International Journal of Contemporary Pediatrics
Seeralar AAT et al. Int J Contemp Pediatr. 2016 May;3(2):456-460
http://www.ijpediatrics.com
pISSN 2349-3283 | eISSN 2349-3291

DOI: http://dx.doi.org/10.18203/2349-3291.ijcp20160651

Research Article

Newborn screening for congenital hypothyroidism in a tertiary care centre

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Received: 26 January 2016
Accepted: 21 February 2016

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ABSTRACT

Background: Congenital hypothyroidism (CH) is one of the most common preventable causes of mental retardation in paediatric population. Universal screening though possible is still not available for neonates even in tertiary care centers because of low priority in spite of proven community benefits. The aim and objective was to determine the prevalence of CH in neonates in a tertiary care center.
Methods: The study was conducted in the neonatal unit of RSRM Lying in hospital- Stanley medical College as a prospective cross sectional study from March 2012 to May 2012. All newborns with gestational age of 34 weeks or more delivered in the hospital were included in the study. Sample was collected after getting informed consent after 48 hours of age till 7 days of age. 1695 babies who met the inclusion criteria were enrolled, from whom sample was collected. The blood sample was collected by heel prick on to a filter paper and TSH levels estimated by dissociation enhanced lanthanide fluorescent immunoassay (DELFIA). Exclusion criteria were preterm infants with gestational age less than 34 weeks, those who have received blood transfusion prior to sampling, neonates more than 7 days of age and refusal of informed consent were excluded from the study.
Results: The study population consists of 1695 newborns. Among 1695 newborns 3 babies had elevated TSH representing a prevalence of 1.7 per 1000.
Conclusions: Our Study results revealed the prevalence of hypothyroidism among infants is 1.7 per thousand.

Keywords: Congenital hypothyroidism, TSH, Neonates

INTRODUCTION

Thyroid hormone plays a vital role in the normal development of the central nervous system. Deficiency of thyroid hormone is one of the most common causes of preventable mental retardation. Congenital hypothyroidism is defined as thyroid hormone deficiency at birth. Screening by blood spot TSH is one of the most recognised tools to diagnose congenital hypothyroidism. It is one of the most effective methods to prevent severe developmental and physical morbidity associated with congenital hypothyroidism.[1-4]

The clinical manifestations are often subtle and not evident at birth. Common symptoms include lethargy, temperature instability, feeding problems and prolonged jaundice. Hypothyroidism in newborn period is often missed in view of subtle manifestation which may lead on to delay in diagnosis and resulting mental retardation and growth failure. This emphasizes the importance neonatal screening for early diagnosis and management. Neonatal screening for congenital hypothyroidism should be done after 48 hours of age. Blood spot TSH or T4 or both can be used for screening for congenital hypothyroidism. Heel prick dry blot method of sample collection is proven to be more appropriate for mass screening.[5-7] In our community

data on prevalence of congenital hypothyroidism is lacking. Therefore the study was planned to estimate the burden of congenital hypothyroidism. This would help in early detection and treat the potential congenital hypothyroid newborns to realize their neurological potential and growth thus reducing the morbidity of preventable mental retardation and growth failure.[3,4]

METHODS

This prospective cross sectional study was conducted in neonatal unit of RSRM Lying in hospital – Stanley medical college, Chennai, India from March to May 2012. The RSRM Lying in hospital is the obstetric and neonatal unit attached to government Stanley medical college hospital, Chennai in Tamilnadu which caters to the middle and lower income population with mother and neonatal care services.

All newborns with gestational age of 34 weeks or more delivered in the hospital were included in the study.

Preterm infants with gestational age less than 34 weeks, those who have received blood transfusion prior to sampling, neonates more than 7 days of age and refusal of informed consent were excluded from the study.

Sample was collected after getting informed consent after 48 hours of age till 7 days of age. Demographic data of gestational age, sex, birth weight was recorded. Maternal history of any thyroid disease and any anti thyroid drugs intake during pregnancy was recorded for accurate interpretation of our data.

