ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 05 | May - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

SERUM TSH LEVEL IN HEALTHY NEONATES A SCREENING TOOL FOR CONGENITAL HYPOTHYROIDISM AND TRENDS OF NORMAL VARIATION OF TSH IN A TERTIARY CARE CENTRE IN WESTERN UTTAR PRADESH"

Paediatrics

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ABSTRACT

Background:-Congenital hypothyroidism is an important cause of mental retardation that can be prevented by timely detection and treatment. The incidence of Congenital Hypothyroidism is 1:2000 -3000 in India [3] as compared to world 1:3000-4000[20] This high level of incidence can be due to advancement of screening methods [19] **Methods: -**This study was carried out in Sarswati Institute of Medical Science, Hapur. This study is conducted for a period of one year from December 2020 to November 2022.It was cross sectional, observational study.238 neonates were screened in present study **Results:-** 238 neonates were screened in present study. In our study the mean age of mother at which Delivery occurred was 25.7±3.62, with maximum age 45 years and minimum age 18 years. 215 babies in our study had serum TSH < 10 mIU/L which is 90.5% of the total. 19 Babies (8%) had serum TSH between 10-20 mIU/L .Only 4 babies out of 238had serum TSH > 20 mIU/L which accounts for 1.34% and one baby had serum TSH >40 mIU/L serum units on first screen. **Conclusion:-** Our Aim of early identification of Congenital Hypothyroidism and starting the treatment within 2 weeks was accomplished through this newborn screening program and we highly recommend universal implementation of newborn screening program for screening of Congenital Hypothyroidism, as it reduces the burden of a disease, which is a preventable cause of mental retardation, in the society.

KEYWORDS

Introduction

Congenital hypothyroidism is an important cause of mental retardation that can be prevented by timely detection and treatment. The incidence of Congenital Hypothyroidism is 1:2000 -3000 in India[3] as compared to world 1:3000-4000[20] This high level of incidence can be due to advancement of screening methods[19] Thyroid Dysgenesis accounts for two thirds of the cases of congenital hypothyroidism [63]. This study was based on the hypothesis that universal thyroid screening and early detection and treatment of Congenital Hypothyroidism will prevent Mental Retardation and disease burden in the society.

MATERIAL AND METHODS

This study was carried out in Sarswati Institute of Medical Science, Hapur. This study is conducted for a period of one year from October 2021 to September 2022.

It was cross sectional, observational study. Pre-test counselling was offered to all families which includes verbal counseling along with written informed consent of Parent/Guardians.

All Healthy Newborns, term or preterm, delivered by vaginal delivery or Caesarean section at our hospital were included in our study.

Sick newborns, Newborns that are admitted in NICU with Birth Asphyxia, respiratory distress, any congenital anomaly, babies of mothers that are hypothyroid, twin deliveries and Intra Uterine Growth Retardation (IUGR) were excluded from our study.

Postnatal venous samples were collected after 48 hours of birth so that less number of babies were missed due to early discharge and to reduce false positives due to physiological TSH rise in first 24 hours.

At least 2 ml of sample was collected in a plain vacutainer by a needle. Samples were sent to the sims biochemistry lab and were processed within 24 hours of withdrawing. Assay was performed on serum samples by Chemiflex (enhanced chemiluminiscence) method by Architect i1000SR Immunoassay Analyser by Abott Core Laboratories A primary TSH based screening strategy was adopted in our study as it is the most sensitive method to detect all forms of primary and compensated Congenital Hypothyroidism.

The value of TSH obtained was converted to Serum Units by multiplying with 2.2 (to adjust for the hematocrit) for uniformity [14,48] Recall rate is the number of neonates called back for confirmatory test after an abnormal result expressed as a percentage of total number of infants screened. If the screening results were abnormal, then the definitive testing was done within 7-10 days of birth.

A cut-off value of >20 mIU/L was used to identify the true positives, and a confirmatory test was done for all babies whose screen TSH was above this level. Mildly elevated screen TSH (between 20-40 mIU/L) patients were recalled early in the second week of life for a repeat screening of TSH. However, immediate recall was done for babies with high TSH >40 mIU/L for a confirmatory test.

