. Neonates requiring resuscitation at birth.
3. Mothers suffering from medical illness such as jaundice, Diabetes mellitus, malnutrition, kidney diseases.
4. Mothers suffering from anaemia during pregnancy, bad obstetrics history
5. Mothers suffering from any active or chronic infection

Approximately 2.5 mL of cord blood taken from the neonates in plain vials and the centrifuged at 3000 R.P.M. and the separated serum was used for estimating TSH by electrochemiluminescence. A repeat Serum TSH estimation at 72 hours of life was carried out from all the neonates to diagnosis of congenital hypothyroidism. In this present study, the reference range of CBTSH used 1.3-10 μIU/mL, as per kit. The normal level of serum TSH and fT4 are 0.50–5.50 μIU/mL and 0.8- 2.0 ng/dL.[13]

The data were compiled in Excel sheet and analyzed in the SPSS software.

**RESULTS**

Total 500 children participated in this study among which 294(58.8%) were male and rest were female (Figure no -1). Out of 500, 309 (61.8%) children were from urban area and others from rural area. In urban children Muslims were majority (52.43%) whereas in case of rural children it was opposite i.e. 56.02% Hindu(Figure no-2).

**Figure 1: Distribution of children according to gender**

**Figure 2: Distribution of children according to address and religion**

Majority of children born from multi gravid mothers (55.4%).(Figure-3).

**Figure 3: Distribution of children according to maternal gravida**
68.2% children belonged from birth weight of 2.5-2.99 kg and 29.4% of children were from low birth weight group i.e. less than 2.5kg (Figure 4).

Majority of the children born belonged to maternal age group of 26-30 years (32.6%)(Figure 5). Majority of the children born at term (77.4%)(Figure 6).

Out of 500 mothers, 61 had hypothyroidism and 91.8% were on treatment. Only 3 mothers had hyperthyroidism and out of 3, 2 were on treatment(Figure 7).

From Table no 1, it is revealed thet only 1.4% children had TSH level more than 30mIU/ml and 11.2% had TSH levels between 20.1-30.0 mIU/ml.(Table no -1).

Table 2: Distribution of children according to different parameters with their cord blood TSH levels

<table>
<thead>
<tr>
<th>Cord Blood TSH (μIU/mL)</th>
<th>No of children</th>
</tr>
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<tbody>
<tr>
<td>Below 1.3</td>
<td>341 (68.2%)</td>
</tr>
<tr>
<td>1.3- 10.0 (Normal)</td>
<td>93 (18.6%)</td>
</tr>
<tr>
<td>10.1-20.0</td>
<td>56 (11.2%)</td>
</tr>
<tr>
<td>&gt;30</td>
<td>7 (1.4%)</td>
</tr>
<tr>
<td>Total</td>
<td>500</td>
</tr>
</tbody>
</table>
From Table 2, we can observe the distribution of children according to different parameters with their cord blood TSH levels (Table 2).

The mean CB TSH value was 9.987 ± 0.654 μIU/mL. The male and female neonates had almost same mean CB TSH values, 9.087 ± 0.435 μIU/mL and 9.134 ± 0.876 μIU/mL respectively. Neonates from rural area had mean CB TSH value 7.986 ± 0.876 μIU/mL. In case of caesarean section, term neonates had TSH values more than 20 μIU/mL. Out of 63, 7 neonates had CB TSH values more than 30 μIU/mL. The neonates born through normal delivery had mean CB TSH level 12.013 ± 0.456 μIU/mL whereas it was 7.988 ± 0.876 μIU/mL in case of caesarean section. Out of 156 neonates, having CB TSH values were more than 10 μIU/mL, only 4 had increased serum TSH levels and decreased fT4 levels on day 3 and had confirmed congenital hypothyroidism. That 4 neonates had the following serum TSH & fT4 levels at 72 hrs of birth- 10.259 μIU/mL & 0.654 ng/dL, 23.256 μIU/mL & 0.326 ng/dl, 21.012 μIU/mL & 0.364 ng/dl and 19.146 μIU/mL & 0.414 ng/dl.

As congenital hypothyroidism is one of the major cause of mental retardation, universal screening of all the newborn is an effective as well as essential method.[14] Some studies used only TSH or fT4 alone or both TSH & fT4 in combined. The reference ranges of cord blood TSH levels are different in different studies. In the present study, the reference ranges of cord blood TSH i.e. 1.3-10 μIU/mL. So, we considered cord blood TSH value more than 10 μIU/mL is to be abnormal. From 10.1 to 20 μIU/mL is considered borderline and more than 20 μIU/mL is considered abnormal. In the present study, 93 neonates had border line i.e. CB TSH values 10.1-20 μIU/mL.

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In a study by Gupta A et al, the median CB-TSH was 8.75 μIU/mL (IQR = 6.475 – 12.82) with 11.5%
neonates having values more than 20. CB TSH was significantly raised in first order neonates (P <0.01) and in babies delivered by assisted vaginal delivery and normal delivery (P <0.01). But, they found neonates who had fetal distress or non-progress of labour had significantly higher CB TSH than those who were delivered by elective caesarean section.[15] In the present study, 1.27% and 1.87% developed CH in normal delivery and caesarean sections respectively.

In a study by Raj S et al., the mean value of CB TSH was 12.88 μIU/mL. One hundred twenty five of the 430 neonates (29.06%) were found to have elevated CB TSH levels. CB TSH levels showed no gender variations but increased significantly with the gestational age of the baby (p=0.001).[19] CB TSH levels increased with increasing maternal age (p<0.001) and were significantly higher in babies of mothers with history of hypothyroidism.[6,9,16] But in the present study we got opposite result.

In another study, a total of 96,015 newborn infants were screened in the period from January 1990 to December 2007. Twenty-six cases of primary congenital hypothyroidism, six cases of transient hypothyroidism and 13 cases of central hypothyroidism were detected. This method of screening resulted in 100% sensitivity and 98% specificity.[17] In a study by Seth A et al., 130 neonates were enrolled. The mean (range) gestational age and birth weight was 38.16 weeks (28-42 weeks) and 2600 g (800-4500 g), respectively. The comparison between TSH from cord blood and TSH from heel prick blood on 4th to 7th day of life was done. There was no statistically significant difference observed in mean TSH values. The TSH from heel prick blood increased with increasing TSH from cord blood with a positive correlation coefficient of 0.87.[16,18]

CONCLUSION

Congenital hypothyroidism is a major preventable cause of mental retardation. To prevent mental retardation, the estimation of cord blood TSH is a must thing. If the any chance of getting second time screening, that should be considered as a golden opportunity to reduce the number of false positives.

Limitations
1. Only one follow up done. Repeated assessment should be done.
2. Lack of time, fund & manpower.

Acknowledgement
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