1695 babies who met the inclusion criteria were enrolled in the study from which sample was collected by proper aseptic precautions. The blood sample was collected by heel prick on to a filter paper and TSH levels estimated by dissociation enhanced lanthanide fluorescent immunoassay (DELFIA).[5]

New-borns that had a TSH value more than 20 µIU/L were labelled as a case of congenital hypothyroidism which was also confirmed by venous sample before treatment was started. Due to financial constraints only TSH estimation was done. The data of sex, age, birth weight and TSH values were analysed and tabulated.

RESULTS

The study population consists of 1695 newborns. Among the 1695 (100%) babies, 914 (53.9%) were male and 781 (46.1%) were female babies. Out of 1695 babies less than 2500 gm was 279 (16.5%) babies more than 2500 gm was 1416 (83.5%) babies. Among the 1695 babies less than 37 weeks of gestation was 107 (6.3%) and more than 37 weeks was 1588 (93.7%).

Among 1695 babies 3 (1.7 per 1000) babies were screen positive with level of above 20 µIU/L. About two babies were female and one male baby. All the three babies were more than 37 weeks also 2500 gm and above.

Table 1: Demography.

Variable	No.(%)
Mother's age (years)	
≥18-25	622 (36.7)
26-30	780 (46)
>30	293 (17.3)
Sex	
Male	914 (53.9)
Female	781 (46.1)
Gestational age (weeks)	
<37 weeks	107 (6.3)
37 weeks & above	1588 (93.7) q
Birth weight (kg)	
<2.5 kg	279(16.5)
2.5 kg and above	1416 (83.5)
Maternal history of hypothyroidism	
Yes	0(0)

DISCUSSION

Our Study results revealed the prevalence of hypothyroidism among infants is 1.7 per thousand. It correlated with a study by Sanghvi U (2.1 per thousand).[1] It did not correlate with the study by Anjum A et al which showed a prevalence of 8 per 1000.[2]

We had 3 positive values in our study above 20 µIU/L. In our study we classified term and pre term Infants TSH values. There seems to be an elevation of mean TSH values among pre term infants than term infants in our study. Further confirmation may be needed for pre-term infants TSH values to decide cut off values than term TSH values.

In our study we had 914 male children (53.9%) and 781 female children (46.1%) (Table 2 and Figure 1).

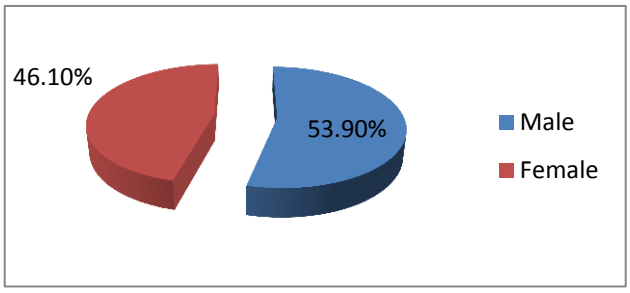

Figure 1: Gender distribution

Table 2: Gender distribution.

	Frequency	Percentage
Male	914	53.9
Female	781	46.1
Total	1695	100.0

Low birth weight 279 (16.5%) and normal birth weight 1416 (83.5%) (Table 3 and Figure 2).

Table 3: Birth weight distribution.

Birth weight	Frequency	Percentage
2500 gm and above	1416	83.5
<2500 gm	279	16.5
Total	1695	100.0

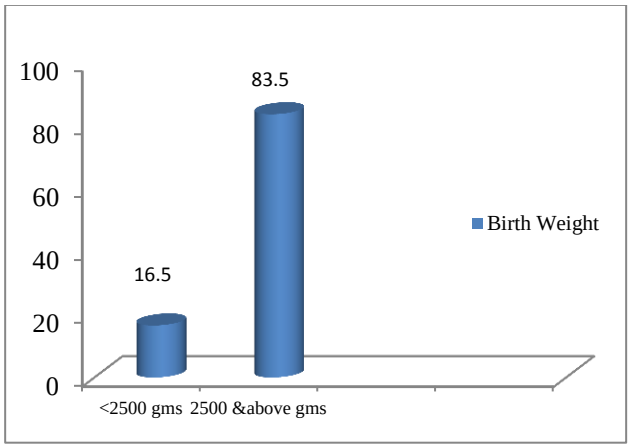

Figure 2: Birth weight distribution.

