

Original Research Article

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Neonatal thyroid screening a tertiary care experience at VSS Medical College and Hospital, Burla

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ABSTRACT

Background: Congenital hypothyroidism is one of the most common preventable etiologies of mental retardation. The worldwide incidence of CH ranges from 1 in 3000 to 1 in 4000 live newborn. Objective of the study was to know the incidence of congenital hypothyroidism in this part of the country, which is necessary to understand the burden of congenital hypothyroidism to the society.

Methods: Primary serum TSH measurement in screening neonates with backup thyroxine (T4) determination in infants with high TSH levels (>20 mIU/l). TSH and FT4 were estimated by chemi luminescence immunoassay (CLIA) method using reagent monobind, INC.

Results: Serum TSH of screened neonates ranged between 0.16 mIU/l and 80.32 mIU/l, Mean±SD of sTSH being 5.80±3.96 mIU/l. Out of 2212 screened newborns, 9 newborns had sTSH value >20 mIU/l, who were recalled for confirmatory test, giving a recall rate of 0.4%. Out of 9 recalled newborns, 3 had persistently elevated sTSH >20 mIU/l making incidence of congenital hypothyroidism of 1:737 in our study.

Conclusions: We found a higher incidence of 1:737 neonatal hypothyroidism in this region as compared to estimated national incidence. CH being preventable cause of mental retardation and other harmful effects on a growing newborn, neonatal screening programme for congenital hypothyroidism is highly recommended.

Keywords: Congenital hypothyroidism, Neonatal thyroid screening, Primary serum TSH measurement, TSH levels

INTRODUCTION

Congenital hypothyroidism (CH) is defined as deficiency of thyroid hormone at birth. Congenital hypothyroidism is one of the most common preventable etiologies of mental retardation. Age of diagnosis and severity of mental retardation due to underlying hypothyroidism have inverse relationship. Congenital hypothyroidism may be classified as permanent or transient and this in turn determines the requirement of duration of therapy.^{1,2}

The worldwide incidence of CH ranges from 1 in 3000 to 1 in 4000 live newborn.^{3,4} However, varied incidence has been found from state, regional, and national screening

programs. Studies reveal that the incidence varies by geographic distribution. In few states of India incidence is as high as 1:300-600 in newborn infants have found.^{1,4}

Congenital hypothyroidism often asymptomatic or present with subtle manifestations at birth. Most often hypothyroidism in the newborn period is underdiagnosed, and delay in diagnosis leads to the most severe effect of congenital hypothyroidism, mental retardation (MR), dictating the importance of newborn screening.^{5,6}

Newborn screening (NS) for CH is one of the major achievement of Preventive and Social Medicine. The problem of CH and its ill effects has been addressed in

developed countries by the introduction of NS since 1972, but many of the developing countries still are deficient in NS programs for CH. In India, such programs are yet to be introduced and implemented as such no definite incidence and hence no burden of this disorder is known.⁷⁻⁹

This study focuses and aims at evaluating the feasibility of thyroid screening program, to know incidence of congenital hypothyroidism in this part of country, which is necessary to recognize the magnitude of the burden of congenital hypothyroidism is to the society and practical implementation of screening program for all neonates in this part of country.

METHODS

Our study was an observational study done for duration of 2 years from December 2013 to November 2015 at VIMSAR, Burla, Sambalpur, Odisha. A total of 2212 newborns attending the well neonatal clinic and normal newborn born at VIMSAR were included in the study after using inclusion and exclusion criteria. Institutional Ethical Committee clearance was sought for conducting the study. Neonates apart from exclusion criteria were involved in congenital hypothyroid screening program on 3rd to 5th day of life after obtaining an informed consent from either of the parents. Detailed history, examination of newborn and short questionnaire was used for screening.