The obtained data was entered in Microsoft Excel sheets Demographic characteristics, clinical and hemodynamic parameters were compared between the two groups using paired t-test for continuous variable and chi-square test for categorical variable .Wilcoxon rank sum test (Mann Whitney test) was used to analyze non- uniformly distributed data. All analyses was done using commercial available software program STATA 15.0

RESULTS

238 neonates were screened in present study. In our study the mean age of mother at which Delivery occurred was 25.7±3.62, with maximum age 45 years and minimum age 18 years.

Out of 238 Newborns screened at our center, 97 (40.8%) were delivered by Caesarean section and 129(54.2%) by vaginal deliveries, which included preterm and breech deliveries., and instrumental delivery was 12(5%) Mean birth weight of babies included in our study was 2.7 kg with a SD of 0.42. Minimum birth weight was 1.8 kg and maximum birth weight was 4.25 kg.. Gestational age of babies included in our study had a mean of 38 weeks of gestation and the minimum and maximum gestational age was 33.5 and 42.6 weeks respectively. Out of 238 newborns screened in our study 124 were males which account to 52.1% and 47.3% i.e. 114 were females, and the male to female ratio was 1.112:1. The mean age at which samples were collected was 4.07 days.

215 babies in our study had serum TSH < 10 mIU/L which is 90.5% of the total. 19 Babies (8%) had serum TSH between 10-20 mIU/L .Only

4 babies out of 238had serum TSH > 20 mIU/L which accounts for 1.34% and one baby had serum TSH >40 mIU/L serum units on first screen.

In our study, the mean serum TSH (in Serum Units) in mIU/L was 3.7776 with a SD of 4.55. Median TSH levels were 2.4700 mIU/L in our study. There was a significant difference between means of serum TSH of newborns who have birth weight <2.5 kg and >2.5 kg., but no significant difference was found in mean TSH of babies delivered vaginally or by LSCS, preterm births and term births, males and females. Out of 1162 patients screened for serum TSH, 4 were recalled for confirmatory testing. The recall rate of our study was 0.34%. One baby was confirmed as a case of congenital hypothyroidism giving a prevalence of 1:1162 which is comparable to other studies. Mean serum TSH at day 3-5 of life is not affected by maternal factors

Discussion

1. 4 newborns had serum TSH level >20 mIU/L on first screen at 3-5 day. So they were called for repeat sample as soon as possible at with in 10 days. Out of four babies called for confirmation, one did not turn up. The three who were retested at 7 day of life ,only one had serum TSH > 10 mIU/L with FT4 value 0.6 ng/dL, so this patient was confirmed as a case of congenital hypothyroidism and was started on Thyroxine @ 10µg/kg/day and was followed up. Thus, the percentage of Congenital Hypothyroidism in present study is 1.6%.

2. In present study , 114 newborns were females(47.9) and 124 were males(52.1) ,the male to female ratio being 1.11: 1.00 ,similar to a study by Manglik et al, 1.076:1.00 , Singh et al. 1.065:1.00 in Manipur and Laxminarayan et al, 1.069:1.00, which was comparable to our study.

3. Mean Birth weight of the babies in present study was 2.74 kg with a SD of 0.47 (the range of birth weight 1.8 to 4.15 kg). similiarly reported by Manglik was 2.84 kg (range 2.5-4.3 kg), Singh et al was 3.01 kg (range 2.1-4 kg) and Laxminarayan et al was 2.75 kg (0.72-4.32kg) which is comparable to our study.

4. The present study percentage of serum TSH >20 mIU/l was 1.34 and the study carried out by Singh et al .20mIU/L was 5.5 and Rameshwar Prasad et al 1.1 % which is similar to present study.

CONCLUSION

1. In present study only one out of 238 babies had a congenital hypothyroidsm Screening of congenital hypothyroidism of all newborns is recommended after birth because Congenital hypothyroidism is the most common preventable cause of mental retardation in children in globally.

2. With the advent of Newborn screening programs, increase in preterm births and use of sensitive methods for screening such as Serum TSH , the incidence has risen dramatically in last few decades.

3. delays in treatment and irregularities in management of congenital hypothyroidism may affect the the neurodevelopmental outcome . Aim of early identification of Congenital Hypothyroidism and starting the treatment within 2 weeks was accomplished through the newborn screening program.

4. We highly recommend universal implementation of newborn screening program for screening of Congenital Hypothyroidism, as it reduces the burden of a disease, in the society.

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