The preterm babies were 107 (6.30%) and term babies were 1588 (93.70%) (Table 4 and Figure 3).

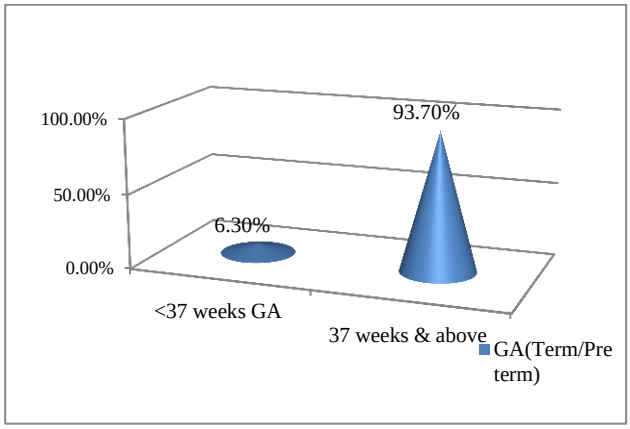

Figure 3: Gestational age-term/pre term distribution.

Table 4: Gestational age-term/pre term distribution.

Gestational age	Frequency	Percentage
37 weeks and above	1588	93.7
< 37 weeks	107	6.3
Total	1695	100.0

There is no statistical significance between low birth weight and normal weight babies with respect to their TSH values (Table 5A-5C).

Table 5A: Group statistics (Birth weight).

Birth weight		N	Mean	SD	Std. error mean
TSH (µIU/L)	<2500 gms	279	0.8709	0.73623	.04408
	2500 gms and above	1416	1.0009	2.04685	.05439

SD: Standard deviation

Since, the above data not followed normal distribution, we have done Non parametric t test.

Table 5B: Non parametric t test (Birth weight).

	Birth weight	N	Mean rank	Sum of ranks
TSH (µIU/L)	2500 gms and above	1416	857.12	1213675.00
	<2500 gms	279	801.74	223685.00
	Total	1695		

Table 5C: Test statistics (Birth weight).

	TSH (µIU/L)
Mann-Whitney U	184625.000
Wilcoxon W	223685.000
Z	-1.728
Asymp. Sig. (2-tailed)-P value	.084

Table 6A: Group statistics (Gestational age).

Gestational age Classification		N	Mean	SD	Std. Error mean
TSH (µIU/L)	<37 weeks	107	0.7514	0.64920	0.06276
	37 weeks and above	1588	0.9949	1.94963	0.04892

Since, the above data not followed normal distribution, we have done non parametric t test. There exists a statistical significance between pre term and term babies with respect to their TSH values (Table 6A-6C). This clearly indicates, there is a need for universal screening TSH program that must be a mandatory to all new born.

Table 6B: Ranks (Gestational age).

Ranks				
	GA Classificatic	N	Mean rank	Sum of ranks
TSH (µIU/L)	37 weeks and above	1588	855.83	1359060.50
	<37 weeks	107	731.77	78299.50
	Total	1695		

GA: Gestational age

Table 6C: Test statistics (Gestational age).

Test Statistics	TSH (µIU/L)
Mann-Whitney U	72521.500
Wilcoxon W	78299.500
Z	-2.538
Asymp. Sig. (2-tailed)	.011

ROC

Sensitivity and specificity

The whole point of an ROC curve is to help you decide where to draw the line between 'normal' and 'not normal'. It tabulates and plots the sensitivity and specificity of the test at various cut-off values. The optimal cutoff value will be shown in the graph.