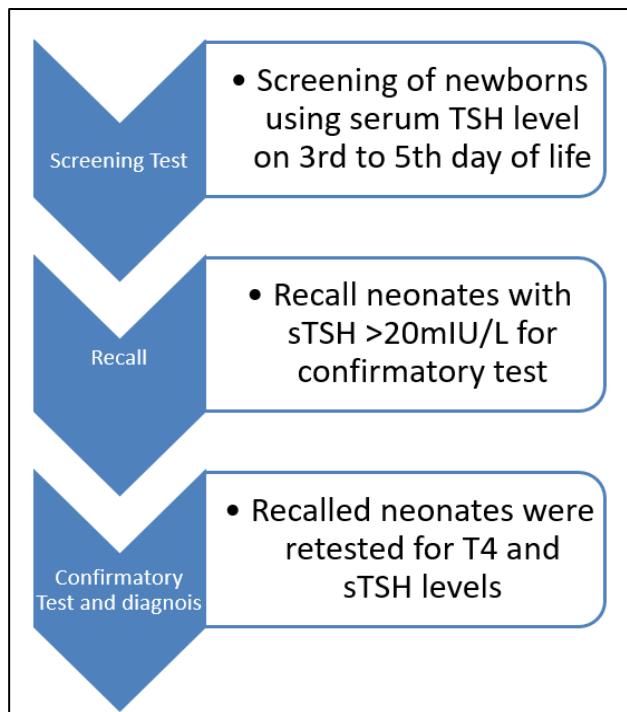


Figure 1: Screening for congenital hypothyroidism in newborns.

In our study most widely accepted screening strategy was used- primary serum TSH measurement in screening

neonates with backup thyroxine (T4) determination in infants with high TSH levels (>20 mIU/l). Newborns with elevated serum TSH level were recalled for repeat testing at a gap of a week time duration to newborn follow up clinic for confirmatory test (serum T4 and TSH levels measurements) by chemi luminescence immunoassay (CLIA) method using reagent monobind, INC.

Statistical methods

Categorical measurements are presented in number (%). significance is assessed at 5% level of significance. The Statistical software namely SPSS 15.0 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

There were 1633 (74%) males and 579 (26%) females, giving a study population male to female ratio 2.8:1 (Table 1).

Table 1: Sex distribution of the recalled neonates.

Sex of neonates	Number of neonates	Percent
Male	7	77.8%
Female	2	22.2%

Neonates involved in study were of average gestation age of 36.8 weeks, and Mean \pm SD of gestation age being 36.88 ± 2.11 . However average gestational age in recalled neonates was 35.8 weeks (Figure 2).

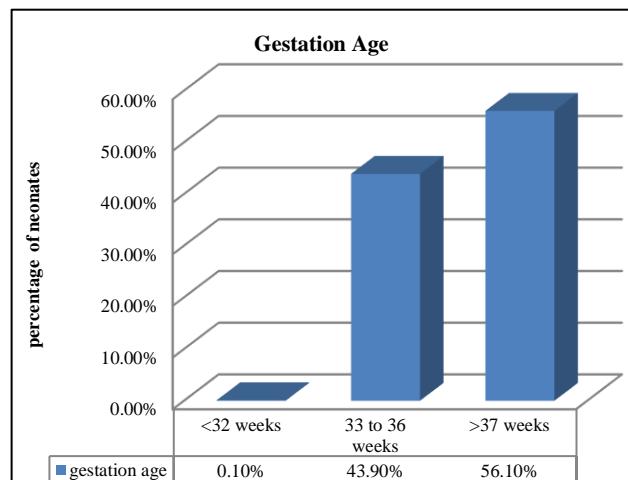


Figure 2: Screened neonates gestational age.

Among 2212. Only 9 neonates recalled neonates, there were 7 (77.8%) males and 2 (22.2%) females and male to female ratio in recalled newborns was 3.5:1.

Serum TSH of screened neonates ranged between 0.16 mIU/l and 80.32 mIU/l, mean \pm SD of sTSH being 5.80 ± 3.96 mIU/l. Mean \pm SD sTSH in screened female

newborns was 5.69 ± 2.8 mIU/l and male newborns was 5.63 (SD=3.9) mIU/l.