Sensitivity: The fraction of people with the disease that the test correctly identifies as positive.

Specificity: The fraction of people without the disease that the test correctly identifies as negative.

Table 7A: ROC curve (Birth weight).

Sample size		1695
Positive group :	BW = 1	279
Negative group :	BW = 0	1416

BW: Birth weight

Table 7B: Area under the ROC curve (AUC) (Birth weight).

Area under the ROC curve (AUC)	0.532669
Standard Error	0.0200
95% Confidence interval	0.508583 to 0.556643
z statistic	1.631
Significance level P (Area=0.5)	0.1029

Using TSH, Area under curve is 0.532669, not statistically significant. The prediction sensitivity is 45.5 and specificity is 64.5.

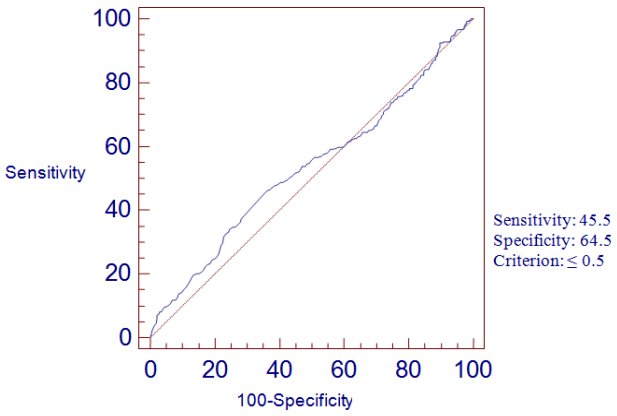

Figure 4: TSH µIU/L (Birth weight)

Table 7C: ROC curve (Gestational age).

Sample size		1695
Positive group :	GA = pre term	107
Negative group :	GA =term	1588

GA: Gestational age

Table 7D: Area under the ROC curve (AUC) (Gestational age).

Area under the ROC curve (AUC)	0.573192
Standard Error	0.0280
95% Confidence interval	0.549241 to 0.596890
z statistic	2.615
Significance level P (Area=0.5)	0.0089

Using TSH values, Area under curve is 0.573192, statistically significant. The prediction sensitivity is 38.3 and specificity is 75.1

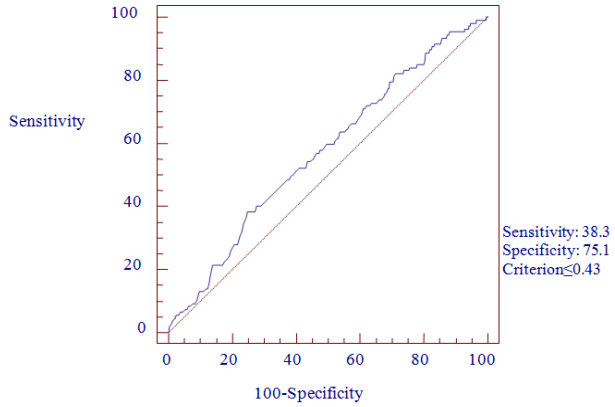

Figure 5: TSH µIU/L (Gestational age).

CONCLUSION

Our study results revealed the prevalence of congenital hypothyroidism among neonates is 1.7 per thousand. It correlated with a study by Sanghvi U (2.1 per thousand). This clearly indicates, there is a need for universal screening for Hypo thyroidism to be implemented regularly in all new borns.

ACKNOWLEDGMENTS

We acknowledge the consistent support provided by ICMR and Dr. Sudha Rathna Prabu, consultant pediatrician, Fetal care research foundation, Chennai.

Funding: Funded by ICMR
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Seeralar AAT, Ganesh J, Padmanaban S. Newborn screening for congenital hypothyroidism in a tertiary care centre. Int J Contemp Pediatr 2016;3:456-60.