Out of 2212 screened newborns, 9 newborns had sTSH value >20 mIU/l, who were recalled for confirmatory test, giving a recall rate of 0.4%. Table 7 showing 99.6% were <20 mIU/l and 0.4% were >20 mIU/l.

4.1% of screened population had sTSH value >10 mIU/l. Indicating mild iodine deficiency in the screened newborns (Table 2).

Table 4: sTSH value <10 mIU/l, iodine deficiency.

sTSH (mIU/L)	Newborns	Percentage
<10	2122	95.9%
>10	90	4.1%

Age of screening ranged from 3 to 5 days of life, mean age of screening being 3.69 (SD=0.70) days of life (Figure 3).

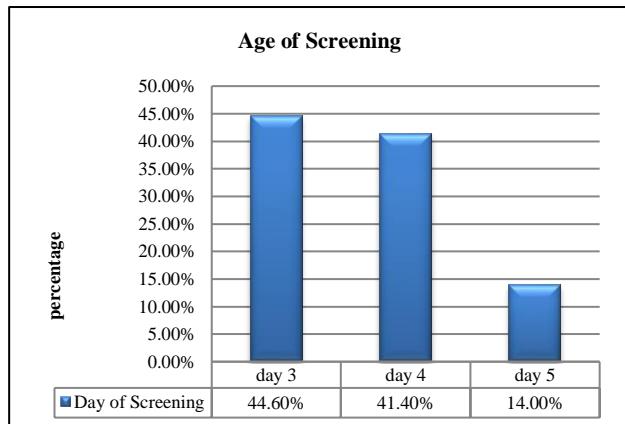


Figure 2: Day of screening.

Screened newborns with sTSH >20 mIU/l were recalled after 7 days of initial screening, day of patients attending OPD varied from day 10 to day 27 of life and mean being 14.6 (SD=5.95) days of life.

Out of 9 recalled newborns, 3 had persistently elevated sTSH >20 mIU/l making incidence of congenital hypothyroidism of 1:737 in our study. Sex ratio-male:female- 2:1. Ethnicity- all belonging to Hindu ethnicity. Mode of delivery- 2 by vaginal and 1 by LSCS. Birth weight- ranging from 1.6 to 2.5 kg, average being 2.1 kg. Maternal age- maximum being 35 years and minimum being 27 years. 29.6 years being average maternal age. Gestational age- all belonging to near term gestational age group.

DISCUSSION

The results were compared with previous studies of well-known workers in this field and significant differences and similarities in various results are discussed below.

In our study out of 3 newborns were diagnosed to have congenital hypothyroidism out of 2212 screened newborns, in which 2 were male and 1 was female, indicating male preponderance with male to female ratio 2:1, this finding is supported by few studies carried out previously which reports male to female ratio with male preponderance like Anjum et al (1.1:1, Pakistan), Anastasovska et al (1.6:1, Macedonia).^{10,11}

Two studies Ittihad et al in Iraq (6949 neonates) and Arash et al in Iran during 1998-2005, reported higher incidence of hypothyroidism in newborns born by vaginal delivery than LSCS.^{12,13} In our study 2 neonates were born out of vaginal delivery (VD) and 1 by caesarean delivery (CD), but our study being of small sample size and by matter of fact that vaginal delivery is preferred choice of delivery in majority of pregnancies.

In the present study we screened neonates between 3rd and 5th days of life and the Mean age of screening being 3.69 (SD=0.70). We screened newborns after day 2 of life to avoid false positive results by too early screening (<48 hours) and to avoid delay in diagnosis by testing within 7 days of life. The age of sampling in the newborn screening program is a matter of debate. The optimum age of sampling depends on many factors like the number of diseases screened for and screening method. Screening of all infants should be performed when the postnatal peak of physiological TSH elevation has already decreased.

Screening programs for congenital hypothyroidism were carried in many countries with different designs. However due to better pick up rate and the lower costs TSH assay is a better screening tool than T4 assessment especially in developing countries where cost effectiveness in implementation of universal screening test matters.^{13,14} In our study we could not perform T4 level along with TSH for neonatal screening due to high cost.

In our study we obtained mean TSH value of 5.80 ± 3.96 mIU/l which was quite comparable to mean TSH value obtained by a study carried out by Manglik et al, in Kolkata (6.13 ± 5.29 mIU/l) but lower than that reported Raj et al, at Trivandrum in Kerala (12.88 mIU/dl).^{4,15} This difference in mean TSH values within different regions of India may be explained by differential iodine sufficiency/insufficiency prevalent in different regions of India.

Our recall rate for repeat testing was 0.40% (9/2212) which is comparable with a large scale, 5-year prospective study from Thailand with a sample size of 35,390 neonates which had a recall rate of 0.43%. The recall rate in other studies were 0.18% (Anastasovska et al, Macedonia), 1.83% (Manglik et al, Kolkata), 31.9% (Raj et al, Kerala).^{4,11,15} This wide range of difference in recall rates in different studies may be due to different sampling methods, different methods of performing the laboratory

tests, different TSH cutoff values, incidence of CH in different parts of world and may also reflect the levels of iodine deficiency in different regions.

The timing of diagnosis, treatment, and monitoring of treatment are crucial in ensuring the best neurodevelopmental outcome in patients with CH. However no guidelines have been laid down regarding recall timings. Since there is an inverse relationship between the age of diagnosis/treatment and intelligence quotient (IQ), we recalled screened newborns with higher sTSH value >20 mIU/l, for confirmatory test depending on day of initial TSH assessment, with a gap of 7 days.¹ Out of 9 neonates, 5 attended Paediatric OPD for confirmatory test between days 10-12, others gave a delayed visit due to various reasons of non availability of transport, financial constraints, etc., ranging from 14 to 27 days of life. In our study the mean age of the recalled neonates visit was 14.6 (SD=5.95) days, which was quite comparable with mean recall timings of Al-Hosani et al, 15.4 days but higher than that of Yousef et al, 12.7 days.¹⁶ There were no dropouts observed. The reason for no dropout in our study may be due to the reason that our hospital being the only tertiary care centre for surrounding districts of Odisha.¹⁶

The incidence of CH among neonates in Odisha has not been separately evaluated before. In our study we screened newborns attending our tertiary care centre from different districts of Western Odisha residing in and around Burla (District Sambalpur) giving the incidence of 1:737 live births. Our study incidence is much higher than the world figure of 1 in 4000 and also higher than the estimated incidence of India which is 1:2500-2800, but other Indian data have observed higher incidences of 1 in 248 and 1 in 1700 in separate studies, from different regions of India.^{4,15}

Our study incidence was closer to the incidence reported by Manglik et al, from neighbouring state West Bengal, which was 1:600.⁴ This similarity in incidence may be accounted to the fact that West Bengal and Odisha, being neighbouring states shares almost similar geographical condition, ethnic group, food habits and genetic makeup, which all are main determining factors for developing hypothyroidism in a neonate. A quite similar incidence was found in other studies conducted by Sundararaman in Chennai and Sanghvi et al, in Kerala, where incidence were 1:625 and 1:476 respectively.^{14,17}

Limitation of study was, as the present study was a hospital based study, it may not represent the whole population. Thus universal screening programme with 100% coverage should be ensured by decentralization of programme.

CONCLUSION

We conclude based on our study a nationwide universal neonatal screening programme should be implemented to

prevent mental retardation in children. Our study reported significant number of neonates with sTSH value >10 mIU/l indicating iodine deficiency prevalent in this part of country. Education and awareness about iodine deficiency and iodine deficiency disorders (IDD) to susceptible population and thereby encourage intake of adequate iodine in food.

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Ethical approval: The protocol was approved by the board of studies and passed by ethical committee of the institution in December 2016

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